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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, 2020**

**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 (§ 232.405 of this chapter) 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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

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 $1.5 billion.

As of February 22, 2021, the registrant had 80,917,013 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 2021 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 CAPLYTA (lumateperone) was approved by the FDA for the treatment of schizophrenia in adults (42mg/day) and we initiated the commercial launch of CAPLYTA in late March 2020. 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.

#### Our Product

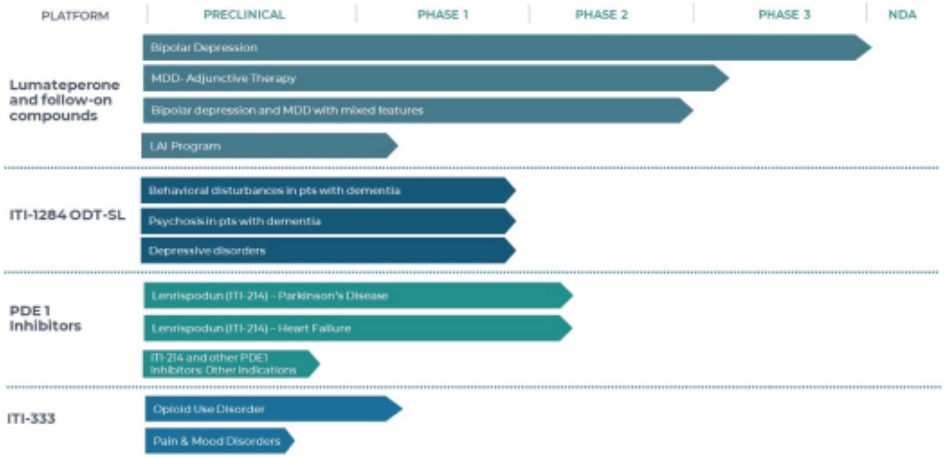
In December 2019, CAPLYTA was approved by the FDA for the treatment of schizophrenia in adults (42mg/day) and we initiated the commercial launch of CAPLYTA in late March 2020. In support of our commercialization efforts, we employ a national sales force consisting of approximately 240 sales representatives. This sales force focuses on promotion to physicians. Our commercial team is comprised of experienced professionals in marketing, access and reimbursement, managed markets, market research, commercial operations, and sales force planning and management.

The efficacy of CAPLYTA 42 mg in schizophrenia 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 versus 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.

**Our Development Programs**

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

**OUR THERAPEUTIC PIPELINE**




The safety and efficacy of investigational agents and/or investigational uses of approved products have not been established.

***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 lacks biologically relevant interactions with other receptors including 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 major depressive disorder (MDD).

*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 features 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.

Lumateperone is in Phase 3 clinical development as a novel treatment for bipolar depression. Our lumateperone bipolar depression clinical program consists of three monotherapy studies and one adjunctive

study. In September 2020, we announced positive topline results from Study 402, conducted globally, evaluating lumateperone as adjunctive therapy to lithium or valproate in the treatment of major depressive episodes associated with Bipolar I or Bipolar II disorder. In Study 402, once daily 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 ($p=0.0206$; effect size = 0.27). Lumateperone 42 mg also met the key secondary endpoint, the Clinical Global Impression Scale for Bipolar for Severity of Illness, or CGI-BP-S, Depression Score ($p=0.0082$; effect size = 0.31). The lower lumateperone dose, 28 mg, showed a trend for a dose-related improvement in symptoms of depression but the results did not reach statistical significance. 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. Following the positive results in Study 402, we amended Study 403 to evaluate major depressive episodes with mixed features in bipolar disorder in patients with Bipolar I or Bipolar II disorder and mixed features in patients with major depressive disorder, or MDD. We expect to complete Study 403 in the second half of 2022 and following completion we intend to discuss the results with the FDA to determine whether Study 403, as amended, will provide supportive data of a potential future regulatory filing for this indication.

In July 2019, we announced topline results from our first monotherapy study, Study 401, conducted in the United States, 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). These benefits were statistically significant in both Bipolar I and Bipolar II patients. Study 404 also met its key secondary endpoint, Clinical Global Impression Scale for Bipolar for Severity of Illness (CGI-BP-S) Total Score ($p<0.001$; effect size = 0.46). 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 all three bipolar depression studies, with a favorable safety profile.

In addition, while our Phase 3 bipolar depression trials were powered for the overall patient population and not powered for subpopulation analyses, statistically significant benefit versus placebo was seen in the subgroup of patients with Bipolar I and Bipolar II disorder in Study 404 and in patients with Bipolar I disorder in Study 402, but the Bipolar II subgroup was not statistically significant in Study 402. In February 2021, we submitted supplemental new drug applications, or sNDAs, to the FDA for potential regulatory approval of lumateperone for the treatment of bipolar depression in patients with Bipolar I or II disorder as monotherapy and adjunctive therapy. Assuming the sNDA submissions are accepted by the FDA, we anticipate an FDA target action date for the sNDAs in the second half of 2021.

*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 currently marketed antipsychotics and antidepressants. Dopamine modulation by lumateperone may also 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. By enhancing AMPA neurotransmission, lumateperone also activates key proteins in the mTOR pathway which has shown antidepressant effects. 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 evaluating lumateperone as an adjunctive therapy to antidepressants for the treatment of MDD and we expect to initiate clinical conduct in two Phase 3 trials in 2021.

*Other Indications for Lumateperone*

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 in December 2020 we initiated a Phase 1 single ascending dose study of lumateperone LAI, a formulation of lumateperone designed to be administered subcutaneously and to maintain therapeutic levels of lumateperone for at least one month. This study will evaluate the pharmacokinetics, safety and tolerability of lumateperone LAI in patients with stable symptoms of schizophrenia. We anticipate topline results from this study will be available in the second half of 2021. Results from this study will inform the dosing strategy for future studies. 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 certain patients.

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 are developing ITI-1284 for the treatment of behavioral disturbances in patients with dementia, the treatment of dementia-related psychosis and for the treatment of certain depressive disorders in the elderly. ITI-1284 is a deuterated form of lumateperone, a new molecular entity formulated as an oral disintegrating tablet for sublingual administration. ITI-1284 is formulated as an oral solid dosage form that dissolves almost instantly when placed under the tongue, allowing for ease of use in the elderly and may be particularly beneficial for patients who have difficulty swallowing conventional tablets. Phase 1 single and multiple ascending dose studies in healthy volunteers and healthy elderly volunteers (> than 65 years of age) evaluated the safety, tolerability and pharmacokinetics of ITI-1284. In these studies, there were no reported serious adverse events in either age group. In the elderly cohort, reported adverse events were infrequent with the most common adverse event being transient dry mouth (mild). Based on these studies, we plan to initiate Phase 2 studies evaluating ITI-1284 for the treatment of behavioral disturbances in dementia, dementia-related psychosis, and certain depressive disorders in the elderly.

We have another 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 aberrant immune system activation in 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, cancers 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. We plan to initiate a Phase 2 clinical trial with ITI-214 for Parkinson's disease in 2021. In addition, in the second quarter of 2020, we announced topline results from Study ITI-214-104, a Phase 1/2 translational study of single ascending doses of ITI-214 in patients with chronic systolic heart failure with reduced ejection fraction. In this study, ITI-214 improved cardiac output by increasing heart contractility and decreasing vascular resistance. Agents that both increase heart contractility (inotropism) and decrease vascular resistance

(vasodilation) are called inodilators. Inodilators in current clinical use are associated with the development of arrhythmias, which are abnormal heart rhythms that when serious can impair heart function and lead to mortality. ITI-214, which acts through a novel mechanism of action, was not associated with arrhythmias in this study and was generally well-tolerated in all patients.

We also have a development program with our ITI-333 compound 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. ITI-333 is a novel compound that uniquely combines activity as an antagonist at serotonin 5-HT2A receptors and a partial agonist at μ-opioid receptors. These combined actions support the potential utility of ITI-333 in the treatment of opioid use disorder and associated comorbidities (e.g., depression, anxiety, sleep disorders) without opioid-like safety and tolerability concerns. In December 2020, we initiated a Phase 1 single ascending dose study evaluating the safety, tolerability and pharmacokinetics of ITI-333 in healthy volunteers. We have received a grant from the National Institute on Drug Abuse under the Helping to End Addiction Long-term Initiative, or NIH HEAL Initiative, that we expect will fund a significant portion of the early stage clinical development costs associated with this program.

**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 American Pediatric Association 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 $12 billion in 2020. These drugs have been used by physicians to address a range of

disorders in addition to schizophrenia, including bipolar disorder, depression and a variety of psychoses and related conditions. 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.

There are over 11 million adult Americans living with bipolar disorder. Decision Resources Group estimated global sales for therapeutics used to treat bipolar disorder to be approximately $6 billion in 2020.

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***

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 (AD) in 2020. 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 $3.5 billion in 2020.

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 was approximately $6 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 2018 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.

***Opioid Use Disorder***

According to the 2019 CDC annual surveillance report of drug-related risks and outcomes, opioid misuse is widespread with over 10 million Americans reporting opioid misuse and nearly 50,000 opioid overdose deaths reported in the United States. The opioid crisis was declared a public health emergency in 2017. Opioids are a class of drugs that include the illegal drug heroin, synthetic opioids such as fentanyl, and pain relievers available legally by prescription, including oxycodone, hydrocodone, codeine and morphine. Opioids produce high levels of positive reinforcement, increasing the odds that people will continue using them despite negative consequences. Opioid use disorder is a chronic lifelong disorder, with serious potential consequences including disability, relapses, and death. While medications including methadone, buprenorphine and naltrexone are approved to treat opioid use disorder, these medications do not effectively treat psychiatric comorbidities (e.g., mood and anxiety disorders) that may drive opioid use/abuse or dysphoria or the dysphoria and mood disturbances (e.g., depression and anxiety) that often accompany opioid withdrawal and abstinence.

**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:

- continue to commercialize CAPLYTA, which has been approved by the FDA for the treatment of schizophrenia in adults, in the United States;
- commercialize lumateperone for the treatment of bipolar depression, if approved by the FDA;
- complete the development of lumateperone for additional neuropsychiatric indications, such as bipolar disorder and 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 advance our other product candidates in clinical development such as ITI-214, for the treatment of CNS and other disorders; ITI-1284, for the treatment of neuropsychiatric disorders and behavioral disturbances in dementia; and ITI-333, for substance use disorders, pain and psychiatric comorbidities including depression and anxiety; and
- advance the earlier stage product candidates in our pipeline.

**Intellectual Property**

***Our Patent Portfolio***

As of February 1, 2021, we owned or controlled approximately 112 patent families filed in the United States and other major markets worldwide, including approximately 94 issued or allowed U.S. patents, 41 pending U.S. patent applications, 305 issued or allowed foreign patents and 232 pending foreign patent applications, directed to novel compounds, formulations, methods of treatment, synthetic methods, and platform technologies.

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, 2021, our lumateperone program consisted of approximately 31 patent families that we own or control, filed in the United States and other major markets, including 34 issued or allowed U.S. patents, 23 pending U.S. patent applications, 121 issued or allowed foreign patents and 106 pending foreign patent applications. Seven 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 |
|---|---|---|
| ITI-007 Product Patent (approved drug product—lumateperone tosylate—in any pharmaceutical form) | **Granted:** US (10,464,938*)<br>Pending in AU | 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<br>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**);<br>March 12, 2029 (ex-US) |
| ITI-007 Dosage and Method of Treatment Patents (including schizophrenia, bipolar depression, sleep disorder indications) | **Granted:** US (8,598,119*; 9,616,061*), AU, CA, CN, JP, MX<br>Pending: US (continuation), (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**);<br>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<br>Pending: US (continuation), AU (divisional), JP (divisional), EP (allowed), 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 | **Granted:** US (10,695,345*)<br>Pending: US (continuation), AU, CA, CN, EP, IN, IL, JP, KR, MX, RU | 2037-2039 |

| Summary Description of Patent or Patent Application | United States or Foreign Jurisdiction | Expiration Date |
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| 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 two 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 two 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 ITI-1284 program relates to novel lumateperone derivatives for the treatment of behavioral disturbances associated with dementia, and other central nervous system disorders. Six families of patent applications have been filed, which have already resulted in five U.S. patents and eight foreign patents. The ITI-1284 molecule has composition of matter protection to 2037, with possible extensions and additional Orange Book-listable protection to 2042.

Our program on PDE1 inhibitors for cognition, dopamine-mediated and other disorders, cardiovascular disorders, as well as several others, includes patent protection across 27 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. 14 families of patent applications have been filed, including two families which have already resulted in three U.S. patents and one EP grant. 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 paid the milestone payment 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 our ongoing Study 403 Phase 3 trial 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.

*The Siegfried Supply Agreement*

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. We agreed to provide Siegfried with a rolling forecast. of our anticipated requirements for supply of the API. 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. As of December 31, 2020, the Company has committed to purchasing a production campaign of API from Siegfried that is expected to be delivered in the first half of 2022.

*The Lonza Manufacturing Services Agreement*

On January 10, 2017, we entered into a manufacturing services agreement, or the Lonza Agreement, with Lonza Ltd., or Lonza. Under the Lonza Agreement, Lonza has agreed to manufacture lumateperone, with purchase prices determined in each project plan. We agreed to provide Lonza with a written forecast of our estimated quarterly requirements. The term of the Lonza Agreement ends on the later of the seventh anniversary of the effective date of the agreement or five years after the first marketing approval by the FDA or European Medicines Agency, or EMA, of lumateperone from the Lonza facility for commercial supply. Either party may terminate the agreement prior to its expiration upon a prior written notice, an uncured material breach by the other party, the insolvency, liquidation, dissolution or bankruptcy of the other party, or a continuing force majeure event affecting the other party, and may be extended by mutual consent. We may terminate the agreement prior to its expiration if we receive notice that the NDA for lumateperone has been rejected, suspended indefinitely or terminated by the FDA. As of December 31, 2020, the Company has committed to purchasing a production campaign of API from Lonza that is expected to be delivered in the second half of 2022.

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 initiated the commercial launch of CAPLYTA in the United States in late March 2020. In support of our commercialization efforts, we hired 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 is priced in line with other currently marketed branded antipsychotics indicated for the treatment of schizophrenia. We distribute CAPLYTA principally through three third party wholesale drug distributors. We do not have a disproportionate concentration with any one of these distributors and we expect our sales volume to be distributed relatively evenly 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 competes and lumateperone for the

treatment of bipolar disorder, if approved, 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, CAPLYTA competes and our product candidates, if approved, would 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. We have applied for, and 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 United States). 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.

**Human Capital**

As of February 1, 2021, we employed 383 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 during 2021. We continually evaluate the business need and opportunity and balance in-house expertise and capacity with outsourced expertise and capacity. Currently, we outsource substantial clinical trial work to clinical research organizations and drug manufacturing to contract manufacturers.

We believe that our future success largely depends upon our continued ability to attract and retain highly skilled employees. Pharmaceutical companies both large and small compete for a limited number qualified applicants to fill specialized positions. To attract qualified applicants, we offer a total rewards package consisting of base salary and cash target bonus, a comprehensive benefit package and equity compensation for every employee. Bonus opportunity and equity compensation increase as a percentage of total compensation based on level of responsibility. Actual bonus payout is based on performance.

Much of our success is rooted in the diversity of our teams and our commitment to inclusion. We value diversity at all levels. We believe that our business benefits from the different perspectives a diverse workforce brings, and we pride ourselves on having a strong, inclusive and positive culture based on our shared mission and values.

**Corporate Information**

We were originally incorporated in the State of Delaware in August 2012 under the name "Oneida Resources Corp." Oneida Resources Corp. was a "shell" company registered under the Securities Exchange Act of 1934, as amended, or the Exchange Act, with no specific business plan or purpose until it began operating the business of Intra-Cellular Therapies, Inc. (now re-named ITI, Inc., or ITI) through a reverse merger transaction on August 29, 2013 (the "Merger"). ITI was incorporated in Delaware in May 2001 to focus primarily on the development of novel drugs for the treatment of neuropsychiatric and neurologic diseases and other disorders of the central nervous system. Effective upon the Merger, a wholly owned subsidiary of the Company merged with and into ITI. ITI and ITI Limited continue as the operating subsidiaries 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. We make available free of charge through the Investors section of our web site our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and all amendments to those reports as soon as reasonably practicable after such material is electronically filed with or furnished to the Securities and Exchange Commission. The Securities and Exchange Commission maintains an internet site (http://www.sec.gov) that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the Securities and Exchange Commission. We include our web site address in this Annual Report on Form 10-K only as an inactive textual reference. Information contained in our website does not constitute a part of this report or our other filings with the SEC.

## 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.*

### Summary of Risk Factors

Our business is subject to numerous risks and uncertainties, including those highlighted in this section below, that represent challenges that we face in connection with the successful implementation of our strategy. The occurrence of one or more of the events or circumstances described in more detail in the risk factors below, alone or in combination with other events or circumstances, may have an adverse effect on our business, cash flows, financial condition and results of operations. Such risks include, but are not limited to:

- 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. We initiated the commercial launch of CAPLYTA in March 2020.
- 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.
- 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 generated limited revenue from product sales and there is no guarantee that our revenue from the sale of CAPLYTA or other product candidates, if approved, will be substantial.
- There is no guarantee that our planned clinical trials for lumateperone will be successful.
- 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 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.
- 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.
- 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.

- 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.
- Preliminary and interim data from our clinical studies that we may announce or publish from time to time may change as more patient data become available.
- 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.
- Even if we successfully complete the clinical trials of one or more of our product candidates, the product candidates may fail for other reasons.
- We are subject to ongoing regulatory obligations and restrictions with regard to lumateperone 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.
- 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.
- CAPLYTA has only recently been, 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 larger scale manufacturing processes that are more efficient and cost-effective to commercialize our product candidates which may not be successful.
- 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 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.
- Our ability to compete may be undermined if we do not adequately protect our proprietary rights.
- 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.
- 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.
- The outbreak of the novel strain of coronavirus, SARS-CoV-2, or similar public health crises, could have a material adverse impact on our business, financial condition and results of operations, including our commercial operations and sales, clinical trials and preclinical studies.
- Numerous factors could result in substantial volatility in the trading price of our stock.
- The price of our common stock could be subject to volatility related or unrelated to our operations.
- 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.

## 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 other 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 continue to build our commercial organization and have hired our U.S. sales force and will need to further develop our commercial organization in order to successfully commercialize CAPLYTA. We expect that continued 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 effectiveness of our commercial strategy for the 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 has 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 as an adjunctive

therapy for the treatment of MDD. For example, in the first quarter of 2021,we submitted sNDAs to the FDA for potential regulatory approval of lumateperone for the treatment of bipolar depression in patients with Bipolar I or II disorder as monotherapy and adjunctive therapy, but there can be no assurance that the FDA will approve lumateperone for those indications. 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 have established or our third-party relationships for the commercialization of lumateperone are not effective, lumateperone may not be successfully commercialized.***

Prior to the commercial launch of CAPLYTA in late March 2020, we had no experience as a company in marketing drugs or with respect to pricing and obtaining adequate third-party reimbursement for drugs. We continue to build our commercial organization and capabilities in the United States in order 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 generated limited revenue from product sales and there is no guarantee that our revenue from the sale of CAPLYTA 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 generated limited product revenues from CAPLYTA and we cannot guarantee that CAPLYTA 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. In September 2020, we announced topline results from Study 402, conducted globally, evaluating lumateperone as adjunctive therapy to lithium or valproate in the treatment of major depressive episodes associated with Bipolar I or Bipolar II disorder. In July 2019, we announced topline results from our first monotherapy study, Study 401, conducted in the United States, 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 addition, we have commenced our Phase 3 clinical program evaluating lumateperone as an adjunctive therapy to antidepressants for the treatment of MDD and we expect to initiate clinical conduct in two Phase 3 trials in 2021.

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 second quarter of 2020, we announced topline results from Study ITI-214-104, a Phase 1/2 translational study of single ascending doses of ITI-214 in patients with chronic systolic heart failure with reduced ejection fraction. In this study, ITI-214 improved cardiac output by increasing heart contractility and decreasing vascular resistance. Agents that both increase heart contractility (inotropism) and decrease vascular resistance (vasodilation) are called inodilators. Inodilators in current clinical use are associated with the development of arrhythmias, which are abnormal heart rhythms that when serious can impair heart function and lead to mortality. ITI-214, which acts through a novel mechanism of action, was not associated with arrhythmias in this study and was generally well-tolerated in all patients.

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 our Study 401 for the treatment of bipolar depression, neither dose of lumateperone met the primary study endpoint.

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 three Phase 3 monotherapy studies in bipolar depression for which we announced topline results in July 2019 and September 2020 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 our independent data monitoring committee'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, 2020, we had an accumulated deficit of approximately $937.1 million. We expect to incur net losses over the next several years as we advance our programs and incur significant clinical development costs. To date, we have received limited revenues from the commercialization of CAPLYTA. Prior to our commercial launch of CAPLYTA in late March 2020, substantially all of our revenues 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, investment securities and restricted cash totaled $658.8 million at December 31, 2020. In January 2020, we completed an underwritten public offering of shares of our common stock resulting in net proceeds to us of approximately $277.0 million, after deducting underwriting discounts and commissions and offering expenses. In June 2020, we sold shares of our common stock under our at-the-market equity program generating approximately $5.6 million in net proceeds. In the third quarter of 2020, we sold additional shares of our common stock under our at-the-market equity program generating approximately $12.3 million in net proceeds. In September 2020, we completed an underwritten public offering of shares of our common stock resulting in net proceeds to us of approximately $357.8 million, after deducting underwriting discounts and commissions and offering expenses.

With our cash, cash equivalents and investment securities, including the net proceeds from our public offerings in January and September 2020, we intend to fund the following: commercialization activities in connection with the commercialization of CAPLYTA for the treatment of schizophrenia and, if approved, bipolar depression; the development of lumateperone in our late stage clinical programs; the development of our other product candidates, including ITI-1284, 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 and September 2020 offerings to continue our clinical development and commercialization activities. Because successful development of our product candidates is uncertain, we are unable to estimate the actual funds we will require to complete research and development and commercialize our products under development.

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

- the 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 continue to commercialize 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.

***Our product candidates have never been manufactured on a commercial scale, and there are risks associated with scaling up manufacturing to commercial scale. In particular, we will need to develop a larger scale manufacturing process that is more efficient and cost-effective to commercialize our potential products, which may not be successful.***

Our product candidates have never been manufactured on a commercial scale, and there are risks associated with scaling up manufacturing to commercial scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, lot consistency and timely availability of raw materials. There is no assurance that our manufacturers will be successful in establishing a larger-scale commercial manufacturing process for our product candidates 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 our product candidates 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 such products 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, in January 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. 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, in January 2017, we entered into a manufacturing services agreement with Lonza under which Lonza has agreed to manufacture and supply the API for lumateperone commercial quantities, with purchase prices determined in each project plan. We agreed to provide Lonza with a written forecast of our estimated quarterly requirements. 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-1284, 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 over the past few years. 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 initiated the commercial launch of CAPLYTA in late March 2020. As such, as an organization, this was the first time we have launched or commercialized any pharmaceutical product. In order to continue 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 continue to appropriately commercialize and generate revenue from sales of CAPLYTA and may not become profitable.

We are employing our own internal sales force to commercialize CAPLYTA for the treatment of schizophrenia as part of our commercialization strategy in the United States. We are 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, 2020, we had net operating loss carryforwards, or NOLs, of approximately $323.0 million, which are available to reduce any future federal and state taxable income and will begin to expire at various dates through 2037 and $191.9 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, 2020, 2019 and 2018, 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 offerings in 2020. 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, 2020, 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.

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. Historically, the majority of our losses incurred did not result in additional NOLs in the United States as the majority of our expenditures related to the lumateperone program. However, as our commercialization efforts continue, we will see more NOLs in the United States to be carried forward and used against future net income of the U.S. operations as the percentage of research and development costs decline as compared to our total expenditures.

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

On December 22, 2017, the “Tax Cuts and Jobs Act,” or TCJA, was signed into law and 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 would receive a refund in future periods for AMT paid in prior years. As of December 31, 2020, the Company received all of these refunds.

On March 27, 2020, the United States enacted The Coronavirus Aid, Relief and Economic Security (CARES) Act which includes several significant business tax provisions, of which the immediate relevance to the Company is the acceleration of refunds of previously generated corporate AMT credits. The CARES Act also adds an employee retention credit to encourage employers to maintain headcounts even if employees cannot report to work because of issues related to the coronavirus, a temporary provision allowing companies to defer remitting to the government the employee share of some payroll taxes, among other things. The Company reviewed the provisions and there was not a material tax impact on its financial statements for the year ended December 31, 2020. The Company did reclassify its deferred tax asset related to the AMT tax credit carryforward of $265,000 to a current tax receivable in the first quarter of 2020 upon the filing of its tax return for year ended December 31, 2019 and received the refund in July 2020.

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 a portion of 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.

***The outbreak of the novel strain of coronavirus, SARS-CoV-2, or similar public health crises, could have a material adverse impact on our business, financial condition and results of operations, including our commercial operations and sales, clinical trials and preclinical studies.***

Public health crises, such as pandemics or similar outbreaks, could adversely impact our business. In December 2019, a novel strain of coronavirus, SARS-CoV-2, which causes coronavirus disease 2019 (COVID-19), surfaced in Wuhan, China. Since then, SARS-CoV-2 and COVID-19 have spread to multiple countries, including the United States. The COVID-19 pandemic is evolving, and to date has led to the implementation of various responses, including government-imposed quarantines, travel restrictions and other public health safety measures. In response to the spread of SARS-CoV-2 and COVID-19, we have instructed the majority of our office-based employees to work from home. In connection with our commercial launch of CAPLYTA, which is approved by FDA for the treatment of schizophrenia in adults, our commercial organization and sales force and medical organization are having significantly reduced personal interactions with physicians and customers and increasingly conduct promotional activities virtually, and elected to cease in-person interactions with physicians and customers entirely for some period of time in the interest of employee and community safety. Even though certain of our sales force and medical organization have begun to have personal interactions with physicians and customers, we may have to cease such personal interactions depending on the COVID-19 situation. In addition, the COVID-19 situation has resulted in a decrease in the number of patient visits to healthcare providers. As a result of the COVID-19 pandemic, or similar pandemics, we may experience disruptions that could severely impact our business, including our ability to successfully commercialize our only commercial product, CAPLYTA, in the United States, and these disruptions could negatively impact our sales of CAPLYTA. Business interruptions from the current or future pandemics may also adversely impact the third parties we rely on to sufficiently manufacture CAPLYTA and to produce our product candidates in quantities we require, which may impair the commercialization and our research and development activities.

We are currently conducting clinical trials for our product candidates in many countries, including the United States, Europe and Russia and may expand to other geographies. Timely enrollment of, completion of and reporting on our clinical trials is dependent upon these global clinical trial sites which are, or in the future may be, adversely affected by the COVID-19 pandemic or other pandemics. Some factors from the COVID-19 pandemic that have or may adversely affect the timing and conduct of our clinical trials and adversely impact our business generally, include but are not limited to delays or difficulties in clinical site initiation, diversion of healthcare resources away from clinical trials to pandemic concerns, limitations on travel, regulatory delays and supply chain disruptions.

In response to the COVID-19 pandemic, on March 10, 2020, the FDA announced its intention to temporarily postpone most inspections of foreign manufacturing facilities and products. On March 18, 2020, the FDA announced its intention to temporarily postpone routine surveillance inspections of domestic manufacturing facilities and provided guidance regarding the conduct of clinical trials, which has since been further updated. As of June 23, 2020, the FDA noted it was continuing to ensure timely reviews of applications for medical products during the COVID-19 pandemic in line with its user fee performance goals and conducting mission critical domestic and foreign inspections to ensure compliance of manufacturing facilities with FDA quality standards. As of July 2020, utilizing a rating system to assist in determining when and where it is safest to conduct such inspections based on data about the virus' trajectory in a given state and locality and the rules and guidelines that are put in place by state and local governments, FDA is either continuing to, on a case-by-case basis, conduct only mission critical inspections, or, where possible to do so safely, resuming prioritized domestic inspections, which generally include pre-approval inspections. Foreign pre-approval inspections that are not deemed mission-

critical remain postponed, while those deemed mission-critical will be considered for inspection on a case-by-case basis. FDA will use similar data to inform resumption of prioritized operations abroad as it becomes feasible and advisable to do so. The FDA may not be able to maintain this pace and delays or setbacks are possible in the future. Should FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel, FDA has stated that it generally intends to issue a complete response letter. Further, if there is inadequate information to make a determination on the acceptability of a facility, FDA may defer action on the application until an inspection can be completed. Additionally, regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

The COVID-19 pandemic continues to rapidly evolve, and the severity and duration of the pandemic remain uncertain. The extent to which the pandemic impacts our business, including our commercial results, clinical trials, and preclinical studies will depend on future developments, which are highly uncertain.

## 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 are 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 laws. 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, 2020, the price per share of our common stock on the Nasdaq Global Select Market has ranged from a high of $34.31 to a low of $10.94. 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 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.

***We have a limited number of authorized shares of common stock available for issuance, which may impair our ability to issue additional shares for future capital raising transactions or strategic transactions unless we obtain stockholder approval to amend our certificate of incorporation to increase the number of authorized shares of common stock.***

Following the closing of our September 2020 underwritten public offering of common stock, we have a limited number of authorized shares of common stock available for future issuance that are not already issued or reserved for issuance. We have 100.0 million authorized shares of common stock. As of December 31, 2020, we had 80.5 million shares of common stock outstanding, 7.2 million shares of common stock issuable upon the exercise of outstanding stock options, or the vesting of outstanding time-based and milestone restricted stock units, and 7.5 million shares of common stock reserved for future issuance under our equity compensation plans. As a result, as of December 31, 2020, we had approximately 4.9 million authorized shares of common stock available for issuance. We will remain limited by the number of additional shares available for future capital raising transactions or strategic transactions unless we obtain stockholder approval to amend our restated certificate of incorporation to increase the number of authorized shares of common stock. This may cause a delay in our future capital raising, collaboration, partnership or other strategic transactions, and may have a material adverse effect on our business and financial condition.

***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 could 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 the quarter ended June 30, 2020, we sold 230,000 shares of common stock under our "at-the-market" equity program which resulted in our receiving net proceeds of $5.6 million in July 2020. In the quarter ended September 30, 2020, we issued an additional 512,791 shares of common stock under our "at-the-market" equity program and received approximately $12.3 million of net proceeds. On September 10, 2020, we terminated the "at-the-market" equity program agreement with SVB Leerink LLC. 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 have been assessed and implemented to address the increased complexity of revenue recognition associated with commercial sales of a pharmaceutical product. 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 cash 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;
- our expectations regarding our commercialization of CAPLYTA, including the impact of COVID-19 on the commercialization of CAPLYTA and our ability to adapt our approach as appropriate;
- the duration and severity of the COVID-19 pandemic and its impact on our business; the supply and availability of and demand for our product;
- 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 our 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 our 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, management or sales and marketing 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 22, 2021, we had 80,917,013 outstanding shares of common stock and no outstanding shares of preferred stock. As of February 22, 2021, there were approximately 93 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

Not applicable.

## 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 CAPLYTA (lumateperone) was approved by the FDA for the treatment of schizophrenia in adults (42mg/day) and we initiated the commercial launch of CAPLYTA in late March 2020. In support of our commercialization efforts, we employ a national sales force consisting of approximately 240 sales representatives. 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 clinical program consists of three monotherapy studies and one adjunctive study. In September 2020, we announced positive topline results from Study 402, conducted globally, evaluating lumateperone as adjunctive therapy to lithium or valproate in the treatment of major depressive episodes associated with Bipolar I or Bipolar II disorder. In Study 402, once daily 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 ($p=0.0206$; effect size = 0.27). Lumateperone 42 mg also met the key secondary endpoint, the Clinical Global Impression Scale for Bipolar for Severity of Illness, or CGI-BP-S, Depression Score ($p=0.0082$; effect size = 0.31). The lower lumateperone dose, 28 mg, showed a trend for a dose-related improvement in symptoms of depression but the results did not reach statistical significance. 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. Following the positive results in Study 402, we amended Study 403 to evaluate major depressive episodes with mixed features in bipolar disorder in patients with Bipolar I or Bipolar II disorder and mixed features in patients with major depressive disorder, or MDD. We expect to complete Study 403 in the second half of 2022 and following completion we intend to discuss the results with the FDA to determine whether Study 403, as amended, will provide supportive data for a potential future regulatory filing for this indication.

In July 2019, we announced topline results from our first monotherapy study, Study 401, conducted in the United States, 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). These benefits were statistically significant in both Bipolar I and Bipolar II patients. Study 404 also met its key secondary endpoint, Clinical Global Impression Scale for Bipolar for Severity of Illness (CGI-BP-S) Total Score ($p<0.001$; effect size = 0.46). 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 all three bipolar depression studies, with a favorable safety profile.

In addition, while our Phase 3 bipolar depression trials were powered for the overall patient population and not powered for subpopulation analyses, statistically significant benefit versus placebo was seen in the subgroup of patients with Bipolar I and Bipolar II disorder in Study 404 and in patients with Bipolar I disorder in Study 402, but the Bipolar II subgroup was not statistically significant in Study 402. In February 2021, we submitted supplemental new drug applications, or sNDAs, to the FDA for potential regulatory approval of lumateperone for the treatment of bipolar depression in patients with Bipolar I or II disorder as monotherapy and adjunctive therapy. Assuming the sNDA submissions are accepted by the FDA, we anticipate an FDA target action date for the sNDAs in the second half of 2021.

We are also pursuing clinical development of lumateperone for the treatment of additional CNS diseases and disorders. At a dose of 42 mg, lumateperone has been shown effective in treating the symptoms associated with schizophrenia, and we believe 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 evaluating lumateperone as an adjunctive therapy to antidepressants for the treatment of MDD and we expect to initiate clinical conduct in two Phase 3 trials in 2021.

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 in December 2020 we initiated a Phase 1 single ascending dose study of lumateperone LAI, a formulation of lumateperone designed to be administered subcutaneously and to maintain therapeutic levels of lumateperone for at least one month. This study will evaluate the pharmacokinetics, safety and tolerability of lumateperone LAI in patients with stable symptoms of schizophrenia. We anticipate topline results from this study will be available in the second half of 2021. Results from this study will inform the dosing strategy for future studies. 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 certain patients.

We hold exclusive, worldwide commercialization rights to lumateperone and a family of compounds from Bristol-Myers Squibb Company pursuant to an exclusive license.

We are developing ITI-1284 for the treatment of behavioral disturbances in patients with dementia, the treatment of dementia-related psychosis and for the treatment of certain depressive disorders in the elderly. ITI-1284 is a deuterated form of lumateperone, a new molecular entity formulated as an oral disintegrating tabl et for sublingual administration. ITI-1284 is formulated as an oral solid dosage form that dissolves almost instantly when placed under the tongue, allowing for ease of use in the elderly and may be particularly beneficial for patients who have difficulty swallowing conventional tablets. Phase 1 single and multiple ascending dose studies in healthy volunteers and healthy elderly volunteers (> than 65 years of age) evaluated the safety, tolerability and pharmacokinetics of ITI-1284. In these studies, there were no reported serious adverse events in either age group. In the elderly cohort, reported adverse events were infrequent with the most common adverse event being transient dry mouth (mild). Based on these studies, we plan to initiate Phase 2 studies evaluating ITI-1284 for the treatment of behavioral disturbances in dementia, dementia-related psychosis, and certain depressive disorders in the elderly.

We have another 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 aberrant immune system activation in 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, cancers 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. We plan to initiate a Phase 2 clinical trial with ITI-214 for Parkinson's disease in 2021. In addition, in the second quarter of 2020, we announced topline results from Study ITI-214-104, a Phase 1/2 translational study of single ascending doses of ITI-214 in patients with chronic systolic heart failure with reduced ejection fraction. In this study, ITI-214 improved cardiac output by increasing heart contractility and decreasing vascular resistance. Agents that both increase heart contractility (inotropism) and decrease vascular resistance (vasodilation) are called inodilators. Inodilators in current clinical use are associated with the development of arrhythmias, which are abnormal heart rhythms that when serious can impair heart function and lead to mortality. ITI-214, which acts through a novel mechanism of action, was not associated with arrhythmias in this study and was generally well-tolerated in all patients.

We also have a development program with our ITI-333 compound 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. ITI-333 is a novel compound that uniquely combines activity as an antagonist at serotonin 5-HT2A receptors and a partial agonist at μ-opioid receptors. These combined actions support the potential utility of ITI-333 in the treatment of opioid use disorder and associated comorbidities (e.g., depression, anxiety, sleep disorders) without opioid-like safety and tolerability concerns. In December 2020, we initiated a Phase 1 single ascending dose study evaluating the safety, tolerability and pharmacokinetics of ITI-333 in healthy volunteers. We have received a grant from the National Institute on Drug Abuse under the Helping to End Addiction Long-term Initiative, or NIH HEAL Initiative, that we expect will fund a significant portion of the early stage clinical development costs associated with this program.

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.

**COVID-19**

In December 2019, a novel strain of coronavirus, SARS-CoV-2, which causes coronavirus disease 2019 (COVID-19), surfaced in Wuhan, China. Since then, SARS-CoV-2 and COVID-19 have spread to multiple countries, including the United States. The COVID-19 pandemic is evolving, and to date has led to the implementation of various responses, including government-imposed quarantines, travel restrictions and other public health safety measures. In response to the spread of SARS-CoV-2 and COVID-19, we have instructed the majority of our office-based employees to work from home. In connection with our commercial launch of CAPLYTA, which is approved by FDA for the treatment of schizophrenia in adults, our commercial organization and sales force and medical organization are having significantly reduced personal interactions with physicians and customers and increasingly conduct promotional activities virtually, and elected to cease in-person interactions with physicians and customers entirely for some period of time in the interest of employee and community safety. Even though certain of our sales force and medical organization have begun to have personal interactions with physicians and customers, we may have to cease such personal interactions depending on the COVID-19 situation. In addition, the COVID-19 situation has resulted in a decrease in the number of patient visits to healthcare providers. As a result of the COVID-19 pandemic, or similar pandemics, we may experience disruptions that could severely impact our business, including our ability to successfully

commercialize our only commercial product, CAPLYTA, in the United States, and these disruptions could negatively impact our sales of CAPLYTA. Business interruptions from the current or future pandemics may also adversely impact the third parties we rely on to sufficiently manufacture CAPLYTA and to produce our product candidates in quantities we require, which may impair the commercialization and our research and development activities.

We are currently conducting clinical trials for our product candidates in many countries, including the United States, Europe and Russia and may expand to other geographies. Timely enrollment of, completion of and reporting on our clinical trials is dependent upon these global clinical trial sites which are, or in the future may be, adversely affected by the COVID-19 pandemic or other pandemics. Some factors from the COVID-19 pandemic that have or may adversely affect the timing and conduct of our clinical trials and adversely impact our business generally, include but are not limited to delays or difficulties in clinical site initiation, patient enrollment, diversion of healthcare resources away from clinical trials to pandemic concerns, limitations on travel, regulatory delays and supply chain disruptions.

In response to the COVID-19 pandemic, on March 10, 2020, the FDA announced its intention to temporarily postpone most inspections of foreign manufacturing facilities and products. On March 18, 2020, the FDA announced its intention to temporarily postpone routine surveillance inspections of domestic manufacturing facilities and provided guidance regarding the conduct of clinical trials, which has since been further updated. As of June 23, 2020, the FDA noted it was continuing to ensure timely reviews of applications for medical products during the COVID-19 pandemic in line with its user fee performance goals and conducting mission critical domestic and foreign inspections to ensure compliance of manufacturing facilities with FDA quality standards. As of July 2020, utilizing a rating system to assist in determining when and where it is safest to conduct such inspections based on data about the virus' trajectory in a given state and locality and the rules and guidelines that are put in place by state and local governments, FDA is either continuing to, on a case-by-case basis, conduct only mission critical inspections, or, where possible to do so safely, resuming prioritized domestic inspections, which generally include pre-approval inspections. Foreign pre-approval inspections that are not deemed mission-critical remain postponed, while those deemed mission-critical will be considered for inspection on a case-by-case basis. FDA will use similar data to inform resumption of prioritized operations abroad as it becomes feasible and advisable to do so. The FDA may not be able to maintain this pace and delays or setbacks are possible in the future. Should FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel, FDA has stated that it generally intends to issue a complete response letter. Further, if there is inadequate information to make a determination on the acceptability of a facility, FDA may defer action on the application until an inspection can be completed. Additionally, regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

The COVID-19 pandemic continues to rapidly evolve, and the severity and duration of the pandemic remain uncertain. The extent to which the pandemic impacts our business, including our commercial results, clinical trials, and preclinical studies will depend on future developments, which are highly uncertain.

**Results of Operations**

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

***Revenues***

Net revenues from product sales consist of sales of CAPLYTA, which was approved by the FDA on December 2019. We initiated the commercial launch of CAPLYTA in late March 2020 and generated

approximately $22.5 million in net revenue from product sales for the year ended December 31, 2020. During this product launch year, 2020 net sales increased steadily from approximately $883,000 in the first quarter of 2020 to approximately $12.4 million in the fourth quarter. In addition, we had approximately $0.3 million of grant revenues for the year ended December 31, 2020, compared to approximately $0.06 million of grant revenues for the year ended December 31, 2019. 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, developing and commercializing 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 ongoing development programs for ITI-214 for Parkinson's disease and for the treatment of 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) costs of product sales; (ii) research and development expenses; (iii) general and administrative expenses and (iv) selling expenses.

Costs of product sales are comprised of:

- Direct costs of formulating, manufacturing and packaging drug product;
- Overhead costs consisting of labor, customs, share-based compensation, shipping, outside inventory management and other miscellaneous operating costs; and
- Royalty payments on product sales.

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.

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.

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.

Product sold through December 31, 2020 generally consisted of drug product that was previously charged to research and development expense prior to FDA approval of CAPLYTA. Because the Company previously expensed drug product, the cost of drug product sold is lower than it would have been and has a positive impact on our cost of product sales for the year ended December 31, 2020. The Company's reported cost of product sales as a percentage of product sales, net was 8.4% or approximately $1.9 million for the year ended December 31, 2020, of which more than half related to royalty payments accrued to BMS.

We will expect to continue to have this favorable impact on cost of product sales and related product gross margins until our sales of CAPLYTA include drug product that is manufactured after the FDA approval. We are currently unable to estimate how long it will be until we begin selling product manufactured post FDA approval.

We expect that research and development expenses will increase as we proceed with our 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 selling, general and administrative costs will increase from prior periods primarily due to costs associated with building and maintaining infrastructure and promotional activities to support the commercial sales of CAPLYTA, which will include hiring additional personnel and increasing technological capabilities. 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 1,833,102 shares of our common stock in 2019 and have granted options to purchase 800,200 shares of our common stock in 2020. We also granted time based restricted stock units, or RSUs, for 950,449 shares of our common stock in 2019 and time based RSUs for 1,007,402 shares of our common stock in 2020. We will recognize expense associated with these RSUs and options over three years in research and development expenses, selling, general and administrative expenses, and inventoriable manufacturing 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 the first quarter of 2020, we also granted performance based RSUs, which vest based on the achievement of certain milestones that include (i) the approval of a planned NDA by the FDA, or the 2020 Milestone RSUs, and (ii) the achievement of certain comparative shareholder returns against our peers, or the 2020 TSR RSUs. The 2020 Milestone RSUs were valued at the closing price of our common stock on February 18, 2020. The 2020 TSR RSUs were valued using the Monte Carlo simulation method. We expect to continue to grant stock options and other share-based awards in the future, which with our growing employee base will increase our share-based compensation expense in future periods.

The following table sets forth our revenues, operating expenses, interest income, net and income tax expense for the years ended December 31, 2020, 2019 and 2018 (in thousands):

| | For the Year Ended December 31, | | |
|---|---|---|---|
| | **2020** | 2019 | **2018** |
| **Revenues, net** | **$ 22,813** | $ 61 | $ — |
| **Expenses** | | | |
| Cost of product sales | **1,895** | — | — |
| Research and development | **65,782** | 89,125 | 132,167 |
| Selling, general and administrative | **186,364** | 64,948 | 30,099 |
| Total costs & expenses | **254,041** | 154,073 | 162,266 |
| Loss from operations | **(231,228)** | (154,012) | (162,266) |
| Interest income, net | **(4,235)** | (6,292) | (7,141) |
| Income tax expense | **13** | 2 | 2 |
| **Net loss** | **$(227,006)** | $(147,722) | $(155,127) |

***Comparison of Years Ended December 31, 2020 and December 31, 2019***

*Total Revenues, Net*

Total revenues, net for the year ended December 31, 2020 were approximately $22.8 million compared to $61,000 for the year ended December 31, 2019. Net product sales were approximately $22.5 million for the year ended December 31, 2020, and were comprised of sales of CAPLYTA, which was approved by the FDA on December 20, 2019 and became available to wholesalers in March 2020. No similar net product sales were recognized during the year ended December 31, 2019. In addition, revenue from a government grant was approximately $282,000 and $61,000 for the years ended December 31, 2020 and 2019, respectively.

*Cost of Product Sales*

Cost of product sales was approximately $1.9 million for the year ended December 31, 2020. Cost of product sales consisted primarily of product royalty fees, overhead and minimal direct costs. Product sold during the year ended December 31, 2020 generally consisted of drug product that was previously charged to research and development expense prior to FDA approval of CAPLYTA. This minimal cost drug product had a positive impact on our cost of product sales and related product gross margins for the year ended December 31, 2020. No similar cost of product sales was recognized during the year ended December 31, 2019.

We will continue to have a lower cost of product sales that excludes the cost of the drug product that was incurred prior to FDA approval until our sales of CAPLYTA include drug product that is manufactured after the FDA approval. We expect that this will be the case for the near-term and as a result, our cost of product sales will be less than we anticipate it will be in future periods.

*Research and Development Expenses*

| | **2020** | 2019 |
|---|---|---|
| External costs | **$38,791** | $ 59,141 |
| Internal costs | **26,991** | 29,984 |
| **Total Research and development expenses** | **$65,782** | $ 89,125 |

| | 2020 | 2019 |
|---|---|---|
| Lumateperone costs | **$32,884** | $ 37,121 |
| Manufacturing costs of drug candidates | **5,585** | 20,684 |
| Share- based compensation | **8,415** | 9,411 |
| Other projects and overhead | **18,898** | 21,909 |
| **Total Research and development expenses** | **$65,782** | $ 89,125 |

Research and development expenses decreased to $65.8 million for the year ended December 31, 2020 as compared to $89.1 million for the year ended December 31, 2019, representing a decrease of approximately $23.3 million, or 26%. This decrease is due primarily to a decrease of approximately $15.1 million in manufacturing expense, which is due to expensing manufacturing costs related to CAPLYTA prior to FDA approval in prior years and capitalizing a significant portion as inventory in the current year, a decrease of approximately $4.2 million of lumateperone clinical and non-clinical expenses, a decrease of approximately $3.0 million relating to other projects and overhead, and a decrease of approximately $1.0 million of share-based compensation expense. Internal costs decreased by approximately $3.0 million for the period due to lower labor related expenses, stock compensation expense, travel and other operating costs.

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 CAPLYTA (lumateperone) for the treatment for schizophrenia in adults. 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, 2020, we employed 43 full time personnel in our research and development group as compared to 56 full time personnel in our research and development group at December 31, 2019. The decrease is due primarily to personnel transitioning from research-related activities to commercial efforts in 2020. 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.

*Selling, General and Administrative Expenses*

Selling, general and administrative costs for the year ended December 31, 2020 were $186.4 million as compared to $64.9 million in the year ended December 31, 2019, which represents an increase of 187%.

Selling costs were $132.5 million for the year ended December 31, 2020 as compared to pre-commercialization costs of $32.5 million in the same period in 2019, or an increase of 307%. This increase is primarily due to an increase in sales related labor costs of $55.2 million and commercialization costs of $41.5 million. Salaries, bonuses and related benefit costs for our sales and marketing functions for the year ended December 31, 2020 and 2019 constituted approximately 46% and 17%, respectively, of our selling costs.

General and administrative expenses for the year ended December 31, 2020 were $53.9 million in 2020 as compared to $32.4 million for the same period in 2019, an increase of 66%. This increase is due to increases in professional and consulting fees of $7.0 million, information technology services of $5.1 million, stock compensation expense of $4.3 million, labor and related expenses of $3.8 million, and the remainder consisting of insurance, lease expense, and other administrative expenses. Salaries, bonuses and related benefit costs for our general and administrative functions for the years ended December 31, 2020 and 2019 constituted approximately 63% and 53%, respectively, of our general and administrative costs.

We expect selling, general and administrative costs to increase in 2021 as compared to the year ended December 31, 2020. We are expanding post approval marketing, including increased efforts to educate physicians due to the limitations related to the COVID-19 virus pandemic and market access efforts as well as our administrative infrastructure.

*Interest Income*

Interest income has decreased to approximately $4.2 million from $6.3 million for the year ended December 31, 2020 as compared to the year ended December 31, 2019. This decrease is primarily a result of lower interest rates during 2020, in addition to decreases in cash balances from 2019 to 2020.

*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 United States 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. On December 22, 2017, the "Tax Cuts and Jobs Act," or 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 the remainder in 2020.

**Liquidity and Capital Resources**

Through December 31, 2020, we provided funds for our operations by obtaining a total of approximately $1.6 billion 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 a terminated license and collaboration agreement. In the year ended December 31, 2020, we have collected approximately $16.8 million from product sales, which we believe will increase going forward. 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 $295.0 million and net proceeds of approximately $277.0 million, after deducting underwriting discounts, commissions and offering expenses.

In June 2020, we sold 230,000 shares of common stock under our at-the-market equity program generating $5.6 million in net proceeds which was received in July 2020. In the third quarter of 2020, we sold an additional 512,791 shares of common stock utilizing our at-the-market program and received $12.3 million of net proceeds.

In September 2020 we completed a public offering of common stock in which we sold 12,666,667 shares of common stock at a public offering price of $30.00 per share for aggregate gross proceeds of $380.0 million. After deducting underwriting discounts, commissions and offering expenses, the net proceeds to the Company were approximately $357.8 million.

As of December 31, 2020, we had a total of approximately $658.8 million in cash and cash equivalents and available-for-sale investment securities, including $1.4 million in restricted cash, and approximately $36.9 million of short-term liabilities consisting entirely of liabilities from operations, including approximately $5.5 million of short-term lease obligations. In the year ended December 31, 2020, we spent approximately $251.4 million in cash for operations and equipment. We have sources of cash which included $4.2 million of interest income and $16.8 million of collected product sales, resulting in net cash used in operations of $230.3 million. The use of cash was primarily for selling and marketing costs in connection with our commercial launch of CAPLYTA, conducting clinical trials and non-clinical testing, product manufacturing, 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 for anticipated future sales of product and in connection with the development of lumateperone; and general operations.

For 2021, we expect to spend up to $395 million primarily related to the marketing and commercialization of CAPLYTA, lumateperone clinical development including clinical trial conduct, regulatory activities, manufacturing and inventory production, expansion of our administrative infrastructure and other development activities. This spending does not include projected receipts from sales of CAPLYTA or revenue generated from grants. Our other development activities will include efforts related to our ITI-1284, ITI-214 and ITI-333 programs, among others. However, the COVID-19 pandemic may negatively impact our commercialization of CAPLYTA, our ability to complete our ongoing or planned preclinical and clinical trials, our ability to obtain approval of any product candidates from the FDA or other regulatory authorities, and our workforce and therefore our research, development and commercialization activities. This may ultimately have a material adverse effect on our liquidity, although we are unable to make any prediction with certainty given the rapidly changing nature of the pandemic and governmental and other responses to it.

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 the development of lumateperone for bipolar depression through potential FDA approval for this indication. We also plan to fund additional clinical trials of lumateperone for the treatment of depressive disorders and other CNS disorders; preclinical and clinical development of our ITI-007 long acting injectable development program; additional clinical trials of lumateperone; clinical development of ITI-1284, continued clinical development of our PDE product candidates, 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 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. In the year ended December 31, 2020, we spent approximately $251.4 million in cash for operations and equipment. We have sources of cash which included $4.2 million of interest income and $16.8 million of collected product sales, resulting in net cash used in operations of $230.3 million. 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 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 included up to $75 million of common stock that we could 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 the quarter ended June 30, 2020, we sold 230,000 shares of common stock under our “at-the-market” equity program which resulted in our receiving net proceeds of $5.6 million in July 2020. In the quarter ended September 30, 2020, we issued an additional 512,791 shares of common stock under our “at-the-market” equity program and received approximately $12.3 million of net proceeds. On September 10, 2020, we terminated the “at-the-market” equity program agreement with SVB Leerink LLC.

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. Additionally, the continued spread of COVID-19 and uncertain market conditions may limit our ability to access any financing. 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.

In addition, following the closing of our September 2020 underwritten public offering of common stock, we have a limited number of authorized shares of common stock available for future issuance that are not already issued or reserved for issuance. We have 100.0 million authorized shares of common stock. As of December 31, 2020, we had 80.5 million shares of common stock outstanding, 7.2 million shares of common stock issuable upon the exercise of outstanding stock options or the vesting of outstanding restricted stock units, and 7.5 million shares of common stock reserved for future issuance under our equity compensation plans. As a result, as of December 31, 2020, we had approximately 4.9 million authorized shares of common stock available for issuance. We will remain limited by the number of additional shares available for future capital raising transactions or strategic transactions unless we obtain stockholder approval to amend our restated certificate of incorporation to increase the number of authorized shares of common stock. This may cause a delay in our future capital raising, collaboration, partnership or other strategic transactions, and may have a material adverse effect on our business and financial condition.

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 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. In addition, our investment portfolio historically has not been adversely impacted by problems in the credit markets, 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. 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. On May 17, 2019, we entered into a vehicle fleet lease with a company to acquire motor vehicles for certain employees. The vehicle fleet lease provides for individual leases for the vehicles, which at each lease commencement was determined to qualify for operating lease treatment. We began leasing vehicles under the vehicle fleet lease in March 2020. Restricted cash of $1.4 million on our consolidated balance sheet relates to a letter of credit issued as part of the vehicle fleet lease.

**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 our 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, 2020, we had no material change in estimates which related to the prior year estimates of accrued expenses for clinical trials. 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.

**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 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. We adopted this standard on January 1, 2020 and evaluated the implications of the new standard, inclusive of the applicable financial statement disclosures required, as well as to its internal controls, business processes, and accounting policies, noting there was no significant impact to the financial statements as of January 1, 2020 and for the year ended December 31, 2020.

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

*Interest Rate Sensitivity.* As of December 31, 2020, we had cash, cash equivalents, marketable securities and restricted cash of approximately $658.8 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, 2020 of approximately $481,000 and an unrealized gain on investments, net, in 2019 totaling approximately $128,000. We plan on holding those investments to maturity, and should interest rates rise, there would be no recognition of impairment required. Declines in interest rates, however, would reduce future investment income.

*Capital Market Risk.* Although we receive product revenues from commercial sales 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.


| Index to Financial Statements and Financial Statement Schedules | Number |
|---|---|
| Report of Independent Registered Public Accounting Firm | F-1 |
| Consolidated Balance Sheets as of December 31, 2020 and 2019 | F-3 |
| Consolidated Statements of Operations for the Years Ended December 31, 2020, 2019 and 2018 | F-4 |
| Consolidated Statements of Comprehensive Loss for the Years Ended December 31, 2020, 2019 and 2018 | F-5 |
| Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 2020, 2019 and 2018 | F-6 |
| Consolidated Statements of Cash Flows for the Years Ended December 31, 2020, 2019 and 2018 | F-7 |
| Notes to Consolidated Financial Statements | F-8 |


## 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, 2020. 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, 2020, 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 the effectiveness 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, 2020 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, 2020, 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, 2020, 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, 2020 and 2019, 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, 2020, and the related notes and our report dated February 25, 2021 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
February 25, 2021

**Item 9B. OTHER INFORMATION**

Not applicable.

## PART III

### Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The response to this item is incorporated by reference from the discussion responsive thereto under the captions “Management and Corporate Governance” and “Code of Ethics and Business Conduct” in the Company’s Proxy Statement for the 2021 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 2021 Annual Meeting of Stockholders.

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

The response to this item is incorporated by reference from the discussion responsive thereto under the captions “Security Ownership of Certain Beneficial Owners and Management” and “Equity Compensation Plan Information” in the Company’s Proxy Statement for the 2021 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 2021 Annual Meeting of Stockholders.

### Item 14. PRINCIPAL ACCOUNTANT 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 2021 Annual Meeting of Stockholders.

## PART IV

**Item 15.** **EXHIBITS AND 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. | | 10-K (Exhibit 4.2) | 3/2/2020 | 001-36274 |

| 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 | | Master Services Agreement, effective as of January 10, 2017, by and between ITI Limited and Lonza Ltd.*** | | 10-Q (Exhibit 10.1) | 11/9/2020 | 001-36274 |
| 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 | | 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 |
| 10.8 | | 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 |
| 10.9 | | Employment Agreement effective as of September 12, 2018 by and between Suresh Durgam, M.D. and Intra-Cellular Therapies, Inc. | X | | | |

| Exhibit Number | Exhibit Description | Filed Herewith | Incorporated by Reference herein from Form or Schedule | Filing Date | SEC File/ Reg. Number |
|---|---|---|---|---|---|
| 10.10 | Employee Proprietary Information, Inventions, and Non-Competition Agreement effective as of September 1, 2003 by and between Sharon Mates, Ph.D. and Intra-Cellular Therapies, Inc.* | | 8-K (Exhibit 10.8) | 9/5/2013 | 000-54896 |
| 10.11 | Employee Proprietary Information, Inventions, and Non-Competition Agreement effective as of July 29, 2014 by and between Michael Halstead and Intra-Cellular Therapies, Inc.* | | 10-K (Exhibit 10.11) | 3/12/2015 | 001-36274 |
| 10.12 | Employee Proprietary Information, Inventions, and Non-Competition Agreement effective as of December 1, 2003 by and between Lawrence J. Hineline and Intra-Cellular Therapies, Inc.* | | 8-K (Exhibit 10.9) | 9/5/2013 | 000-54896 |
| 10.13 | Employee Proprietary Information, Inventions, 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 |
| 10.14 | 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 |
| 10.15 | Form of Indemnification Agreement by and between the Company and its directors and executive officers.* | | 8-K (Exhibit 10.13) | 9/5/2013 | 000-54896 |
| 10.16 | 2003 Equity Incentive Plan, as amended.* | | 8-K (Exhibit 10.14) | 9/5/2013 | 000-54896 |
| 10.17 | Form of Stock Option Agreement under the 2003 Equity Incentive Plan, as amended.* | | 8-K (Exhibit 10.15) | 9/5/2013 | 000-54896 |
| 10.18 | Amended and Restated 2013 Equity Incentive Plan.* | | 8-K (Exhibit 10.1) | 6/18/2015 | 001-36274 |
| 10.19 | Form of Stock Option Agreement under the 2013 Equity Incentive Plan.* | | 10-K (Exhibit 10.19) | 3/25/2014 | 001-36274 |
| 10.20 | Amended and Restated 2018 Equity Incentive Plan.* | | 8-K (Exhibit 10.1) | 5/28/2020 | 001-36274 |

| Exhibit Number | Exhibit Description | Filed Herewith | Incorporated by Reference herein from Form or Schedule | Filing Date | SEC File/ Reg. Number |
|---|---|---|---|---|---|
| 10.21 | Form of Stock Option Agreement under the 2018 Equity Incentive Plan.* | | 8-K (Exhibit 10.2) | 6/21/2018 | 001-36274 |
| 10.22 | Form of Director Stock Option Agreement under the 2018 Equity Incentive Plan.* | | 8-K (Exhibit 10.3) | 6/21/2018 | 001-36274 |
| 10.23 | Form of Restricted Stock Unit Agreement under the 2018 Equity Incentive Plan.* | | 8-K (Exhibit 10.4) | 6/21/2018 | 001-36274 |
| 10.24 | Form of Director Restricted Stock Unit Agreement under the 2018 Equity Incentive Plan.* | | 8-K (Exhibit 10.5) | 6/21/2018 | 001-36274 |
| 10.25 | Form of Stock Option Agreement under the Amended and Restated 2018 Equity Incentive Plan.* | | 10-Q (Exhibit 10.2) | 8/10/2020 | 001-36274 |
| 10.26 | Form of Director Stock Option Agreement under the Amended and Restated 2018 Equity Incentive Plan.* | | 10-Q (Exhibit 10.3) | 8/10/2020 | 001-36274 |
| 10.27 | Form of Restricted Stock Unit Agreement under the Amended and Restated 2018 Equity Incentive Plan.* | | 10-Q (Exhibit 10.4) | 8/10/2020 | 001-36274 |
| 10.28 | Form of Director Restricted Stock Unit Agreement under the Amended and Restated 2018 Equity Incentive Plan.* | | 10-Q (Exhibit 10.5) | 8/10/2020 | 001-36274 |
| 10.29 | Non-Employee Director Compensation Policy, as amended.* | | 10-K (Exhibit 10.28) | 3/2/2020 | 001-36274 |
| 10.30 | 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 |
| 10.31 | 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 |
| 10.32 | 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 |
| 10.33 | Intra-Cellular Therapies, Inc. 2019 Inducement Award Plan.* | | 10-K (Exhibit 10.32) | 3/2/2020 | 001-36274 |
| 10.34 | Form of Restricted Stock Unit Agreement under the 2019 Inducement Award Plan.* | | 10-K (Exhibit 10.33) | 3/2/2020 | 001-36274 |

| Exhibit Number | | Exhibit Description | Filed Herewith | Incorporated by Reference herein from Form or Schedule | Filing Date | SEC File/ Reg. Number |
|---|---|---|---|---|---|---|
| 10.35 | | Form of Stock Option Agreement under the 2019 Inducement Award Plan.* | | 10-K (Exhibit 10.34) | 3/2/2020 | 001-36274 |
| 21.1 | | Subsidiaries. | | 10-K (Exhibit 21.1) | 3/1/2017 | 001-36274 |
| 23.1 | | Consent of Ernst & Young LLP. | X | | | |
| 31.1 | | Certification of the Chief Executive Officer. | X | | | |
| 31.2 | | Certification of the Chief Financial Officer. | X | | | |
| 32.1 | | Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. | X | | | |
| 101 | .INS | 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 | | | |
| | .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.
*** Certain confidential portions of this Exhibit were omitted by means of marking such portions with brackets ("[***]") because the identified confidential portions (i) are not material and (ii) would be competitively harmful if publicly disclosed.

**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: February 25, 2021

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

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

| Signatures | Title | Date |
|---|---|---|
| By: /s/ Sharon Mates, Ph.D.<br>Sharon Mates, Ph.D. | Chairman, President and Chief Executive Officer (principal executive officer) | February 25, 2021 |
| By: /s/ Lawrence J. Hineline<br>Lawrence J. Hineline | Senior Vice President of Finance and Chief Financial Officer (principal financial officer and principal accounting officer) | February 25, 2021 |
| By: /s/ Christopher Alafi, Ph.D.<br>Christopher Alafi, Ph.D. | Director | February 25, 2021 |
| By: /s/ Richard Lerner, M.D.<br>Richard Lerner, M.D. | Director | February 25, 2021 |
| By: /s/ Joel S. Marcus<br>Joel S. Marcus | Director | February 25, 2021 |
| By: /s/ Rory B. Riggs<br>Rory B. Riggs | Director | February 25, 2021 |
| By: /s/ Robert L. Van Nostrand<br>Robert L. Van Nostrand | Director | February 25, 2021 |

## 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, 2020 and 2019, 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, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020, 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, 2020, 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 February 25, 2021 expressed an unqualified opinion thereon.

### Basis for Opinion

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

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

### 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, 2020 consolidated balance sheet and also recorded prepaid clinical trial expenses, which are included in prepaid expenses and other current assets on the December 31, 2020 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, 2020.<br><br>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.<br><br>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, and observed management hold discussions with the Clinical Research Organization 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 by 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
February 25, 2021

Intra-Cellular Therapies, Inc. and Subsidiaries

Consolidated Balance Sheets

| | December 31, 2020 | December 31, 2019 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | **$ 60,045,933** | $ 107,636,849 |
| Investment securities, available-for-sale | **597,402,126** | 116,373,335 |
| Restricted cash | **1,400,000** | — |
| Accounts receivable, less allowance of $120,000 and $0 at December 31, 2020 and 2019, respectively | **10,764,583** | — |
| Inventory | **7,056,385** | — |
| Prepaid expenses and other current assets | **14,235,455** | 6,313,785 |
| Total current assets | **690,904,482** | 230,323,969 |
| Property and equipment, net | **1,998,346** | 2,259,740 |
| Right of use assets, net | **24,324,762** | 18,252,074 |
| Deferred tax asset, net | **—** | 264,609 |
| Other assets | **86,084** | 86,084 |
| Total assets | **$ 717,313,674** | $ 251,186,476 |
| **Liabilities and stockholders' equity** | | |
| Current liabilities: | | |
| Accounts payable | **$ 5,501,825** | $ 7,425,024 |
| Accrued and other current liabilities | **10,902,117** | 16,138,909 |
| Lease liabilities, short-term | **5,541,802** | 3,187,435 |
| Accrued employee benefits | **14,907,479** | 9,472,651 |
| Total current liabilities | **36,853,223** | 36,224,019 |
| Lease liabilities | **23,600,347** | 19,955,186 |
| Total liabilities | **60,453,570** | 56,179,205 |
| Stockholders' equity: | | |
| Common stock, $0.0001 par value: 100,000,000 shares authorized; 80,463,089 and 55,507,497 shares issued and outstanding at December 31, 2020 and 2019, respectively | **8,046** | 5,551 |
| Additional paid-in capital | **1,593,475,506** | 904,971,772 |
| Accumulated deficit | **(937,104,032)** | (710,098,369) |
| Accumulated comprehensive income | **480,584** | 128,317 |
| Total stockholders' equity | **656,860,104** | 195,007,271 |
| Total liabilities and stockholders' equity | **$ 717,313,674** | $ 251,186,476 |

*See accompanying notes to consolidated financial statements.*

Intra-Cellular Therapies, Inc. and Subsidiaries

Consolidated Statements of Operations

| | Years Ended December 31, | | |
|---|---|---|---|
| | **2020** | 2019 | 2018 |
| Revenues | | | |
| Product sales, net | **$ 22,530,753** | $ — | $ — |
| Grant revenue | **282,226** | 60,613 | — |
| Total revenues, net | **22,812,979** | 60,613 | — |
| Operating expenses: | | | |
| Cost of product sales | **1,895,029** | — | — |
| Research and development | **65,782,137** | 89,124,838 | 132,166,913 |
| Selling, general and administrative | **186,363,444** | 64,947,625 | 30,099,855 |
| Total operating expenses | **254,040,610** | 154,072,463 | 162,266,768 |
| Loss from operations | **(231,227,631)** | (154,011,850) | (162,266,768) |
| Interest income | **(4,235,481)** | (6,291,272) | (7,140,957) |
| Loss before provision for income taxes | **(226,992,150)** | (147,720,578) | (155,125,811) |
| Income tax expense | **13,513** | 1,600 | 1,600 |
| Net loss | **$ (227,005,663)** | $ (147,722,178) | $ (155,127,411) |
| Net loss per common share: | | | |
| Basic & Diluted | **$ (3.23)** | $ (2.68) | $ (2.84) |
| Weighted average number of common shares: | | | |
| Basic & Diluted | **70,364,800** | 55,186,206 | 54,707,865 |

*See accompanying notes to consolidated financial statements.*

Intra-Cellular Therapies, Inc. and Subsidiaries

Consolidated Statements of Comprehensive Loss

| | Years Ended December 31, | | |
|---|---|---|---|
| | **2020** | **2019** | **2018** |
| Net loss | **$ (227,005,663)** | $ (147,722,178) | $ (155,127,411) |
| Other comprehensive income: | | | |
| Unrealized gain on investment securities | **352,267** | 796,074 | 131,467 |
| Comprehensive loss | **$ (226,653,396)** | $ (146,926,104) | $ (154,995,944) |

*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 Income (Loss) | Total Stockholders' Equity |
|---|---|---|---|---|---|---|
| | Shares | Amount | | | | |
| 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 issuances 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 issuances 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** |
| Common shares issued | **23,409,458** | **2,341** | **652,709,670** | **—** | **—** | **652,712,011** |
| Exercise of stock options and issuances of restricted stock | **1,536,797** | **153** | **11,464,765** | **—** | **—** | **11,464,918** |
| Stock issued for services | **9,337** | **1** | **214,102** | **—** | **—** | **214,103** |
| Share-based compensation | **—** | **—** | **24,115,197** | **—** | **—** | **24,115,197** |
| Net loss | **—** | **—** | **—** | **(227,005,663)** | **—** | **(227,005,663)** |
| Other comprehensive income | **—** | **—** | **—** | **—** | **352,267** | **352,267** |
| Balance at December 31, 2020 | **80,463,089** | **$ 8,046** | **$ 1,593,475,506** | **$ (937,104,032)** | **$ 480,584** | **$ 656,860,104** |

*See accompanying notes to consolidated financial statements.*

Intra-Cellular Therapies, Inc. and Subsidiaries

Consolidated Statements of Cash Flows

| | Years Ended December 31, | | |
|---|---|---|---|
| | 2020 | 2019 | 2018 |
| **Cash flows used in operating activities** | | | |
| Net loss | **$ (227,005,663)** | $ (147,722,178) | $ (155,127,411) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | |
| Depreciation | **528,118** | 477,121 | 368,673 |
| Share-based compensation | **24,115,197** | 20,788,688 | 17,396,146 |
| Stock issued for services | **214,103** | 194,205 | 192,530 |
| Amortization of premiums and discounts on investment securities, net | **(648,248)** | (1,131,597) | (943,239) |
| Changes in operating assets and liabilities: | | | |
| Accounts receivable, net | **(10,764,583)** | — | — |
| Inventory | **(7,056,385)** | — | — |
| Prepaid expenses and other assets | **(7,921,670)** | 1,465,384 | (3,026,908) |
| Long term deferred tax asset, net | **264,609** | 264,609 | 529,217 |
| Accounts payable | **(1,923,199)** | (6,536,036) | 7,787,521 |
| Accrued liabilities and other | **198,036** | 3,327,095 | 14,386,774 |
| Lease liabilities, net | **(73,160)** | 889,468 | — |
| Deferred rent | **—** | — | 267,584 |
| Net cash used in operating activities | **(230,072,845)** | (127,983,241) | (118,169,113) |
| **Cash flows (used in) provided by investing activities** | | | |
| Purchases of investments | **(755,629,547)** | (80,720,301) | (271,156,707) |
| Maturities of investments | **275,601,271** | 258,857,683 | 406,189,288 |
| Purchases of property and equipment | **(266,724)** | (700,395) | (391,268) |
| Net cash (used in) provided by investing activities | **(480,295,000)** | 177,436,987 | 134,641,313 |
| **Cash flows provided by financing activities** | | | |
| Proceeds from exercise of stock options | **11,464,918** | 3,235,601 | 674,206 |
| Proceeds of public offerings, net | **652,712,011** | — | — |
| Proceeds from stock warrant | **—** | — | 10,982 |
| Net cash provided by financing activities | **664,176,929** | 3,235,601 | 685,188 |
| Net (decrease) increase in cash, cash equivalents, and restricted cash | **(46,190,916)** | 52,689,347 | 17,157,388 |
| Cash, cash equivalents, and restricted cash at beginning of period | **107,636,849** | 54,947,502 | 37,790,114 |
| Cash, cash equivalents, and restricted cash at end of period | **$ 61,445,933** | $ 107,636,849 | $ 54,947,502 |
| Cash paid for taxes | **$ 1,600** | $ 1,600 | $ 1,600 |
| **Non-cash investing and financing activities** | | | |
| Right of use assets under operating vehicle fleet leases | **$ 8,917,935** | $ — | $ — |
| Right of use assets under operating real estate leases | **$ —** | $ 219,703 | $ — |

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the consolidated balance sheets that sum to the total of the same such amounts shown in the consolidated statements of cash flows:

| | | | |
|---|---|---|---|
| Cash and cash equivalents | **$ 60,045,933** | $ 107,636,849 | $ 54,947,502 |
| Restricted cash | **1,400,000** | — | — |
| Total cash, cash equivalents and restricted cash | **$ 61,445,933** | $ 107,636,849 | $ 54,947,502 |

*See accompanying notes to consolidated financial statements.*

Intra-Cellular Therapies, Inc. and Subsidiaries

Notes to Consolidated Financial Statements

December 31, 2020

**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) had been approved by the U.S. Food and Drug Administration ("FDA") for the treatment of schizophrenia in adults (42mg/day). The Company initiated the commercial launch of CAPLYTA in late March 2020. 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 major depressive disorder.

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 $295.0 million. After deducting underwriting discounts, commissions and offering expenses, the net proceeds to the Company were approximately $277.0 million. On September 15, 2020, the Company completed a public offering of common stock in which the Company sold 12,666,667 shares of common stock at an offering price of $30.00 per share for aggregate gross proceeds of $380.0 million. After deducting underwriting discounts, commissions and offering expenses, the net proceeds to the Company were approximately $357.8 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 included up to $75 million of common stock that the Company could issue and sell from time to time, through SVB Leerink LLC acting as its sales agent, pursuant to the sale agreement that the Company entered into with SVB Leerink on August 29, 2019 for the Company's "at-the-market" equity program. On September 10, 2020, the Company terminated the "at-the-market" equity program sales agreement with SVB Leerink LLC. During the year ended December 31, 2020, the Company issued an aggregate 742,791 shares of common stock under the Company's "at-the-market" equity program which resulted in the Company receiving net proceeds of $17.9 million.

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 primarily for the treatment of neurological and psychiatric disorders.

### Use of Estimates

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

### Cash and Cash Equivalents

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

### Investment Securities

Investment securities may consist of investments in U.S. Treasuries, various U.S. governmental agency debt securities, corporate bonds, certificates of deposit, and other fixed income securities with an average maturity of twelve months or less. Management classifies the Company's investments as available-for-sale. Such securities are carried at estimated fair value, with any unrealized holding gains or losses reported, net of any tax effects reported, as accumulated other comprehensive income, which is a separate component of stockholders' equity. Realized gains and losses and declines in value judged to be other-than-temporary, if any, are included in consolidated results of operations. A decline in the market value of any available-for-sale security below cost that is deemed to be other-than-temporary results in a reduction in fair value, which is charged to earnings in that period, and a new cost basis for the security is established. Dividend and interest income 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, 2020 | | | |
|---|---|---|---|---|
| | Amortized Cost | Unrealized Gains | Unrealized (Losses) | Estimated Fair Value |
| U.S. Government Agency Securities | $259,304 | $ 3 | $ (31) | $259,276 |
| Certificates of Deposit | 10,500 | — | — | 10,500 |
| Commercial Paper | 124,368 | 23 | (21) | 124,370 |
| Corporate Notes/Bonds | 202,749 | 624 | (117) | 203,256 |
| | $596,921 | $ 650 | $ (169) | $597,402 |

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

| | 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 |

The Company has classified all of its investment securities as 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, 2020 and 2019, the Company held $188.5 million and $3.0 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 overall risk, specifically credit loss, quarterly or more frequently if circumstances warrant. The company would estimate the expected credit loss over the lifetime of the asset and record an allowance for the portion of the amortized cost basis of the financial asset that the company does not expect to collect.

The aggregate related fair value of investments with unrealized losses as of December 31, 2020 was $372.3 million, which consisted of $180.0 million from U.S. government agency securities, $84.4 million of commercial paper, and $107.8 million of corporate notes/bonds. The aggregate amount of unrealized losses as of December 31, 2020 was approximately $169,000, which consisted of $31,000 from U.S. government agency securities, $21,000 from commercial paper, and $117,000 from corporate notes/bonds. The $372.3 million aggregate fair value of investments with unrealized losses as of December 31, 2020 has been held in a continuous unrealized loss position for less than 12 months. 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 had 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 Company reviewed all of the investments which were in a loss position at the respective balance sheet dates, as well as the remainder of the portfolio. The Company has analyzed the unrealized losses and determined that market conditions were the primary factor driving these changes. After analyzing the securities in an unrealized loss position, the portion of these losses that relate to changes in credit quality is insignificant. 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.

**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.

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

- 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, 2020 and December 31, 2019. The carrying value of cash held in money market funds of approximately $27.9 million as of December 31, 2020 and $49.9 million as of December 31, 2019 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 $0 and approximately $47.6 million as of December 31, 2020 and 2019, 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.

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

| | | Fair Value Measurements at Reporting Date Using | | |
|---|---|---|---|---|
| | December 31, 2020 | Quoted Prices in Active Markets for Identical Assets (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) |
| Money Market Funds | $ 27,917 | $ 27,917 | $ — | $ — |
| U.S. Government Agency Securities | 259,276 | — | 259,276 | — |
| Certificates of Deposit | 10,500 | — | 10,500 | — |
| Commercial Paper | 124,370 | — | 124,370 | — |
| Corporate Notes/Bonds | 203,256 | — | 203,256 | — |
| | **$ 625,319** | **$ 27,917** | **$ 597,402** | **$ —** |

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

| | 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 Notes/Bonds | 38,861 | — | 38,861 | — |
| | **$ 216,874** | **$ 49,882** | **$ 166,992** | **$ —** |

**Financial Instruments**

The Company considers the recorded costs of its financial assets and liabilities, which consist of cash equivalents, restricted cash, accounts receivable, prepaid expenses, right of use asset, net, other assets, accounts payable, accrued liabilities, accrued employee benefits, and, lease liabilities, short term, to approximate their fair value because of their relatively short maturities at December 31, 2020 and December 31, 2019. 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.

**Restricted Cash**

Restricted cash is collateral used under the letter of credit arrangement for the Company's vehicle lease agreement (see Note 5). The Company adopted ASU No. 2016-18, "Restricted Cash" ("ASU 2016-18") and now includes restricted cash balances within the cash, cash equivalents and restricted cash balance on the statement of cash flows.

**Accounts Receivable, net**

The Company's accounts receivable, net, primarily arise from product sales. They are generally stated at the invoiced amount and do not bear interest. Revenues from product sales are recorded at the net sales price (transaction price), which includes estimates of variable consideration for which reserves are established and which result from chargebacks, prompt pay discounts, and distribution fees.

The Company monitors the financial performance and creditworthiness of its customers so that it can properly assess and respond to changes in the customers' credit profiles. The Company reserves against accounts receivable for estimated losses that may arise from a Customer's inability to pay and any amounts determined to be uncollectible are written off against the reserve when it is probable that the receivable will not be collected. The reserve amount for estimated collectability losses was not significant as of December 31, 2020.

We are also subject to credit risk from our accounts receivable related to our product sales. We monitor our exposure within accounts receivable and record a credit loss reserve against uncollectible accounts receivable as necessary. We extend credit primarily to pharmaceutical wholesale distributors. Customer creditworthiness is monitored and collateral is not required. Historically, we have not experienced credit losses on our accounts receivable and as of December 31, 2020, our credit loss reserve on receivables was not material.

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

**Concentration of Credit Risk**

Financial instruments which potentially subject the Company to concentrations of credit risk consist of accounts receivable, net from customers and cash, cash equivalent and investments held at financial institutions. For the year ended December 31, 2020, all of the Company's accounts receivable, net arose from product sales in the U.S. and all customers have standard payment terms which generally require payment within 60 days. For the year ended December 31, 2020, 96% of sales were generated from three major industry wholesalers, respectively.

Three individual customers accounted for approximately 39%, 29%, and 28% of product sales for the year ended December 31, 2020. As of December 31, 2020, the Company believes that such customers are of high credit quality.

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.

**Inventory**

The Company values its inventories at the lower of cost or estimated net realizable value. The Company determines the cost of its inventories, which includes amounts related to materials and manufacturing overhead, on a first-in, first-out ("FIFO") basis. The Company performs an assessment of the recoverability of capitalized inventory during each reporting period, and it writes down any excess and obsolete inventories to their estimated net realizable value in the period in which the impairment is first identified. Such impairment charges, if they occur, are recorded within cost of product sales.

The Company capitalizes inventory costs associated with the Company's products after regulatory approval when, based on management's judgment, future commercialization is considered probable and the future economic benefit is expected to be realized. Inventory acquired and manufactured prior to receipt of regulatory approval of a product candidate is expensed as research and development expense as incurred. Inventory that can be used in either the production of clinical or commercial product is expensed as research and development expense when selected for use in a clinical manufacturing campaign. Inventory that is used in the production of sample product is reclassified to prepaid and other current assets and is then expensed to selling, general and administrative expenses when the sample product is distributed.

Shipping and handling costs for product shipments to customers are recorded as incurred in cost of product sales along with costs associated with manufacturing the product, and any inventory write-downs.

**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.

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

**Revenue Recognition**

Effective January 1, 2018, the Company adopted FASB ASC Topic 606, *Revenue from Contracts with Customers* ("ASC Topic 606"). The Company did not generate any product related revenue prior to January 1, 2020, and therefore the adoption of ASC Topic 606 did not have an impact in the Company's financial statements for any prior periods. In accordance with ASC Topic 606, the Company recognizes revenue when the customer obtains control of a promised good or service, in an amount that reflects the consideration that the Company expects to receive in exchange for the good or service. The reported results for the year ended December 31, 2020 reflect the application of ASC Topic 606.

To determine revenue recognition for arrangements that the Company determines are within the scope of ASC Topic 606, the Company performs the following five steps: (i) identify the contract(s) with a customer, (ii) identify the performance obligations in the contract, (iii) determine the transaction price, (iv) allocate the transaction price to the performance obligations in the contract, and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to arrangements that meet the definition of a contract under ASC Topic 606, including when it is probable that the Company will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC Topic 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. For additional discussion of accounting for product sales, see *Product Sales, net* (below).

To date, the Company's only source of product sales has been from sales of CAPLYTA in the U.S., which the Company began shipping to customers in March 2020.

*Product Sales, net*

The Company sells CAPLYTA to a limited number of customers which include a number of national and select regional distributors. These customers subsequently resell the Company's products to specialty pharmacy providers, as well as other retail pharmacies and certain medical centers or hospitals. In addition to distribution agreements with customers, the Company enters into arrangements with health care providers and payers that provide for government mandated and/or privately negotiated rebates, chargebacks, and discounts with respect to the purchase of the Company's products. The Company recognizes revenue on product sales when the Customer obtains control of the Company's product, which occurs at a point in time (upon delivery). Product revenues are recorded net of applicable reserves for variable consideration, including rebates, discounts and allowances, among others. If taxes should be collected from customers relating to product sales and remitted to governmental authorities, they will be excluded from revenue.

*Reserves for Variable Consideration*

Revenues are calculated based on the wholesale acquisition cost that the Company charges to distributors for CAPLYTA less variable consideration for which reserves are established. Components of variable consideration may include trade discounts and allowances, product returns, provider chargebacks and discounts, government rebates, payer rebates, and other incentives, such as voluntary patient assistance, and other allowances that are offered within contracts between the Company and its customers, payers, and other indirect customers relating to the Company's sales of its product.

These reserves, as detailed below, are based on the amounts earned, or to be claimed on the related sales, include estimates that take into consideration a range of possible outcomes which are either considered more likely or probability-weighted in accordance with the expected value method in ASC Topic 606 for relevant factors such as current contractual and statutory requirements, specific known market events and trends, forecasted customer

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

buying and payment patterns. The Company's estimates regarding the payer mix for CAPLYTA and historical industry information regarding the payer mix for comparable pharmaceutical products and product portfolios, in particular, historical information related to similar products in their initial launch stages. Overall, these reserves reflect the Company's best estimates of the amount of consideration to which it is entitled based on the terms of the respective underlying contracts after considering whether revenue should be constrained under ASC 606.

The amount of variable consideration which is included in the transaction price may be constrained, and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized under the contract will not occur in a future period. The Company's analyses also contemplated application of the constraint in accordance with the guidance, under which it determined a material reversal of revenue would not occur in a future period for the estimates detailed below as of December 31, 2020 and, therefore, the transaction price was not reduced further during the year ended December 31, 2020. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results in the future vary from the Company's estimates, the Company will adjust these estimates, which would affect net product sales and earnings in the period such variances become known.

*Trade Discounts and Allowances*— The Company generally provides customers with discounts which include incentive fees that are explicitly stated in the Company's contracts and are recorded as a reduction of revenue in the period the related product revenue is recognized. In addition, the Company compensates (through trade discounts and allowances) its customers for sales order management, data, and distribution services. However, the Company has determined such services received to date are not distinct from the Company's sale of products to the Customer and, therefore, these payments have been recorded as a reduction of product sales, net within the consolidated statements of operations through December 31, 2020, as well as a reduction to accounts receivables, net on the consolidated balance sheets.

*Product Returns*— Consistent with industry practice, the Company generally offers customers a limited right of return for product that has been purchased from the Company based on the product's expiration date, which lapses upon shipment to a patient. The Company estimates the amount of its product sales that may be returned by its customers and records this estimate as a reduction of revenue in the period the related product revenue is recognized, as well as accrued expenses and other current liabilities on the consolidated balance sheets. The Company currently estimates product return liabilities using available industry data and its own sales information, including its visibility into the inventory remaining in the distribution channel. The Company has not received any returns to date.

*Provider Chargebacks and Discounts*— Chargebacks for fees and discounts to providers represent the estimated obligations resulting from contractual commitments to sell products to qualified healthcare providers at prices lower than the list prices charged to customers who directly purchase the product from the Company. Customers charge the Company for the difference between what they pay for the product and the ultimate selling price to the qualified healthcare providers. These reserves are established in the same period that the related revenue is recognized, resulting in a reduction of product revenue and accounts receivables, net. Chargeback amounts are generally determined at the time of resale to the qualified healthcare provider by customers, and the Company generally issues credits for such amounts within a few weeks of the customer's notification to the Company of the resale. Reserves for chargebacks consist of credits that the Company expects to issue for units that remain in the distribution channel inventories at each reporting period-end that the Company expects will be sold to qualified healthcare providers, and chargebacks that customers have claimed, but for which the Company has not yet issued a credit. For the year ended December 31, 2020, these amounts were not significant.

*Government Rebates*— The Company is subject to discount obligations under state Medicaid and Medicare programs. These reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included in accrued expenses and other current liabilities on the consolidated balance sheets. For Medicare, the Company also estimates the

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

number of patients in the prescription drug coverage gap for whom the Company will owe an additional liability under the Medicare Part D program. The Company's liability for these rebates consists of invoices received for claims from prior quarters that have not been paid or for which an invoice has not yet been received, estimates of claims for the current quarter, and estimated future claims that will be made for product that has been recognized as revenue, but which remains in the distribution channel inventories at the end of each reporting period.

*Payer Rebates*— The Company contracts with certain private payer organizations, primarily insurance companies and pharmacy benefit managers, for the payment of rebates with respect to utilization of its product. The Company estimates these rebates and records such estimates in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability recorded as an accrued expenses and other current liabilities on the consolidated balance sheets.

*Other Incentives*— Other incentives which the Company offers include voluntary patient assistance programs, such as the co-pay assistance program, which are intended to provide financial assistance to qualified commercially-insured patients with prescription drug co-payments required by payers. The calculation of the accrual for co-pay assistance is based on an estimate of claims and the cost per claim that the Company expects to receive associated with product that has been recognized as revenue but remains in the distribution channel inventories at the end of each reporting period. The Company also has a voucher program whereby a patient can receive a prescription at no cost and whereby the Company reimburses the pharmacy for 100% of the sales price of the prescription. The Company applies the claims for vouchers for product that is in the distribution channel and reduces recognized revenue accordingly.

The adjustments are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included as a component of accrued expenses and other current liabilities on the consolidated balance sheets.

Chargebacks, discounts, fees, and returns are recorded as reductions of trade receivables, net on the consolidated balance sheets. Government and other rebates are recorded as a component of accrued expenses and other current liabilities on the consolidated balance sheets.

**Cost of Product Sales**

Our cost of product sales relates to sales of CAPLYTA. Cost of product sales primarily includes product royalty fees, overhead, and direct costs (inclusive of material, shipping, and manufacturing costs).

For the product royalty fees, the Company entered into an exclusive License Agreement with Bristol-Myers Squibb Company ("BMS"), for which the Company is obliged to make tiered single digit percentage royalty payments ranging between 5 – 9% on sales of licensed products. The related royalties are recorded within cost of product sales on the statement of operations.

Prior to the FDA approval of CAPLYTA, the Company expensed all costs associated with the manufacturing of lumateperone as part of research and development expenses. From December 20, 2019, the date of approval of CAPLYTA, through December 31, 2019 there was no production and no inventory costs were incurred. Therefore, at December 31, 2019, no inventory costs had been capitalized. The cost of product sales in the year ended December 31, 2020 are lower than incurred because of previously expensed inventory.

***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

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

personnel and resources and the costs of clinical trials. Other research and development expenses include preclinical analytical testing, manufacturing of drug product for use in clinical and nonclinical trials, 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 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, 2020, the company had no material change in estimates which related to the prior year estimates of accrued expenses for clinical trials. 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.

**Advertising Expense**

In connection with the FDA approval of CAPLYTA in 2019, the Company began to incur advertising costs in connection with the subsequent commercial launch of CAPLYTA in 2020. Advertising costs are expensed when services are rendered. The Company incurred $36.3 million in advertising costs during the year ended December 31, 2020, and $0 in advertising costs during the years ended December 31, 2019, and 2018, respectively, related to its marketed product, CAPLYTA.

**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.

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

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.

The Company's effective tax rate for the years ended December 31, 2020 and 2019 was approximately 0%. This effective tax rate is substantially lower than the U.S. statutory rate of 21% due to valuation allowances recorded on current year losses where the Company is not more-likely than not to recognize a future tax benefit.

On March 27, 2020, the United States enacted The Coronavirus Aid, Relief and Economic Security (CARES) Act which includes several significant business tax provisions, of which the immediate relevance to the Company is the acceleration of refunds of previously generated corporate Alternative Minimum Tax ("AMT") credits. The CARES Act also adds an employee retention credit to encourage employers to maintain headcounts even if employees cannot report to work because of issues related to the coronavirus, and a temporary provision allowing companies to defer remitting to the government the employee share of some payroll taxes, among other things. The Company reviewed the provisions and there was not a material tax impact on its financial statements for the year ended December 31, 2020. The Company did reclassify its deferred tax asset related to the AMT tax credit carryforward of $265,000 to a current tax receivable in the first quarter of 2020 upon the filing of its tax return for year ended December 31, 2019 and received the refund in July 2020.

**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 related to stock options 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, 2020, 2019 and 2018 accounts for forfeitures as they occur.

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.

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

Expected volatility rates for quarterly periods prior to December 31, 2019 were 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. In the fourth quarter of 2019 and for all periods thereafter, expected volatility rates are based entirely on the historical volatility of the Company's common stock. The expected life of stock options is the period of time for which the stock options are expected to be outstanding. Given the 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.

In the first quarter of each fiscal year beginning in 2016, 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 vest based on the achievement of certain milestones that include (i) the submission of a new drug application ("NDA") to the FDA for lumateperone for the treatment of schizophrenia, (ii) the approval of the NDA by the FDA (together, the "Milestone RSUs") and (iii) the achievement of certain comparative shareholder returns against the Company's peers (the "TSR RSUs"). The Milestone RSUs related to the NDA submission were fully amortized on 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 Milestone RSUs related to the approval of the NDA were 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.

In the first quarter of 2020, the Company granted performance-based RSUs for approximately 86,000 shares of common stock, which vest based on the achievement of certain milestones that include (i) the approval of a planned NDA by the FDA and (ii) the achievement of certain comparative shareholder returns against the Company's peers (the "2020 TSR RSUs"). The 2020 TSR RSUs were valued using the Monte Carlo Simulation method and will be amortized over the life of the RSUs based on the agreements.

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 is 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.

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 (the "2018 Plan") pursuant to which 4,750,000 additional shares of common stock were reserved for future equity grants. In

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

May 2020, the Company's stockholders approved the Company's 2018 Amended and Restated Equity Incentive Plan (the "Amended 2018 Plan") pursuant to which 6,500,000 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, RSUs, stock awards and other share-based awards for up to a total of 1,000,000 shares of common stock to new employees of the Company. As of December 31, 2020, stock options and RSUs for 314,138 shares have been granted under the 2019 Inducement Plan. The Company does not intend to make additional grants under the 2019 Inducement Plan.

**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, 2020, 2019 and 2018:

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2020 | 2019 | 2018 |
| Stock options | 5,517,622 | 6,039,945 | 4,748,391 |
| RSUs | 1,600,083 | 1,268,679 | 647,411 |
| TSR RSUs | 36,339 | 67,080 | 206,484 |

**Recently Issued Accounting Standards**

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. The Company adopted this standard on January 1, 2020. The Company evaluated the implications of the new standard, inclusive of the applicable financial statement disclosures required, as well as to its internal controls, business processes, and accounting policies, noting there was no significant impact to the financial statements as of January 1, 2020 and for the year ended December 31, 2020.

**3. Inventory**

Inventory consists of the following:

| | December 31, 2020 |
|---|---|
| Raw materials | $ 2,483,801 |
| Work in process | 1,781,101 |
| Finished goods | 2,791,483 |
| | **$ 7,056,385** |

**3. Inventory (continued)**

Inventory acquired prior to receipt of the FDA approval on December 20, 2019 for CAPLYTA was expensed as research and development expense as incurred. No inventory was produced from the FDA approval date through the end of 2019; therefore, no inventory was capitalized on the consolidated balance sheet as of December 31, 2019.

**4. Property and Equipment**

Property and equipment consist of the following:

| | December 31, 2020 | December 31, 2019 |
|---|---|---|
| Computer equipment | **$ 243,532** | $ 243,532 |
| Furniture and fixtures | **423,097** | 423,097 |
| Scientific equipment | **4,127,951** | 3,861,227 |
| Leasehold improvements | **1,240,315** | 1,240,315 |
| | **6,034,895** | 5,768,171 |
| Less accumulated depreciation | **(4,036,549)** | (3,508,431) |
| | **$ 1,998,346** | $ 2,259,740 |

Depreciation expense for the years ended December 31, 2020, 2019 and 2018 was $528,118, $477,121 and $368,673, respectively.

**5. Right Of Use Assets and Lease Liabilities**

*Real Estate Leases*

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 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 consolidated balance sheets. 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

**5. Right Of Use Assets and Lease Liabilities (continued)**

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 $17.0 million and $21.8 million as of December 31, 2020, respectively. The operating cash outflows related to operating lease obligations for the year ended December 31, 2020 were approximately $3.3 million.

Maturity analysis under the lease agreements are as follows:

| | |
|---|---|
| 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 |
| Year ending December 31, 2025 | 3,787,248 |
| Thereafter | 13,839,791 |
| Total | 31,808,190 |
| Less: Present value discount | (9,961,556) |
| Total Lease liability | 21,846,634 |
| Less: Current portion | (3,284,540) |
| Long-term lease liabilities | $ 18,562,094 |

Lease expense for the year ended December 31, 2020, 2019 and 2018 was approximately $3.3 million $3.3 million and $1.8 million, respectively.

*Vehicle Fleet Lease*

On May 17, 2019, the Company entered into an agreement (the "Vehicle Lease") with a company (the "Lessor") to acquire motor vehicles for certain employees. The Vehicle Lease provides for individual leases for the vehicles, which at each lease commencement was determined to qualify for operating lease treatment. The Company began leasing vehicles under the Vehicle Lease in March 2020.

The contractual period of each lease is 12 months, followed by month-to-month renewal periods. The Company estimates the lease term for each vehicle to be 30 months based on industry standards. The lease permits either party to terminate the lease at any time via written notice to the other party. The Company neither acquires ownership of, nor has the option to purchase the vehicles at any time. The Company is required to maintain an irrevocable $1.4 million letter of credit that the Lessor may draw upon in the event the Company defaults on the Vehicle Lease. The $1.4 million is recorded as restricted cash on the consolidated balance sheet.

The nature of the lease is one commonly referred to as "TRAC" lease, as it contains a terminal rental adjustment clause, or "TRAC" clause." The TRAC clause limits lessee exposure, or likelihood of having a variable lease payment due at lease termination. This variable lease payment amount would be any difference between the vehicle stipulated (capitalized) cost and the sum of the reserve and net proceeds from disposal as described in the Vehicle Lease. Further, the Lessor guarantees that the net proceeds will not be less than 20% of the vehicle capitalized cost in the first 12 months, and 30% of the vehicle capitalized cost at the beginning of subsequent 12-month period increments.

**5. Right Of Use Assets and Lease Liabilities (continued)**

Right of use asset and lease liability for the vehicle fleet lease were approximately $7.3 million and $0, respectively, as of December 31, 2020 and December 31, 2019. The vehicle leases entered into since March 2020 represent non-cash transactions. The total operating lease cost for the year ended December 31, 2020 was $1,183,072. The operating cash outflows related to vehicle fleet operating lease obligations for the year ended December 31, 2020 were $1,183,072.

The following table presents the Vehicle Lease balances within the consolidated balance sheet, weighted average remaining fleet lease term, and the weighted average discount rates related to the Vehicle Lease as of December 31, 2020:

| Lease Assets and Liabilities – Fleet | Classification | December 31, 2020 |
|---|---|---|
| **Assets** | | |
| Right of use assets, net | Operating lease right of use assets | $ 7,295,515 |
| | | $ 7,295,515 |
| **Liabilities** | | |
| Current | | |
| Lease liabilities, short-term | Operating lease liabilities | $ 2,257,262 |
| Non-Current | | |
| Lease liabilities | Non-current operating lease liabilities | 5,038,253 |
| Total lease liabilities | | $ 7,295,515 |
| Weighted average remaining lease term | | |
| | | 2.0 years |
| Weighted average discount rate | | 1.74% |

The following table presents the maturity of the Company's fleet lease liability as of December 31, 2020:

| | |
|---|---|
| Year ending December 31, 2021 | $ 2,363,058 |
| Year ending December 31, 2022 | 3,458,449 |
| Year ending December 31, 2023 | 1,640,337 |
| Year ending December 31, 2024 | — |
| Thereafter | — |
| Total | 7,461,844 |
| Less: Present value discount | (166,329) |
| Total operating lease liabilities | 7,295,515 |
| Less: Current portion | (2,257,262) |
| Long-term lease liabilities | $ 5,038,253 |

Right of use assets and lease liabilities for all operating leases were approximately $24.3 million and $29.1 million, respectively, as of December 31, 2020.

**6. Share-Based Compensation**

On June 18, 2018, the Company's stockholders approved the 2018 Plan which provided for the granting of share-based awards, such as stock options, restricted common stock, RSUs and stock appreciation rights to employees, directors and consultants as determined by the Board of Directors. On May 27, 2020, the Company's stockholders approved the Amended 2018 Plan, which provides for the granting of up to 6,500,000 additional share-based awards, such as stock options, restricted common stock, RSUs and stock appreciation rights to

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

employees, directors and consultants as determined by the Board of Directors. 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 to newly hired employees.

As of December 31, 2020, the total number of shares reserved under all equity plans was 17,787,390 and the Company had 7,459,117 shares available for future issuance under the Amended 2018 Plan and the 2019 Inducement Plan. Stock options granted under the Amended 2018 Plan and the 2019 Inducement Plan may be either incentive stock options ("ISOs") as defined by the Internal Revenue Code of 1986, as amended, 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 stock options granted under the Amended 2018 Plan and the 2019 Inducement Plan must be at least equal to the fair market value of the common stock on the date of grant. The Company does not intend to issue any additional equity awards under the 2019 Inducement Plan.

Total share-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, 2020, 2019 and 2018, was comprised of the following:

| | Years Ended December 31, | | |
|---|---|---|---|
| | **2020** | **2019** | **2018** |
| Inventoriable costs | **$ 1,342,262** | — | — |
| Research and development | **7,072,545** | $ 9,411,056 | $ 7,380,814 |
| Selling, general and administrative | **15,700,390** | 11,377,632 | 10,015,332 |
| Total share-based compensation expense | **$ 24,115,197** | $ 20,788,688 | $ 17,396,146 |

The following table describes the assumptions used for calculating the value of options granted during the years ended December 31, 2020, 2019 and 2018:

| | **2020** | **2019** | **2018** |
|---|---|---|---|
| Dividend yield | **0%** | 0% | 0% |
| Expected volatility | **91.6%-95.5%** | 85.7-96.5% | 85.2%-85.8% |
| Weighted-average risk-free interest rate | **1.29%** | 2.32% | 2.48% |
| Expected term (in years) | **6.0** | 6.0 | 6.0 |

Information regarding stock option awards under the 2019 Inducement Plan, including with respect to grants to employees as of December 31, 2020, 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, 2019 | — | $ — | |
| Options granted in 2020 | 39,728 | $ 17.18 | 9.2 years |
| Outstanding at December 31, 2020 | 39,728 | $ 17.18 | 9.2 years |
| Vested or expected to vest at December 31, 2020 | 39,728 | $ 17.18 | |
| Exercisable at December 31, 2020 | — | $ — | |

The weighted-average grant date fair value for awards granted during the years ended December 31, 2020, 2019 and 2018 was $12.84, $0 and $0 per share, respectively. The total intrinsic value of the options exercised during the years ended December 31, 2020, 2019 and 2018 was $0, respectively. The total intrinsic value of the options

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

outstanding as of December 31, 2020 was $580,877. The total intrinsic value of the options exercisable as of December 31, 2020 was $0. The total fair value of shares vested during the years ended December 31, 2020, 2019 and 2018 was $0, respectively.

The unrecognized share-based compensation expense related to stock option awards at December 31, 2020 was $377,146 and will be recognized over a weighted-average period of 2.2 years.

Information regarding RSU awards under the 2019 Inducement Plan during the period then ended are summarized as follows:

| | Number of Shares | Weighted-Average Grant Date Fair Value Per Share | Weighted-Average Contractual Life |
|---|---|---|---|
| Outstanding at December 31, 2019 | — | $ — | |
| Time based RSUs granted in 2020 | 274,410 | $ 16.01 | 2.2 years |
| Time based RSUs cancelled in 2020 | (22,543) | $ 15.81 | 2.2 years |
| Outstanding at December 31, 2020 | 251,867 | $ 16.03 | 2.2 years |
| Vested or expected to vest at December 31, 2020 | 251,867 | $ 16.03 | |

The total intrinsic value of the time based RSUs vested during the years ended December 31, 2020, 2019 and 2018 was $0, respectively. The total intrinsic value of the time based RSU's outstanding as of December 31, 2020 was $8,009,370. The total fair value of time based RSUs vested during the years ended December 31, 2020, 2019 and 2018 was $0, 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.

As of December 31, 2020, there was $2,859,070 of unrecognized compensation costs related to unvested time based RSUs which will be recognized over a weighted-average period of 2.2 years.

During the year ended December 31, 2020, the Company issued options and time based RSUs totaling 314,138 shares in the 2019 Inducement Plan. The Company does not intend to issue any additional equity awards under the 2019 Inducement Plan.

Information regarding the stock options activity, including with respect to grants to employees, directors and consultants as of December 31, 2020, and changes during the year then ended, are summarized as follows:

| | Number of Shares | Weighted-Average Exercise Price | Weighted-Average Contractual Life |
|---|---|---|---|
| Outstanding at December 31, 2019 | 6,039,945 | $ 16.81 | 7.0 years |
| Options granted in 2020 | 760,472 | $ 24.03 | 9.2 years |
| Options exercised in 2020 | (999,479) | $ 12.58 | 4.8 years |
| Options canceled or expired in 2020 | (323,044) | $ 19.42 | 7.6 years |
| Outstanding at December 31, 2020 | 5,477,894 | $ 18.43 | 6.6 years |
| Vested or expected to vest at December 31, 2020 | 5,477,894 | $ 18.43 | |
| Exercisable at December 31, 2020 | 3,441,115 | $ 19.19 | 5.6 years |

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

The weighted-average grant date fair value for awards granted during the years ended December 31, 2020, 2019 and 2018 was $17.98, $9.17 and $15.22 per share, respectively. The total intrinsic value of the options exercised during the years ended December 31, 2020, 2019 and 2018 was $11,099,951, $3,127,412 and $1,683,679, respectively. The total intrinsic value of the options outstanding as of December 31, 2020 was $81,234,131. The total intrinsic value of the options exercisable as of December 31, 2020 was $51,341,624. The total fair value of shares vested during the years ended December 31, 2020, 2019 and 2018 was $13,366,276, $11,983,108 and $11,348,595, respectively.

The unrecognized share-based compensation expense related to stock option awards at December 31, 2020 was $16,083,760, and will be recognized over a weighted-average period of 1.7 years.

Information regarding time based RSU activity, including with respect to grants to employees as of December 31, 2020, 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, 2019 | 1,268,679 | $ 13.60 | **1.7 years** |
| Time based RSUs granted in 2020 | 732,992 | $ 23.09 | **2.4 years** |
| Time based RSUs vested in 2020 | (519,994) | $ 13.90 | **0.7 years** |
| Time based RSUs cancelled in 2020 | (169,800) | $ 17.23 | **1.3 years** |
| Outstanding at December 31, 2020 | 1,311,877 | $ 18.77 | **1.7 years** |

The total intrinsic value of the time based RSUs vested during the years ended December 31, 2020, 2019 and 2018 was $14,553,421, $3,109,328 and $1,165,323, respectively. The total intrinsic value of the time based RSU's outstanding as of December 31, 2020 was $40,816,730. The total fair value of time based RSUs vested during the years ended December 31, 2020, 2019 and 2018 was $7,230,027, $4,623,030 and $2,109,705, 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.

As of December 31, 2020, there was $14,600,601 of unrecognized compensation costs related to unvested time based RSUs which will be recognized over a weighted-average period of 1.8 years.

The Company recognized non-cash share-based compensation expense related to Milestone RSU's for the years ended December 31, 2020, 2019 and 2018 of approximately $0, $0.9 million and $0.5 million, respectively. The total fair value of shares vested with respect to Milestone RSUs during the years ended December 31, 2020, 2019 and 2018 was $0, $921,972 and $1,062,212, respectively.

Information related to the Company's Milestone RSUs and the TSR RSUs during the year ended December 31, 2020 are summarized as follows:

| | Number of Shares | Weighted-Average Grant Date Fair Value Per Share | Weighted-Average Contractual Life |
|---|---|---|---|
| Outstanding at December 31, 2019 | 67,080 | $ 17.08 | 0.2 years |
| Milestone RSUs and TSR RSUs granted in 2020 | 86,044 | $ 28.25 | 2.1 years |
| Milestone RSUs and TSR RSUs vested in 2020 | (67,080) | $ 17.08 | 0.2 years |
| Milestone RSUs and TSR RSUs cancelled in 2020 | (13,366) | $ 28.25 | 2.1 years |
| Outstanding at December 31, 2020 | 72,678 | $ 28.25 | 2.1 years |

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

The total intrinsic value of the Company's Milestone RSUs and the TSR RSUs vested during the years ended December 31, 2020, 2019 and 2018 was $1,583,759, $2,233,958, and $781,434, respectively. The total intrinsic value of the Company's Milestone RSU's and the TSR RSUs outstanding as of December 31, 2020 was $2,311,160. The total fair value of the Company's Milestone RSUs and the TSR RSUs vested during the years ended December 31, 2020, 2019 and 2018 was $1,145,732, $921,972, and $971,475, respectively.

As of December 31, 2020 and 2019 there were $1,658,764 and $0 respectively of unrecognized compensation costs related to unvested Milestone RSU grants and TSR RSU grants which will be recognized over a weighted average period of 2.1 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 ended and vested 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 was settled was a percentage of shares for which the award was targeted and 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 Company's peer group (as defined below). The number of shares for which the TSR RSUs were settled varied depending 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 Company's peer group originally included 223 companies that comprised the Nasdaq Biotechnology Index at December 31, 2018, which was selected by the Compensation Committee of the Company's Board of Directors and included a range of biotechnology companies operating in several business segments. 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 weighted average estimated fair value per share of the TSR RSUs granted in 2020 was $32.56, 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 1.4%, and expected volatility of 91.3%. The TSR RSUs granted in 2020 will entitle the grantee to receive a number of shares of the Company's common stock determined over a three-year performance period ending and vesting on December 31, 2022, provided the grantee remained in the service of the Company on the settlement date. The Company is expensing the cost of these awards ratably over the requisite service period. The number of shares for which the TSR RSUs will be settled is a percentage of shares for which the award is targeted and depends on the Company's total shareholder return, expressed as a percentile ranking of the Company's total shareholder return as compared to the Company's peer group, which is consistent with the TSR RSUs granted in 2017. The number of shares for which the TSR RSUs will be settled will vary depending on the level of achievement of the goal. Total shareholder return will be determined by dividing the average share value of the Company's common stock over the 30 trading days preceding January 1, 2023 by the average share value of the Company's common stock over the 30 trading days beginning on January 1, 2020, with a deemed reinvestment of any dividends declared during the performance period. The Company's peer group included companies that compromised the Nasdaq Biotechnology Index at December 31, 2019.

**7. Income Taxes**

On December 22, 2017, former President Donald 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

**7. Income Taxes (continued)**

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, 2020, the Company's foreign operations do not generate positive 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 2020. Therefore, the Company has not included any tax impacts of BEAT in its consolidated financial statements for the year ended December 31, 2020.

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.

Loss before income taxes is as follows:

| | 2020 | 2019 | 2018 |
|---|---|---|---|
| U.S. | **(155,615,614)** | (56,121,258) | $ (30,299,751) |
| Non-U.S. | **(71,376,536)** | (91,599,320) | (124,826,060) |
| Total loss before taxes | **(226,992,150)** | (147,720,578) | $ (155,125,811) |

Total income tax expense for the years ended December 31, 2020, 2019 and 2018 is allocated as follows:

| | 2020 | 2019 | 2018 |
|---|---|---|---|
| Current | **$ 13,513** | $ 1,600 | $ 1,600 |
| Deferred | **(40,049,094)** | (8,484,822) | (5,054,468) |
| Valuation allowance | **40,049,094** | 8,484,822 | 5,054,468 |
| Provision for income taxes | **$ 13,513** | $ 1,600 | $ 1,600 |

**7. Income Taxes (continued)**

A reconciliation of the difference between the statutory federal income tax rate and the effective income tax rate for the years ended December 31, 2020, 2019 and 2018 is as follows:

| | December 31, | | |
|---|---|---|---|
| | 2020 | 2019 | 2018 |
| Income tax benefit at statutory federal rate | **21.00%** | **21.00%** | 21.00% |
| Other permanent differences | **(1.01)** | **(0.67)** | (0.58) |
| Foreign rate differential | **(6.60)** | **(13.02)** | (16.90) |
| Change in effective state tax rates | **1.12** | **(0.16)** | (0.38) |
| State income tax expense | **3.14** | **(1.40)** | 0.12 |
| Change in valuation allowance | **(17.65)** | **(5.75)** | (3.26) |
| Provision for income taxes | **0.0%** | **0.0%** | 0.00% |

Deferred income taxes reflect the net tax effect of temporary differences that exist between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes, using enacted tax rates in effect for the year in which the differences are expected to reverse. As of December 31, 2020, the Company had $323.0 million of federal net operating loss carryforwards, of which $131.1 million expire at various dates through 2037 and $191.9 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, 2020, 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, 2020, however, the Company does not believe that the Section 382 annual limitation will impact the Company's ability to utilize the tax attributes that existed as of the date of the ownership change in a material manner. If the Company experiences an ownership change in the future, the tax benefits related to the NOLs and tax credit carryforwards may be further limited or lost.

The following summarizes the significant components of the Company's deferred tax assets and liabilities as of December 31, 2020 and 2019, respectively:

| | December 31, | |
|---|---|---|
| | 2020 | 2019 |
| **Deferred tax assets:** | | |
| Net operating loss carryforwards | $ 85,751,154 | $ 49,668,232 |
| Accrued employee benefits | 1,363,082 | 589,667 |
| Research and development credit | 9,321,214 | 9,321,214 |
| Stock compensation | 15,137,990 | 12,965,250 |
| Other accruals | 850,900 | — |
| Federal AMT credit | — | 264,609 |
| Capital lease | 7,461,587 | 4,973,618 |
| **Deferred tax liabilities:** | | |
| Right of use asset—capital lease | (6,228,138) | (3,922,583) |
| Unrealized gains on investment | (123,049) | (27,577) |
| Depreciation | (244,058) | (230,760) |
| Net deferred tax asset before valuation allowance | 113,290,682 | 73,601,670 |
| Valuation allowance | (113,290,682) | (73,337,061) |
| Net deferred tax asset | $ — | $ 264,609 |

**7. Income Taxes (continued)**

Based upon the Company's historical operating performance and the reported cumulative net losses to date, the Company presently does not have sufficient objective evidence to support the recovery of its net deferred tax assets. Accordingly, the Company has established a full valuation allowance against its net deferred tax assets in 2020 and 2019, 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. The Company did reclassify its deferred tax asset related to the AMT tax credit carryforward of $265,000 to a current tax receivable in the first quarter of 2020 upon the filing of its tax return for year ended December 31, 2019 and received the refund in July 2020. As of December 31, 2020, the Company received all of these refunds.

The total amount of unrecognized tax benefits was $1.7 million as of December 31, 2020 and December 31, 2019. 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, 2020 and 2019, respectively:

| | December 31, | |
|---|---|---|
| | **2020** | **2019** |
| 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 |

**8. Commitments and Contingencies**

*License and Royalty Commitments*

On May 31, 2005, the Company entered into a worldwide, exclusive License Agreement with Bristol-Myers Squibb Company ("BMS"), pursuant to which the Company holds a license to certain patents and know-how of BMS relating to lumateperone and other specified compounds. The agreement was amended on November 3, 2010. The licensed rights are exclusive, except BMS retains rights in specified compounds in the fields of obesity, diabetes, metabolic syndrome and cardiovascular disease. However, BMS has no right to use, develop or commercialize lumateperone and other specified compounds in any field of use. The Company has the right to grant sublicenses of the rights conveyed by BMS. The Company is obliged under the 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 in 2005, 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, 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 of 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.

**8. Commitments and Contingencies (continued)**

The agreement extends, and royalties are payable, on a country-by-country and product-by-product basis, through the later of 10 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. With the initial recognition of product sales revenue in the year ended December 31, 2020, the Company expensed approximately $1,126,538 in cost of product sales to satisfy its obligation under the BMS agreement.

*Research and Other Commitments*

As of December 31, 2020, the Company has committed to purchasing a production campaign for active pharmaceutical ingredients (API) from each of our supply vendors – Siegfried Evionnaz SA (Siegfried) and Lonza Ltd. (Lonza). Both campaigns are expected to be received into inventory during 2022. The Company has a total commitment of $16.4 million related to these two agreements. As of December 31, 2020, the Company had paid a deposit of $3.0 million for the Siegfried campaign which is recorded within prepaids and other current assets. Over the course of the vendors' manufacturing period, the Company will remit payment to each vendor based on executed agreement. Each payment will subsequently be recorded into prepaid and other current assets. Upon title transfer of the product, the Company will recognize the material as inventory.

*Retirement savings plan 401(k) contributions*

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, 2020, 2019 and 2018. Participant and Company contributions vest immediately. During the years ended December 31, 2020, 2019 and 2018, the Company recorded matching contribution expense of $1,771,380, $658,179 and $429,318, respectively.

*Contingencies*

During the normal course of our business, we are occasionally involved with various claims and litigation. Reserves are established in connection with such matters when a loss is probable and the amount of such loss can be reasonably estimated. At December 31, 2020 and 2019, no material reserves were recorded. The determination of probability and the estimation of the actual amount of any such loss are inherently unpredictable, and it is therefore possible that the eventual outcome of such claims and litigation could exceed the estimated reserves, if any. However, we believe that the likelihood that any such excess might have a material adverse effect on our financial statements is remote.

**9. 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

**9. Related Parties (continued)**

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.

**10. Unaudited Quarterly Financial Information**

The tables herein set forth the Company's unaudited condensed consolidated 2020 and 2019 quarterly statements of operations.

*The following table sets forth the Company's unaudited condensed consolidated statements of operations for the 2020 quarters ended:*

| 2020 Quarter Ended | December 31, | September 30, | June 30, | March 31, |
|---|---|---|---|---|
| Revenue, net | $ 12,454,270 | $ 7,368,594 | $ 1,906,636 | $ 1,083,479 |
| Operating expenses | (73,787,606) | (63,305,048) | (66,778,953) | (50,169,003) |
| Interest income | 644,390 | 752,829 | 1,160,059 | 1,678,203 |
| Income tax expense | (13,513) | — | — | (3,281) |
| Net loss | (60,699,178) | (55,183,625) | (63,712,258) | (47,410,602) |
| Basic and diluted net loss per share | $ (0.76) | $ (0.79) | $ (0.96) | $ (0.73) |

*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, |
|---|---|---|---|---|
| Revenue, net | 60,613 | — | — | — |
| Operating expenses | (41,829,272) | (36,376,236) | (39,171,114) | (36,695,841) |
| Interest income | 1,185,808 | 1,513,837 | 1,731,550 | 1,860,077 |
| Income tax expense | — | — | (1,600) | — |
| Net loss | (40,582,851) | (34,862,399) | (37,441,164) | (34,835,764) |
| Basic and diluted net loss per share | $ (0.73) | $ (0.63) | $ (0.68) | $ (0.63) |

**Exhibit 10.9**

EMPLOYMENT AGREEMENT

THIS EMPLOYMENT AGREEMENT (the "Agreement"), is effective this 12th day of September, 2018 (the "Effective Date") between Dr. Suresh Durgam ("Executive") and Intra-Cellular Therapies, Inc. (the "Company").

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

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

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

3. Compensation and Benefits.

3.1 Salary. Executive will receive for Executive's services to be rendered under this Agreement an initial annualized base salary at the rate of $420,000 per year, subject to annual review and adjustment by the Company in the discretion of the Board, payable subject to standard federal and state payroll withholding requirements in accordance with the Company's standard payroll practices ("***Base Salary***").

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

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

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

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

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

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

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

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

(d) material breach of fiduciary duty; or

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

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

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

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

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

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

4.3 Death or Disability. The Executive's employment will terminate upon the death or determination of disability of Executive. As used in this Agreement, the determination of "disability" shall occur when the Executive is unable due to a physical or mental condition to perform the essential functions of his position with or without reasonable accommodation for 90 consecutive days, or 180 days in the aggregate whether or not consecutive, during any 360-day period, or based on the written certification by a licensed physician of the likely continuation of such condition for such period. A determination of disability shall be made by a physician satisfactory to both Executive and the Company, *provided that* if Executive and the Company do

not agree on a physician, Executive and the Company shall each select a physician and these two together shall select a third physician, whose determination as to disability shall be binding on all parties. This definition shall be interpreted and applied consistent with the Americans with Disabilities Act, the Family and Medical Leave Act, and other applicable law.

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

5. Effect of Termination.

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

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

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

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

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

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

5.3 Code Sections 409A and 280G.

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

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

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

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

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

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

5.4 Effect of a Change in Control.

(a) In the event either (i) Executive's employment with the Company is terminated by the Company for reasons other than death or Disability (as defined above) within three months before or 12 months following a Change in Control (as defined below) or (ii) Executive terminates his employment for Good Reason (as defined above) within three months before or 12 months following a Change in Control (as defined below), then provided that Executive executes the Release (as defined in Section 5.2) within the consideration period specified therein and it becomes effective and can no longer be revoked by Executive under its terms, and provided further that Executive returns all Company property' complies with his post termination obligations under this Agreement and the Proprietary Information, Inventions and Non-Competition Agreement, and complies with the Release including without limitation any non-disparagement and confidentiality provisions contained therein, Executive shall be entitled to the payments, equity acceleration and benefits described in this Section 5.4 in lieu of, and not in addition to, the benefits provided for in Section 5.2. The Company shall pay to the Executive, in lieu of the severance described in Section 5.2(a), severance equivalent to 18 months of his annual Base Salary then in effect, together with an additional amount calculated by dividing by 365 the number of days employed in the year of termination and multiplying that number by the amount of the Executive's previous year's bonus (if any), paid in a lump sum on the eighth day following the date the Release becomes effective, subject to standard payroll deductions and

withholdings, provided, however, that if the Release Review Period begins in one tax year and ends in a later tax year, the payments under this Section 5.4(a) will be made following the date that the Release is effective that occurs in the later tax year. On the date of termination of Executive's employment, any unvested equity awards granted to the Executive shall immediately vest and, in the case of stock options, become exercisable. Additionally, if Executive timely elects and remains eligible for continued coverage under COBRA, the Company, as part of this Agreement, will pay that portion of Executive's COBRA premiums it was paying prior to the Separation Date for eighteen (18) months.

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

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

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

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

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

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

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

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

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

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

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

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

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

14. Successors and Assigns.

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

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

15. Miscellaneous.

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

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

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

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

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

| | |
|---|---|
| **INTRA-CELLULAR THERAPIES, INC.** | **EXECUTIVE** |
| **By:** /s/ Lawrence Hineline | /s/ Dr. Suresh Durgam |
| **LAWRENCE HINELINE** | **DR. SURESH DURGAM** |
| **CHIEF FINANCIAL OFFICER** | |

**SCHEDULE A**

**PERMITTED ACTIVITIES**

**SCHEDULE B**

**RELEASE OF CLAIMS**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**INTRA-CELLULAR THERAPIES, INC.**

**By:** _____

**[NAME]**

**[NAME]**

_____

Date

_____

Date

**Exhibit 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. 333-243716) pertaining to the Intra-Cellular Therapies, Inc. Amended and Restated 2018 Equity Incentive Plan of Intra-Cellular Therapies, Inc.,

(4) Registration Statement (Form S-8 No. 333-236828) pertaining to the Intra-Cellular Therapies, Inc. 2019 Inducement Award Plan of Intra-Cellular Therapies, Inc.,

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

(6) 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.,

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

(8) 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 February 25, 2021, 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, 2020.

/s/ Ernst & Young LLP
Baltimore, Maryland
February 25, 2021

**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: February 25, 2021

/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: February 25, 2021

/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, 2020 (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: February 25, 2021

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

Dated: February 25, 2021

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