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

Form 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 8, 2018

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

Commission File Number: 001-36274

Delaware
(State or other jurisdiction
of incorporation)

36-4742850
(IRS Employer
Identification No.)

430 East 29th Street
New York, New York 10016
(Address of principal executive offices, including zip code)

(646) 440-9333
(Registrant's telephone number, including area code)

Not applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
-

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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.

ITEM 8.01 Other Events.

On January 8, 2018, Intra-Cellular Therapies, Inc. (the “Company”) updated its corporate presentation, which is posted under the “Investors” section of the Company’s website at www.intracellulartherapies.com. Representatives of the Company will use the updated presentation in various meetings with investors from time to time. A copy of the presentation is filed herewith as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

ITEM 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit Number</u>	<u>Description</u>
99.1	Corporate Presentation of Intra-Cellular Therapies, Inc., dated as of January 8, 2018

SIGNATURES

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

INTRA-CELLULAR THERAPIES, INC.

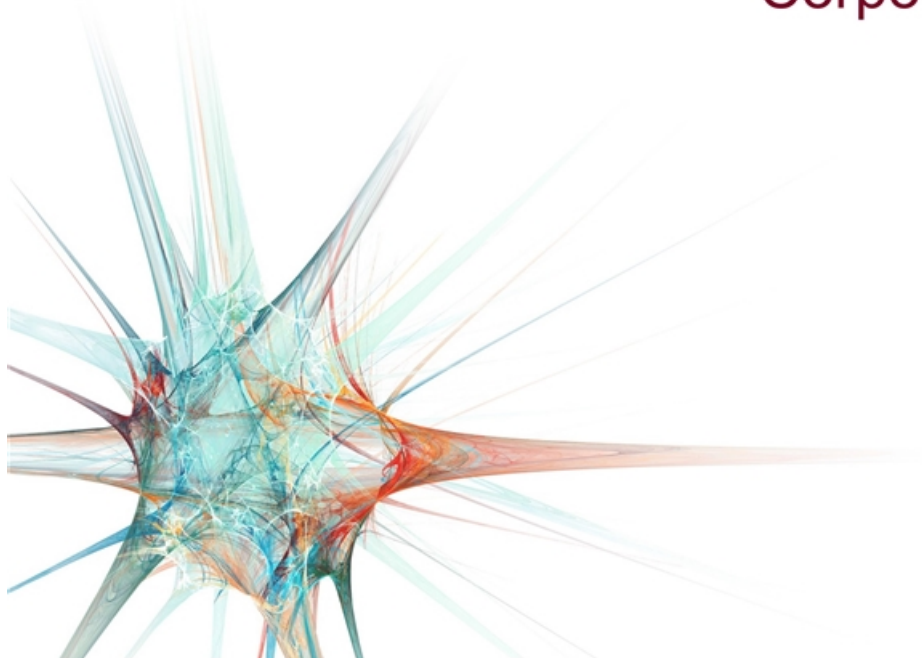
By: /s/ Lawrence J. Hinline
Lawrence J. Hinline
Vice President of Finance and Chief
Financial Officer

Date: January 8, 2018

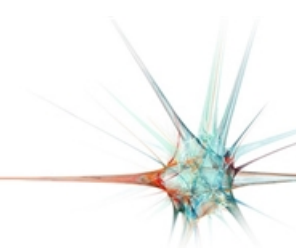


Corporate Presentation

January 2018

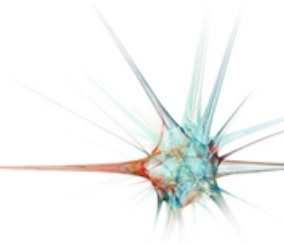


Safe Harbor Statement



This presentation contains “**forward-looking statements**” within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements concern our product candidates, our development efforts, our collaborations, our technology, our intellectual property, our financial condition, our plans and our development programs. These statements involve risks, uncertainties and assumptions, and are based on the current estimates and assumptions of the management of Intra-Cellular Therapies, Inc. (the “Company” or “ITCI”) as of the date of this presentation and are subject to uncertainty and changes. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Important factors that could cause actual results to differ materially from those indicated by such forward-looking statements include, among others, those set forth in our Annual Report on Form 10-K for the year ended **December 31, 2016** filed with the Securities and Exchange Commission, as well as any updates to those risk factors filed from time to time in our periodic and current reports. All statements contained in this presentation are made only as of the date of this presentation, and the Company undertakes no duty to update this information unless required by law.

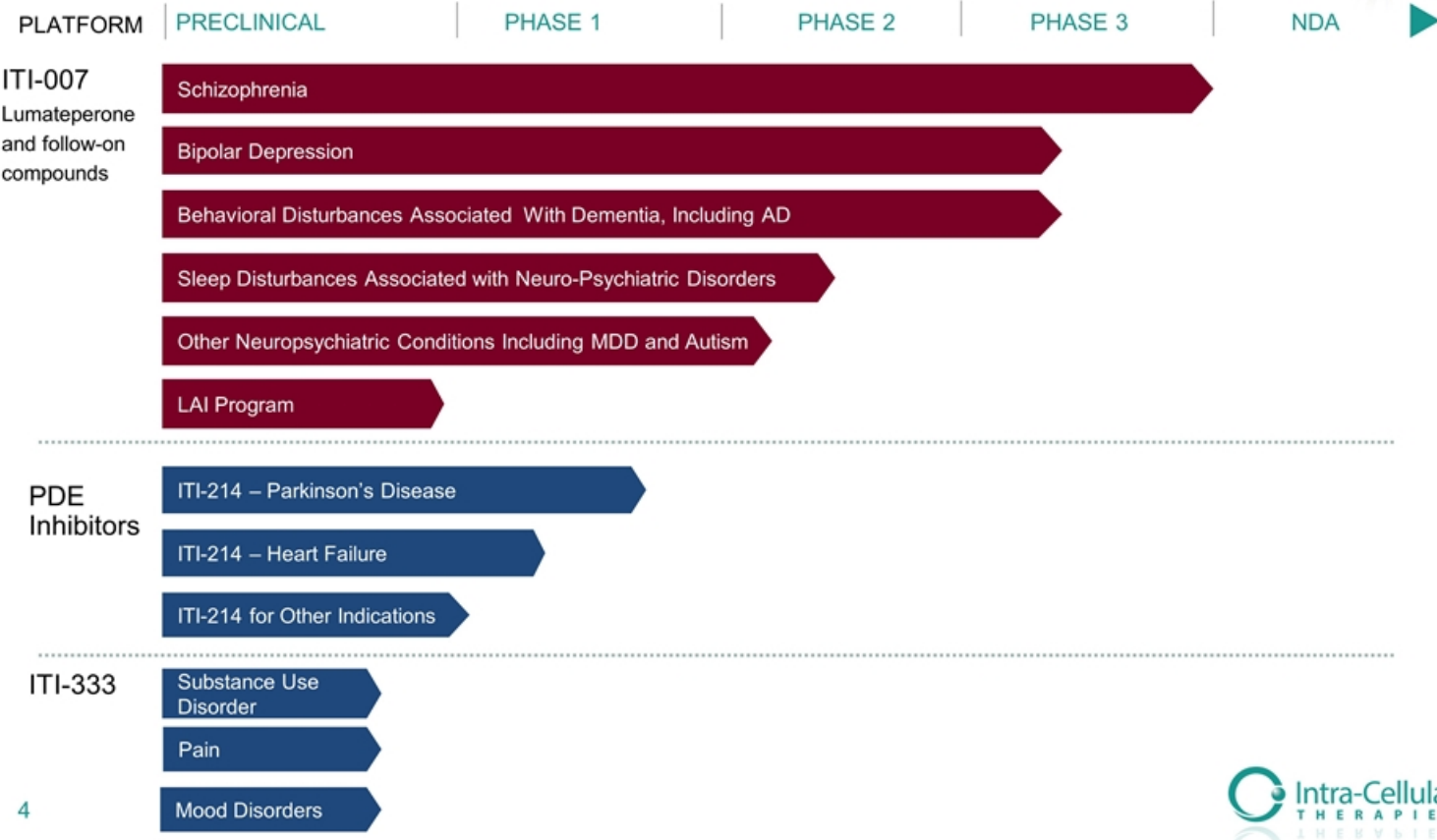
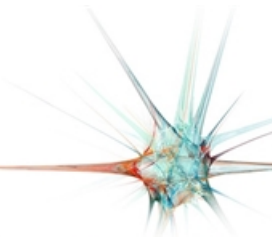
Intra-Cellular Therapies, Inc. (ITCI)



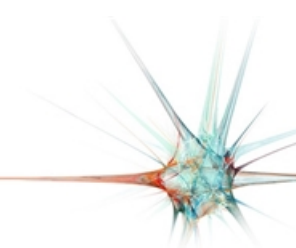
- Focus on advancements in the treatment of CNS disorders
 - Lead program: Lumateperone (ITI-007)
 - Phase 3 program in schizophrenia
 - Anticipated NDA filing for schizophrenia by mid-2018
 - Other Phase 3 programs:
 - Bipolar depression
 - Agitation associated with dementia, including Alzheimer's disease
 - Leader in the field of PDE1 inhibitors
 - Lead drug candidate ITI-214 being developed for the treatment of Parkinson's disease and other CNS and non-CNS disorders including heart failure
- Founded in 2002, leveraging technology from the lab of Nobel Laureate Dr. Paul Greengard
- Located in New York City
- Well-capitalized
 - \$328.1 million in cash, cash equivalents and investment securities at 09/30/2017 (In October 2017, the Company raised net proceeds of \$162 million in a public offering of its common stock)



ITCI Therapeutic Pipeline

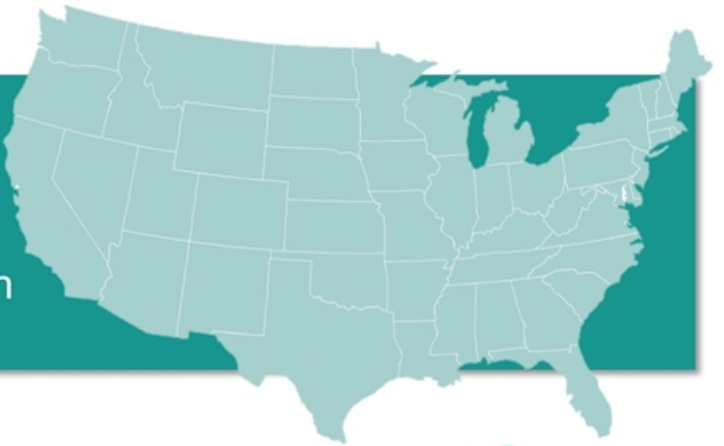


Schizophrenia, A Common Disabling Neuropsychiatric Disease



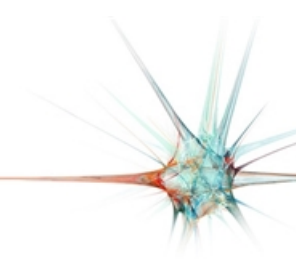
- Schizophrenia affects approximately **1%** of the global population¹
- Schizophrenia is one of the 25 leading causes of disability worldwide²

- **2.2 million** adults in the United States have schizophrenia¹
- **~100,000** people are newly diagnosed with schizophrenia each year in the United States¹



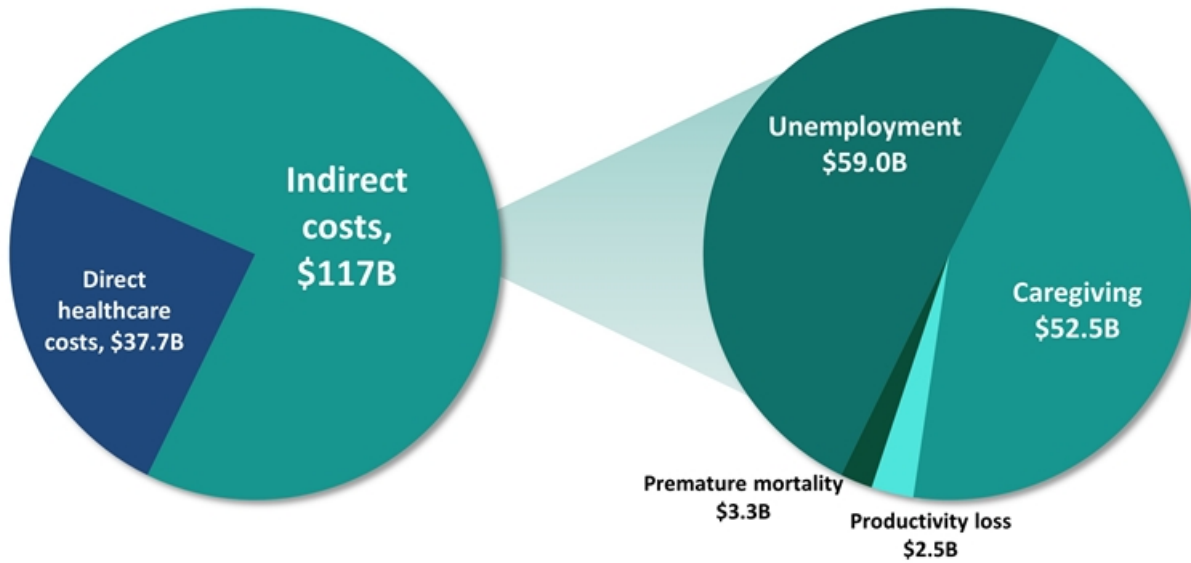
1. Schizophrenia facts and statistics. Schizophrenia.com website. Accessed April 9, 2017.
2. Chong HY, et al. *Neuropsychiatr Dis Treat*. 2016;12:357-373.

Economic Burden of Schizophrenia Exceeds \$154 Billion in the United States



Schizophrenia: Direct and Indirect Costs¹

Indirect Costs¹



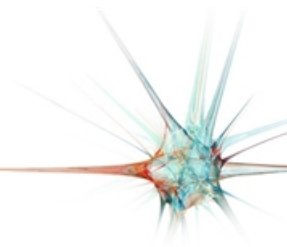
It is estimated that only about one-third of patients with schizophrenia can work regularly.^{2,3}

Costs of schizophrenia exceed many common conditions, including stroke, hypertension, breast/cervical cancers⁴

Onset in early adulthood leads to life-long disability and economic burden

1. Cloutier M, et al. *J Clin Psychiatry*. 2016;77(6):764-771.
2. Albus M. *Pharmacopsychiatry*. 2012;45(suppl 1):S31-S35.
3. Bellack AS, et al. *Schizophr Bull*. 2007;33(3):805-822.
4. Kockaya G, et al. *Health*. 2010;2(10):1174-1178.

Lumateperone is Designed to Address Unmet Needs in Schizophrenia



- Existing therapies have significant adverse events including extrapyramidal symptoms, akathisia, metabolic and cardiovascular dysfunction
 - Impact quality of life
 - Lead to poor adherence with 74% of US patients discontinuing medication within 18 months (CATIE Study, 2005)
- Only positive symptoms are effectively treated by existing drugs; negative symptoms and depression are not effectively treated
- Social function is not improved

We believe the unique pharmacology of lumateperone can translate into an advancement in the treatment of schizophrenia as a single, stand-alone drug therapy

Lumateperone: Novel, First-in-Class Molecule With an MOA That Predicts Clinical Benefits Across CNS Disorders



	<u>nM Ki</u>
5HT-2A	0.5
D2	32
D1	52
SERT	62

5-HT_{2A} Receptor Antagonist

- Improves sleep quality
- Reduces anxiety and hostility
- Enhances antipsychotic and antidepressant activity

Glutamatergic Phosphoprotein Modulator

NMDA & AMPA Enhancement via D1

- Efficacy for negative and positive symptoms
- Improved cognition
- Rapid-acting antidepressant activity

Dopamine Phosphoprotein D₂ Modulator (DPPM)

D₂ Pre-synaptic partial agonist and post-synaptic antagonist

- Antipsychotic efficacy for positive symptoms
- Reduced agitation

PHARMACOLOGY PREDICTS ROBUST EFFICACY ACROSS A BROAD RANGE OF SYMPTOM DOMAINS

AND PREDICTS HIGHLY FAVORABLE SAFETY/TOLERABILITY PROFILE

Serotonin Reuptake Inhibitor

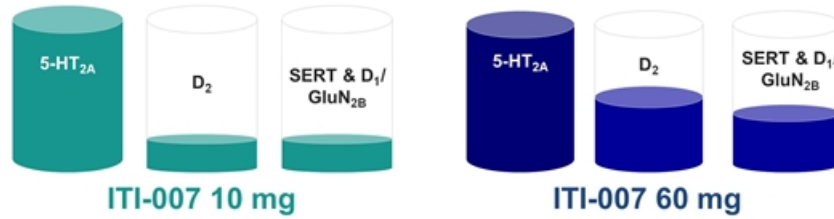
- Antidepressant activity

Snyder GL et al. (2015). Functional profile of a novel modulator of serotonin, dopamine, and glutamate neurotransmission. *Psychopharmacology (Berl)* 232(3):605-21.

Lumateperone: Differentiated Pharmacology Provides Opportunities to Treat Multiple CNS Disorders

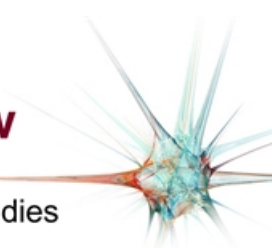


Broad separation between 5-HT_{2A} and other target affinities allows for full saturation of 5-HT_{2A} while adding only as much D₂, D₁/GluN_{2B} (glutamate), and SERT as needed



LOWER DOSES (1-10 mg)	HIGHER DOSES (40-60 mg)
Behavioral and Psychiatric Disturbances in AD and PD	Schizophrenia
Sleep Disturbances Associated With Neurologic and Psychiatric Disorders	Bipolar I and II Disorder (Depressive Episodes)
Behavioral Disturbances Associated With Autism Spectrum Disorder	Bipolar I Disorder (Manic Episodes)
Sleep Maintenance Insomnia	Major Depressive Disorder (MDD)

Lumateperone Schizophrenia Program Overview

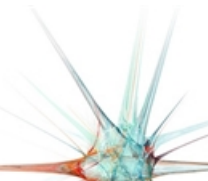


- Lumateperone (ITI-007 60 mg) met primary endpoint in 2 entirely U.S.-based studies
- Well-tolerated with a safety profile similar to placebo in all studies
- Once daily oral dosing with no need for titration to 60 mg
- Two studies with risperidone as active control showed statistically significant safety & tolerability benefits for lumateperone over risperidone
- Lumateperone and risperidone demonstrated similar efficacy on primary endpoint in Study '005
- Pre-NDA meeting with the FDA scheduled for late Q1 2018
- Anticipated NDA filing by mid-2018

3 Large Randomized, Double-Blind Trials Primary outcome measure: change from baseline on Positive and Negative Syndrome Scale (PANSS) Total Score		
ITI-007-005 ¹	ITI-007-301	ITI-007-302
N=335 4-week treatment period: - ITI-007 (60 mg or 120 mg) - Risperidone 4 mg or - Placebo	N=450 4-week treatment period: - ITI-007 (60 mg or 40 mg) or - Placebo	N=696 6-week treatment period: - ITI-007 (60 mg or 20 mg) - Risperidone 4 mg or - Placebo
Open-Label Safety Switching Study with ITI-007 60 mg - First Part (N=302) 6-week treatment duration - Completed - Second Part with 1-year treatment duration - Ongoing		

¹Lieberman et al., Biological Psychiatry. 2016 June; 79:952–961.

Acute Controlled Studies Demonstrate Safety Profile Similar to Placebo on Key Parameters And Superiority Over Risperidone



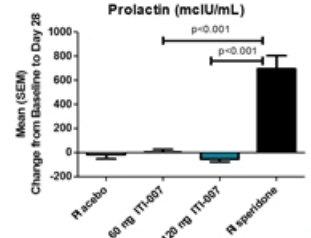
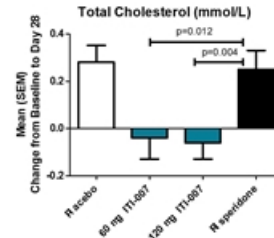
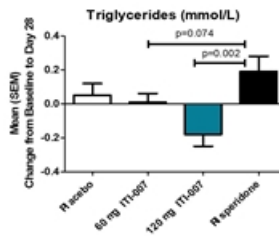
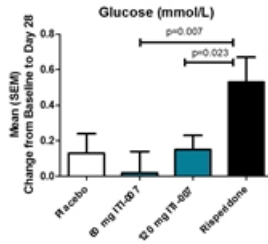
GLUCOSE

TRIGLYCERIDES

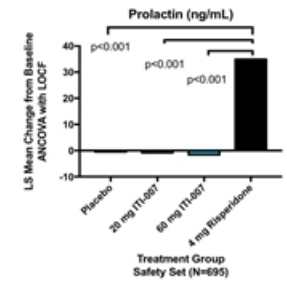
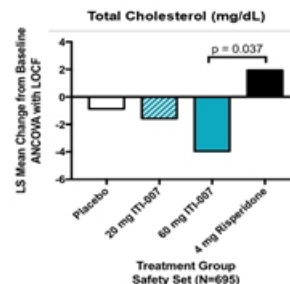
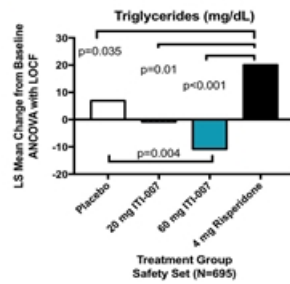
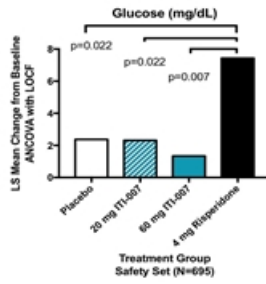
CHOLESTEROL

PROLACTIN

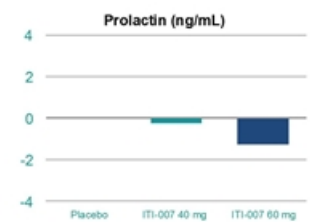
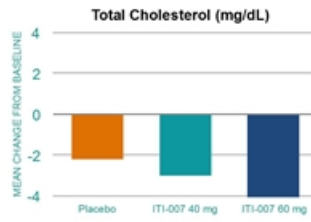
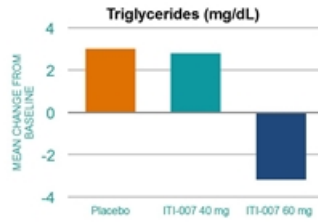
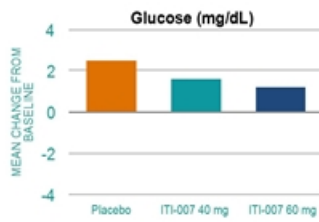
STUDY 005



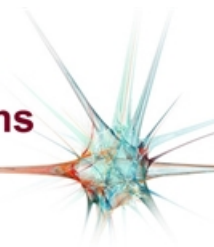
STUDY 302



STUDY 301

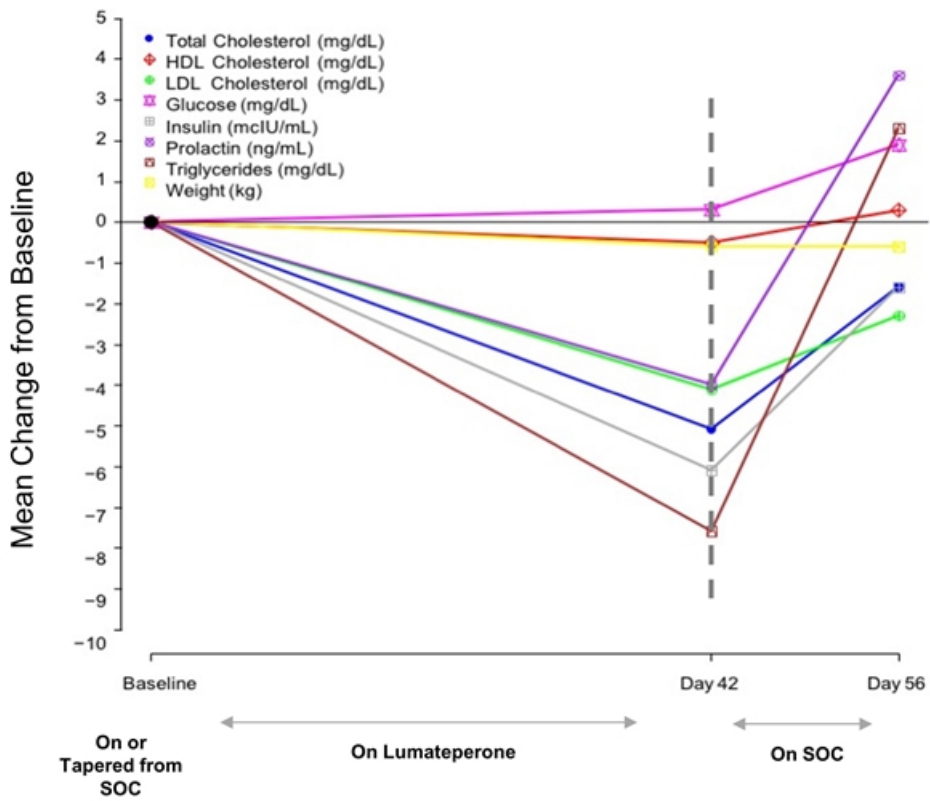


Lumateperone Profile Confirmed in a 6-Week Open-label Safety Switching Study in Patients with Stable Schizophrenia Symptoms

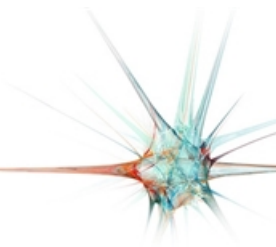


- The study evaluated stable patients with schizophrenia in an outpatient setting similar to common clinical practice
- The study assessed both the impact of switching to lumateperone (ITI-007 60 mg) from standard-of-care (SOC) antipsychotics as well as the impact of switching back to SOC from lumateperone (no dose titration necessary for lumateperone)
- Lumateperone was generally well tolerated with a favorable safety profile. The most frequent drug-related AE was somnolence occurring at a low rate when administered in the evening
- Statistically significant improvements from SOC baseline were observed in body weight, cardiometabolic and endocrine parameters over 6 weeks of treatment with lumateperone and worsened again when switched back to SOC medication
- Symptoms of schizophrenia did not worsen upon switch to lumateperone from SOC; rather statistically significant improvement from baseline was observed in PANSS mean total score (with greater improvements seen in subgroups of patients with comorbid symptoms of depression or prominent negative symptoms)

In Open Label Safety Switching Study, Key Cardiometabolic Parameters Improved on Lumateperone and Worsened Again After Switch Back to SOC

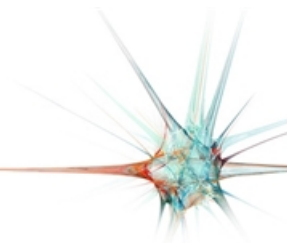


Summary: Lumateperone Efficacy and Safety in Schizophrenia



- Two large, well-controlled positive studies and supportive data from a third study collectively provide evidence of the efficacy and safety of lumateperone (ITI-007 60 mg) for the treatment of schizophrenia
- In all three studies, lumateperone was well-tolerated with a safety profile similar to placebo
- In the 2 studies with risperidone as the active control, lumateperone was statistically significantly better than risperidone on key safety and tolerability parameters
- In open label safety switching study, key cardiometabolic parameters improved on lumateperone and worsened again after switch back to SOC

Lumateperone: Advancing Treatments in Bipolar Depression



Bipolar disorder is a highly prevalent disease (2.6% 12-month prevalence in US adults; NIMH) with bipolar depression being the predominant clinical presentation

Depressive episodes are longer and recur more often than manic/hypomanic episodes

Safety and tolerability trade-offs limit use of current agents

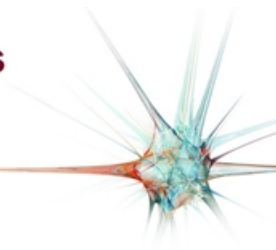
Few treatment options available

Lumateperone for the Treatment of Bipolar Depression and Other Depressive Disorders



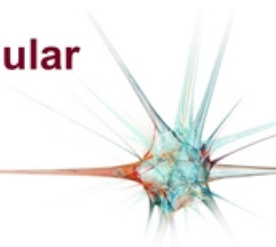
- In previous studies depressed schizophrenia patients experienced robust improvements in depressive symptoms
 - Well-tolerated with a safety profile similar to placebo in all studies completed to date
 - Recent preclinical data support potential for rapid-acting antidepressant effects
-
- Bipolar depression Phase 3 clinical program includes
 - Two monotherapy studies
 - One adjunctive study (lithium or valproate)
 - Planning late-stage studies in MDD to begin in 2018

Lumateperone for the Treatment of Agitation in Alzheimer's Disease

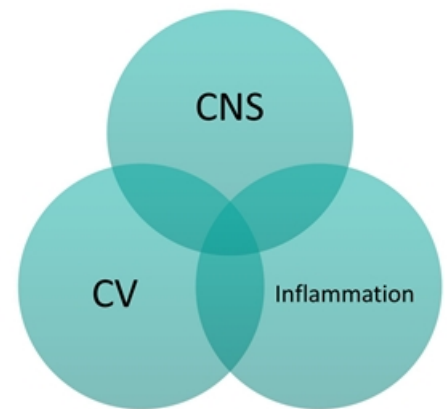


- **Large Market Potential**
 - 44.4 million people worldwide with AD
 - >50% with behavioral disturbances
 - Agitation is a leading cause of early institutionalization
 - Affects patients, relatives, and caregivers
- **Unmet Need**
 - Currently no approved agents
- **Low dose lumateperone targeted to reduce agitation, including aggression**
- **Potential benefit across a wide range of behavioral disturbances**
 - Improved sleep & restored circadian rhythms
 - Antidepressant and anxiolytic efficacy/reduced emotional distress
 - Antipsychotic efficacy
- **Phase 1/2 study demonstrated a favorable safety profile in geriatric subjects and patients with dementia**
- **Clinical Development Plan**
 - Phase 3 clinical trial in the treatment of agitation in patients with dementia ongoing

PDE1 Inhibition: Novel Approach to Modulation of Intracellular Signaling with Broad Therapeutic Potential

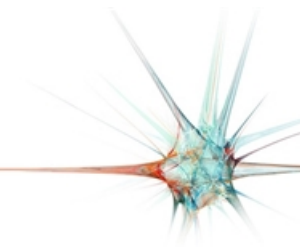


- PDE1 enzymes are highly active across a variety of neurological and cardiovascular diseases
- Our PDE1 inhibitors are designed to reestablish normal function in these disease states
 - Inhibitors of PDE1 block the breakdown of cyclic nucleotides (cAMP, cGMP) potentiating downstream intracellular signaling
- Within our PDE1 portfolio, ITI-214 is the most advanced
- In four completed Phase I studies, ITI-214 was generally well tolerated with a favorable safety profile



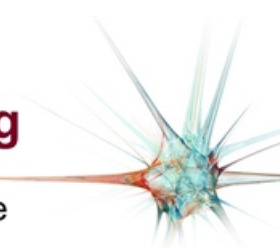
We believe ITI-214 provides an opportunity to treat age-related diseases including CNS, cardiovascular, and inflammatory disorders

ITI-214 for the Treatment of Parkinson's Disease

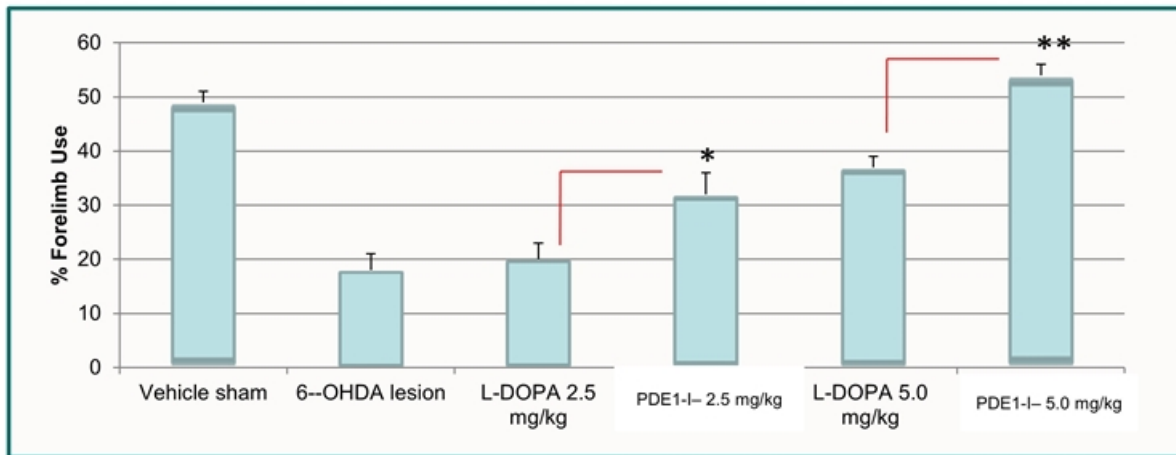


- **Large Market Potential**
 - Over 2.2 million patients in the US and Europe
 - Progressive neurodegenerative disorder with motor and non-motor symptoms
- **Unmet Need**
 - Dopamine replacement therapies (L-DOPA as gold standard) address early motor symptoms, but are insufficient as disease progresses and have limiting side effects
 - Effective treatments to address non-motor symptoms are lacking
- **ITI-214 as a multi-pronged approach to the treatment of PD**
 - Symptomatic treatment for primary motor symptoms
 - Address non-motor symptoms
 - Potentially disease modifying
- **Clinical Development Plan**
 - Phase 1/2 clinical trial of ITI-214 in patients with Parkinson's disease to evaluate safety and tolerability is ongoing. First cohort completed with no safety concerns identified

PDE1 Inhibitors Improve Motor Symptoms in Models of PD by Enhancing Dopamine Signaling



Preclinical evidence shows that PDE1 inhibitors restore affected limb use in animal models of PD

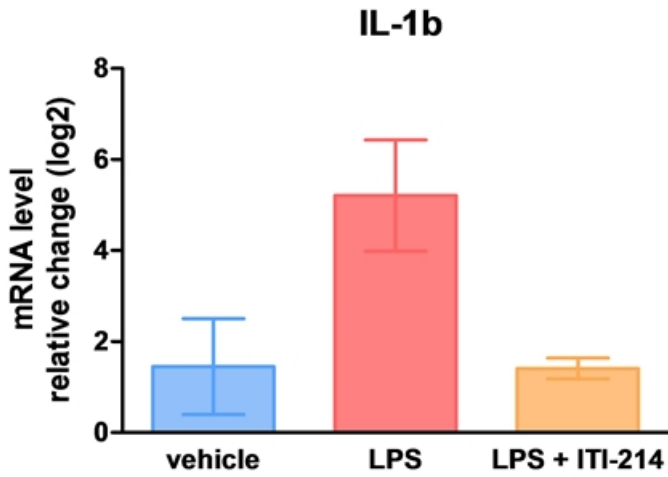


- Stand-alone treatment in early PD may be possible where sufficient endogenous dopamine is available to support synaptic activity
- L-DOPA & DA agonist sparing as disease progresses to prolong utility of DA replacement strategies and reduce side effects
- Additional preclinical data indicate improved cognition and enhanced wakefulness by PDE1 inhibition, without psychomotor stimulation

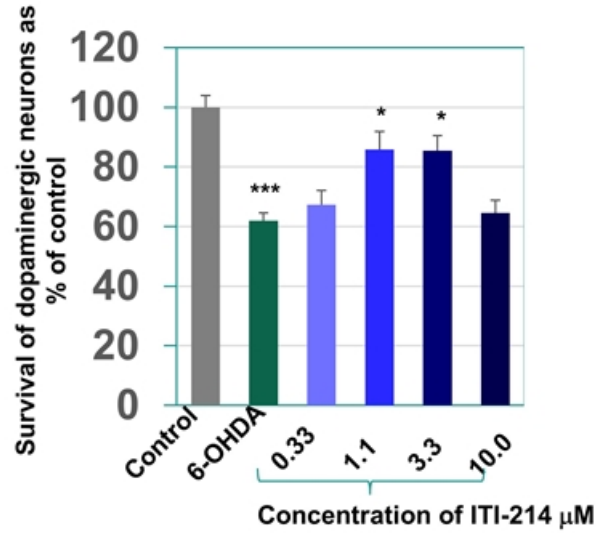
ITI-214 Prevents Neuroinflammation and is Neuroprotective



ITI-214 prevents increases in pro-inflammatory cytokines, such as IL-1 β in microglia



In animals with lesions in the part of the brain where dopamine neurons are lost in PD, ITI-214 improves dopamine neuron survival

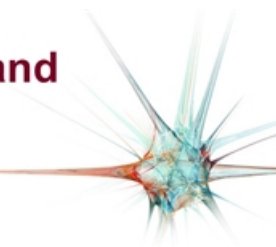


ITI-214: Represents A Novel Mechanism of Action for The Treatment of Heart Failure



- **Medical Need**
 - Heart failure (HF) affects approximately 5.7 million people and has a mortality rate of ~50% within 5 years
 - Need for approaches that improve heart function acutely and with longer exposure, also counter maladaptive remodeling of the ventricle
- **Preclinical Data Has Shown Beneficial Effects on Cardiac Function**
 - PDE-1 inhibition increases cardiac contractility and cardiac output
 - Potential for attenuation or reversal of cardiac remodeling
- **A randomized, double-blind, placebo-controlled study of escalating single doses of ITI-214 in patients with systolic heart failure is expected to begin in Q1 2018**

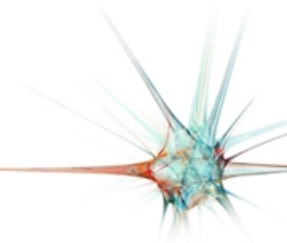
ITI-333 For Treatment of Substance Use Disorders, Pain, and Mood Disorders



Receptor or Transporter	Ki (nM)
Serotonin 5-HT _{2A}	8.3
Dopamine D ₁	50
Mu opioid (MOP)	11

- High affinity at serotonin 5-HT_{2A}, dopamine D₁ and mu opiate receptors (MOP), acting as a partial agonist at MOP receptors
- Exhibits potent morphine-like analgesia in animal models, yet attenuates several morphine mediated behaviors
- No safety concerns have been noted with ITI-333 in animal models
 - Does not alter either GI motility or respiratory function
 - Elicits no significant signs of physical dependence or withdrawal

Key Financial Information



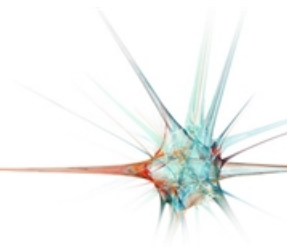
KEY METRICS

Total Cash, Cash Equivalents, and Investments^{(1) (2)}	\$328.1 million
Total Debt⁽¹⁾	\$0.0 million
Common Shares Outstanding^{(1) (2)}	43,427,344
Stock Options / Restricted Stock Units Outstanding⁽¹⁾	4,219,143

(1)As of September 30, 2017 (unaudited)

(2)In October 2017, the Company completed a follow on public offering resulting in net proceeds of approximately \$162 million from the sale of 11,129,032 shares of its common stock

Management Team



Sharon Mates, PhD, Founder, Chairman, President & Chief Executive Officer

Andrew Satlin, MD, Executive Vice President & Chief Medical Officer

Michael I. Halstead, Senior Vice President and General Counsel

Kimberly Vanover, PhD, Senior Vice President of Clinical Development

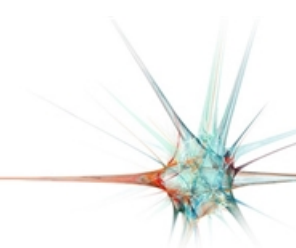
Robert Davis, PhD, Senior Vice President, Chief Scientific Officer

Larry Hineine, Vice President of Finance & Chief Financial Officer

Jennifer Rinaldo, Vice President, Commercial Development

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