
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): December 14, 2015

International Stem Cell Corporation
(Exact name of registrant as specified in its charter)

Commission File Number: 000-51891

Delaware
(State or other jurisdiction
of incorporation)

20-4494098
(IRS Employer
Identification No.)

5950 Priestly Drive, Carlsbad, CA 92008
(Address of principal executive offices, including zip code)

(760) 940-6383
(Registrant's telephone number, including area code)

(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))
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Item 8.01 Other Events.

On December 14, 2015, International Stem Cell Corporation (the “Company”) announced that the Therapeutic Goods Administration (TGA) of Australia had cleared a regulatory submission from CytoTherapeutics, the Company’s wholly owned subsidiary, to initiate a Phase I/IIa clinical trial, dose escalation trial using human parthenogenetic stem cells-derived neural stem cells (ISC-hpNSC) in patients with moderate to severe Parkinson’s disease.

A copy of a press release announcing the clearance of the regulatory submission for the Phase I/IIa clinical trial is attached as Exhibit 99.1 to this Report.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release, dated December 14, 2015.

Signature(s)

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.

INTERNATIONAL STEM CELL CORPORATION

Date: December 14, 2015

By: /s/ Mahnaz Ebrahimi

Mahnaz Ebrahimi
Chief Financial Officer



International Stem Cell Corporation Receives Authorization to Initiate Phase I/IIa Clinical Trial of ISC-hpNSC for the Treatment of Parkinson's Disease

Regulatory submission (CTX) cleared for Phase I dose escalation trial in patients with moderate to severe Parkinson's disease

CARLSBAD, CA—(Marketwired – December 14, 2015) - International Stem Cell Corporation (OTCQB: ISCO), a leader in using pluripotent stem cells in regenerative medicine, announced today that the Therapeutics Goods Administration (TGA) of Australia cleared a regulatory submission of ISCO's wholly owned subsidiary, Cyto Therapeutics, to initiate a Phase I/IIa clinical trial, dose escalation trial of human parthenogenetic stem cells-derived neural stem cells (ISC-hpNSC) in patients with moderate to severe Parkinson's disease (PD). Currently, there is no cure for PD, which is the second most common neurodegenerative disease and affects over 7 million people worldwide.

"We are very pleased to start the first human study of ISC-hpNSC's for the treatment of this debilitating disease. There is a large unmet medical need for new treatments that may halt or reverse the progression of Parkinson's disease and we believe our human neural stem cells may fill this need for the millions of people with this disease" commented Andrey Semechkin, PhD, ISCO's chief executive officer. "We look forward to reporting on the progress of the clinical trial over the coming months."

The Company last year announced positive results from its preclinical studies for its ISC-hpNSC therapeutic candidate. In those preclinical studies, the cells demonstrated an improvement in Parkinson's disease symptoms and increase in brain dopamine levels following the intracranial administration of ISC-hpNSC. The studies further noted that the ISC-hpNSCs provided neurotrophic support and cell replacement to dying dopaminergic neurons.

About the clinical study

The Phase I/IIa clinical study is a dose escalation safety and preliminary efficacy study of human parthenogenetic stem cells-derived neural stem cells (ISC-hpNSC) intracranially transplanted into patients with moderate to severe Parkinson's disease. The open-label, single center, uncontrolled clinical trial will evaluate three different dose regimens of 30,000,000 to 70,000,000 neural cells. A total of 12 participants with moderate to severe Parkinson's disease will be treated. Following transplantation, the patients will be monitored for 12 months at specified intervals, to evaluate the safety and biologic activity of ISC-hpNSC. PET scan will be performed at baseline, as part of the screening assessment, and at 6 and 12 months after surgical intervention. Clinical responses compared to baseline after the administration of ISC-hpNSC will be evaluated using various neurological assessments.

The study will be performed at Royal Melbourne Hospital in Melbourne, Australia.

"We are the first company in the world to conduct clinical trials of human pluripotent stem cells based product for the treatment of Parkinson's disease. We believe the outcome of the study will produce findings in-line with our preclinical studies, where we demonstrated not only safety of our proprietary

neural stem cells, but also their functional efficacy. The cells were able to successfully integrate into the brain and provide a significant increase of dopamine levels in the nigrostriatal system” commented Russell Kern, PhD, ISCO’s Executive Vice President and chief scientific officer.

About Parkinson’s disease

Parkinson’s disease is a degenerative disorder of the central nervous system mainly affecting the motor system. The motor symptoms of Parkinson’s disease result from the death of dopamine-generating cells in the substantia nigra, a region of the midbrain. Early in the course of the disease, the most obvious symptoms are movement-related; these symptoms include shaking, rigidity, slowness of movement and difficulty with walking and gait. Later, thinking and behavioral problems may arise, with dementia commonly occurring in the advanced stages of the disease, and depression is the most common psychiatric symptom. Parkinson’s disease is more common in older people, with most cases occurring after the age of 50.

Currently, medications typically used in the treatment of Parkinson’s, L-DOPA and dopamine agonists, improve the early symptoms of the disease. As the disease progresses and dopaminergic neurons continue to be lost, the drugs eventually become ineffective while at the same time frequently producing a complication marked by involuntary writhing movements. In 2013 PD resulted in about 103,000 deaths globally, up from 44,000 deaths in 1990.

About ISC-hpNSC

International Stem Cell Corporation’s proprietary ISC-hpNSC consists of a highly pure population of neural stem cells derived from human parthenogenetic stem cells. ISC-hpNSC is a suspension of clinical grade cells manufactured under cGMP conditions that have undergone stringent quality control measures and are clear of any microbial and viral contaminants. Preclinical studies in rodents and non-human primates have shown improvement in Parkinson’s disease symptoms and increase in brain dopamine levels following the intracranial administration of ISC-hpNSC. ISC-hpNSC provides neurotrophic support and cell replacement to the dying dopaminergic neurons of the recipient PD brain. Additionally, ISC-hpNSC are safe, well tolerated and do not cause adverse events such as dyskinesia, systemic toxicity or tumors in preclinical models. International Stem Cell Corporation believes that ISC-hpNSC may have broad therapeutic applications for many neurological diseases affecting the brain, the spinal cord and the eye.

About International Stem Cell Corporation

International Stem Cell Corporation (ISCO) is focused on the therapeutic applications of human parthenogenetic stem cells (hpSCs) and the development and commercialization of cell-based research and cosmetic products. ISCO’s core technology, parthenogenesis, results in the creation of pluripotent human stem cells from unfertilized oocytes (eggs). hpSCs avoid ethical issues associated with the use or destruction of viable human embryos. ISCO scientists have created the first parthenogenetic, homozygous stem cell line that can be a source of therapeutic cells for hundreds of millions of individuals of differing genders, ages and racial background with minimal immune rejection after transplantation. hpSCs offer the potential to create the first true stem cell bank, UniStemCell™. ISCO also produces and markets specialized cells and growth media for therapeutic research worldwide

through its subsidiary Lifeline Cell Technology (www.lifelinecelltech.com), and stem cell-based skin care products through its subsidiary Lifeline Skin Care (www.lifelineskincare.com). More information is available at www.intlstemcell.com.

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Safe harbor statement

Statements pertaining to anticipated developments, expected results of clinical studies, potential applications of ISC-hpNSCs to other diseases, progress of research and development initiatives, and other opportunities for the company and its subsidiaries, along with other statements about the future expectations, beliefs, goals, plans, or prospects expressed by management constitute forward-looking statements. Any statements that are not historical fact (including, but not limited to statements that contain words such as “will,” “believes,” “plans,” “anticipates,” “expects,” “estimates,”) should also be considered to be forward-looking statements. Forward-looking statements involve risks and uncertainties, including, without limitation, risks inherent in the development and/or commercialization of potential products, regulatory approvals, need and ability to obtain future capital, application of capital resources among competing uses, and maintenance of intellectual property rights. Actual results may differ materially from the results anticipated in these forward-looking statements and as such should be evaluated together with the many uncertainties that affect the company’s business, particularly those mentioned in the cautionary statements found in the company’s Securities and Exchange Commission filings. The company disclaims any intent or obligation to update forward-looking statements.

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