Intra-Cellular Therapies, Inc.
Form S-3
September 02, 2016
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As filed with the Securities and Exchange Commission on September 2, 2016

Registration No. 333-

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM S-3

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

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

(646) 440-9333

(Address, including zip code, and telephone number, including area code, of registrant s principal executive offices)

Sharon Mates, Ph.D.

Chairman, President and Chief Executive Officer

Intra-Cellular Therapies, Inc.

430 East 29th Street

New York, New York 10016

(646) 440-9333

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

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One Financial Center

Boston, MA 02111

(617) 542-6000

Approximate date of commencement of proposed sale to the public: From time to time after the effective date of this registration statement as determined by the registrant.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box: ¨

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box: x

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. ¨

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box. ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one).

Large accelerated filer x	Accelerated filer ¨
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company ¨

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CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount to be Registered	Proposed Maximum Offering Price per Unit	Proposed Maximum Aggregate Offering Price	Amount of Registration Fee[1]
Common Stock, $0.0001 par value	(2)	(3)	(3)	
Preferred Stock, $0.0001 par value	(2)	(3)	(3)	
Debt Securities	(2)	(3)	(3)	
Warrants	(2)	(3)	(3)	
Rights	(2)	(3)	(3)	
Purchase Contracts	(2)	(3)	(3)	
Units	(2)	(3)	(3)	
Total	(2)		$350,000,000	$34,758.87(4)

(1) Calculated pursuant to Rule 457(o) under the Securities Act of 1933, as amended, based on the proposed maximum aggregate offering price.

(2) There are being registered hereunder such indeterminate number of shares of common stock and preferred stock, such indeterminate principal amount of debt securities, such indeterminate number of warrants, rights and purchase contracts to purchase common stock, preferred stock or debt securities, and such indeterminate number of units, as shall have an aggregate initial offering price not to exceed $350,000,000. If any debt securities are issued at an original issue discount, then the offering price of such debt securities shall be in such greater principal amount as shall result in an aggregate initial offering price not to exceed $350,000,000, less the aggregate dollar amount of all securities previously issued hereunder. Any securities registered hereunder may be sold separately or as units with other securities registered hereunder. The proposed maximum initial offering price per unit will be determined, from time to time, by the registrant in connection with the issuance by the registrant of the securities registered hereunder. The securities registered also include such indeterminate number of shares of common stock and preferred stock and amount of debt securities as may be issued upon conversion of or exchange for preferred stock or debt securities that provide for conversion or exchange, upon exercise of warrants or rights or performance of purchase contracts or pursuant to the anti-dilution provisions of any such securities. In addition, pursuant to Rule 416 under the Securities Act of 1933, as amended, the shares being registered hereunder include such indeterminate number of shares of common stock and preferred stock as may be issuable with respect to the shares being registered hereunder as a result of stock splits, stock dividends or similar transactions.

(3) The proposed maximum aggregate offering price per class of security will be determined from time to time by the registrant in connection with the issuance by the registrant of the securities registered hereunder and is not specified as to each class of security pursuant to General Instruction II.D. of Form S-3 under the Securities Act of 1933, as amended.

(4) Pursuant to Rule 415(a)(6) under the Securities Act of 1933, as amended, this registration statement includes a total of $4,827,500 of unsold securities that had previously been registered under the Registrant s registration statement on Form S-3 initially filed on May 28, 2015, File No.333-204509 (the Prior Registration Statement). The Prior Registration Statement registered securities for a maximum offering price of $350,000,000. The Registrant sold an aggregate of $345,172,500 of securities thereunder, leaving a balance of unsold securities with an

aggregate offering price of $4,827,500. In connection with the registration of such unsold securities on the Prior Registration Statement, the Registrant paid a registration fee of $561 for such unsold securities, which fee will continue to be applied to such unsold securities. Accordingly, the amount of the registration fee has been calculated based on the proposed maximum offering price of the additional $345,172,500 of securities registered on this registration statement. Pursuant to Rule 415(a)(6), the offering of the unsold securities registered under the Prior Registration Statement will be deemed terminated as of the date of effectiveness of this registration statement.

THE REGISTRANT HEREBY AMENDS THIS REGISTRATION STATEMENT ON SUCH DATE OR DATES AS MAY BE NECESSARY TO DELAY ITS EFFECTIVE DATE UNTIL THE REGISTRANT SHALL FILE A FURTHER AMENDMENT WHICH SPECIFICALLY STATES THAT THIS REGISTRATION STATEMENT SHALL THEREAFTER BECOME EFFECTIVE IN ACCORDANCE WITH SECTION 8(a) OF THE SECURITIES ACT OF 1933, AS AMENDED, OR UNTIL THE REGISTRATION STATEMENT SHALL BECOME EFFECTIVE ON SUCH DATE AS THE SECURITIES AND EXCHANGE COMMISSION, ACTING PURSUANT TO SAID SECTION 8(a), MAY DETERMINE.

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THE INFORMATION IN THIS PROSPECTUS IS NOT COMPLETE AND MAY BE CHANGED. WE MAY NOT SELL THESE SECURITIES UNTIL THE REGISTRATION STATEMENT FILED WITH THE SECURITIES AND EXCHANGE COMMISSION IS EFFECTIVE. THIS PROSPECTUS IS NOT AN OFFER TO SELL THESE SECURITIES AND IS NOT SOLICITING AN OFFER TO BUY THESE SECURITIES IN ANY STATE WHERE THE OFFER OR SALE IS NOT PERMITTED.

SUBJECT TO COMPLETION, DATED SEPTEMBER 2, 2016

PROSPECTUS

Intra-Cellular Therapies, Inc.

$350,000,000

COMMON STOCK

PREFERRED STOCK

DEBT SECURITIES

WARRANTS

RIGHTS

PURCHASE CONTRACTS

UNITS

This prospectus will allow us to issue, from time to time at prices and on terms to be determined at or prior to the time of the offering, up to $350,000,000 of any combination of the securities described in this prospectus, either individually or in units. We may also offer common stock or preferred stock upon conversion of or exchange for the debt securities; common stock upon conversion of or exchange for the preferred stock; common stock, preferred stock or debt securities upon the exercise of warrants, rights or performance of purchase contracts; or any combination of these securities upon the performance of purchase contracts.

This prospectus describes the general terms of these securities and the general manner in which these securities will be offered. We will provide you with the specific terms of any offering in one or more supplements to this prospectus. The prospectus supplements will also describe the specific manner in which these securities will be offered and may also supplement, update or amend information contained in this document. You should read this prospectus and any prospectus supplement, as well as any documents incorporated by reference into this prospectus or any prospectus supplement, carefully before you invest.

Our securities may be sold directly by us to you, through agents designated from time to time or to or through underwriters or dealers. For additional information on the methods of sale, you should refer to the section entitled Plan of Distribution in this prospectus and in the applicable prospectus supplement. If any underwriters or agents are involved in the sale of our securities with respect to which this prospectus is being delivered, the names of such

underwriters or agents and any applicable fees, commissions or discounts and over-allotment options will be set forth in a prospectus supplement. The price to the public of such securities and the net proceeds that we expect to receive from such sale will also be set forth in a prospectus supplement.

Our common stock is listed on The NASDAQ Global Select Market under the symbol ITCI. On September 1, 2016, the last reported sale price of our common stock was $40.63 per share. The applicable prospectus supplement will contain information, where applicable, as to any other listing, if any, on The NASDAQ Global Select Market or any securities market or other securities exchange of the securities covered by the prospectus supplement. Prospective purchasers of our securities are urged to obtain current information as to the market prices of our securities, where applicable.

Investing in our securities involves a high degree of risk. Before deciding whether to invest in our securities, you should consider carefully the risks that we have described on page 7 of this prospectus under the caption Risk Factors. We may include specific risk factors in supplements to this prospectus under the caption Risk Factors. This prospectus may not be used to sell our securities unless accompanied by a prospectus supplement.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is , 2016.

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ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission, or SEC, utilizing a shelf registration process. Under this shelf registration process, we may offer shares of our common stock and preferred stock, various series of debt securities and/or warrants, rights or purchase contracts to purchase any of such securities, either individually or in units, in one or more offerings, with a total value of up to $350,000,000. This prospectus provides you with a general description of the securities we may offer. Each time we offer a type or series of securities under this prospectus, we will provide a prospectus supplement that will contain specific information about the terms of that offering.

This prospectus does not contain all of the information included in the registration statement. For a more complete understanding of the offering of the securities, you should refer to the registration statement, including its exhibits. The prospectus supplement may also add, update or change information contained or incorporated by reference in this prospectus. However, no prospectus supplement will offer a security that is not registered and described in this prospectus at the time of its effectiveness. This prospectus, together with the applicable prospectus supplements and the documents incorporated by reference into this prospectus, includes all material information relating to the offering of securities under this prospectus. You should carefully read this prospectus, the applicable prospectus supplement, the information and documents incorporated herein by reference and the additional information under the heading Where You Can Find More Information before making an investment decision.

You should rely only on the information we have provided or incorporated by reference in this prospectus or any prospectus supplement. We have not authorized anyone to provide you with information different from that contained or incorporated by reference in this prospectus. No dealer, salesperson or other person is authorized to give any information or to represent anything not contained or incorporated by reference in this prospectus. You must not rely on any unauthorized information or representation. This prospectus is an offer to sell only the securities offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. You should assume that the information in this prospectus or any prospectus supplement is accurate only as of the date on the front of the document and that any information we have incorporated herein by reference is accurate only as of the date of the document incorporated by reference, regardless of the time of delivery of this prospectus or any sale of a security.

We further note that the representations, warranties and covenants made by us in any agreement that is filed as an exhibit to any document that is incorporated by reference in the accompanying prospectus were made solely for the benefit of the parties to such agreement, including, in some cases, for the purpose of allocating risk among the parties to such agreements, and should not be deemed to be a representation, warranty or covenant to you. Moreover, such representations, warranties or covenants were accurate only as of the date when made. Accordingly, such representations, warranties and covenants should not be relied on as accurately representing the current state of our affairs.

This prospectus may not be used to consummate sales of our securities, unless it is accompanied by a prospectus supplement. To the extent there are inconsistencies between any prospectus supplement, this prospectus and any documents incorporated by reference, the document with the most recent date will control.

Unless the context otherwise requires, Intra-Cellular, ITCI, the Company, we, us, our and similar terms refer Intra-Cellular Therapies, Inc. and our subsidiaries.

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PROSPECTUS SUMMARY

The following is a summary of what we believe to be the most important aspects of our business and the offering of our securities under this prospectus. We urge you to read this entire prospectus, including the more detailed consolidated financial statements, notes to the consolidated financial statements and other information incorporated by reference from our other filings with the SEC or included in any applicable prospectus supplement. Investing in our securities involves risks. Therefore, carefully consider the risk factors set forth in any prospectus supplements and in our most recent annual and quarterly filings with the SEC, as well as other information in this prospectus and any prospectus supplements and the documents incorporated by reference herein or therein, before purchasing our securities. Each of the risk factors could adversely affect our business, operating results and financial condition, as well as adversely affect the value of an investment in our securities.

Overview

We are a biopharmaceutical company focused on the discovery and clinical development of innovative, small molecule drugs that address underserved medical needs in neuropsychiatric and neurological disorders by targeting intracellular signaling mechanisms within the central nervous system, or CNS. ITI-007 is our lead product candidate with mechanisms of action that, we believe, may represent an effective treatment across multiple therapeutic indications. In our pre-clinical and clinical trials to date, ITI-007 combines potent serotonin 5-HT2A receptor antagonism, dopamine receptor phosphoprotein modulation, or DPPM, glutamatergic modulation, and serotonin reuptake inhibition into a single drug candidate for the treatment of acute and residual schizophrenia and for the treatment of bipolar disorder, including bipolar depression. At dopamine D2 receptors, ITI-007 has been demonstrated to have dual properties and to act as both a pre-synaptic partial agonist and a post-synaptic antagonist. ITI-007 has also been demonstrated to have affinity for dopamine D1 receptors and indirectly stimulate phosphorylation of glutamatergic NMDA GluN2B receptors in a mesolimbic specific manner. We believe that this regional selectivity in brain areas thought to mediate the efficacy of antipsychotic drugs, together with serotonergic, glutamatergic, and dopaminergic interactions, may result in efficacy for a broad array of symptoms associated with schizophrenia and bipolar disorder with improved psychosocial function. The serotonin reuptake inhibition potentially allows for antidepressant activity in the treatment of schizoaffective disorder, other disorders with co-morbid depression, and/or as a stand-alone treatment for major depressive disorder. We believe ITI-007 may also be useful for the treatment of other psychiatric and neurodegenerative disorders, particularly behavioral disturbances associated with dementia, autism, and other CNS diseases. ITI-007 is in Phase 3 clinical development as a novel treatment for schizophrenia, bipolar depression and agitation associated with dementia, including Alzheimer s disease.

ITI-007 for the Treatment of Schizophrenia

In September 2015, we announced top-line clinical results from our first Phase 3 clinical trial of ITI-007 for the treatment of patients with schizophrenia. This randomized, double-blind, placebo-controlled Phase 3 clinical trial was conducted at 12 sites in the United States with 450 patients randomized (1:1:1) to receive either 60 mg of ITI-007, 40 mg of ITI-007 or placebo once daily in the morning for 28 days. The pre-specified primary efficacy measure was change from baseline versus placebo at study endpoint (4 weeks) on the centrally rated Positive and Negative Syndrome Scale, or PANSS, total score. In this trial, the once-daily dose of 60 mg of ITI-007 met the primary endpoint and demonstrated antipsychotic efficacy with statistically significant superiority over placebo at week 4 (study endpoint) with additional improvements observed in social function. Moreover, the 60 mg dose of ITI-007 showed significant antipsychotic efficacy as early as week 1, which was maintained at every time point throughout the entire study. ITI-007 showed a dose-related improvement in symptoms of schizophrenia with the 40 mg dose approximating the trajectory of improvement seen with the 60 mg dose, but the effect with 40 mg did not reach statistical significance on the primary endpoint. In addition, the 60 mg dose of ITI-007 met the key secondary

endpoint of statistically significant improvement on the Clinical Global Impression Scale for Severity of Illness, or CGI-S. The 40 mg dose of ITI-007 also demonstrated a statistically

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significant improvement versus placebo on the CGI-S, though not formally tested against placebo as a key secondary endpoint since it did not separate on the primary endpoint. A high treatment completion rate was observed with ITI-007 (87% of patients completed treatment on ITI-007 60 mg, 82% completed on ITI-007 40 mg, and 75% completed on placebo). Patients randomized to ITI-007 60 mg demonstrated a statistically significant longer time to treatment discontinuation due to any reason compared to placebo (p=0.006) and a statistically significant longer time to treatment discontinuation due to lack of efficacy (p=0.01). Consistent with previous studies, ITI-007 had a favorable safety and tolerability profile as evidenced by motoric, metabolic, and cardiovascular characteristics similar to placebo, and no clinically significant changes in akathisia, extrapyramidal symptoms, prolactin, body weight, glucose, insulin, or lipids. The number of patients who discontinued treatment in this study due to an adverse event was low and the time to treatment discontinuation due to an adverse event was not statistically significantly different from placebo for either dose of ITI-007.

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

The top-line results from our first Phase 3 clinical trial of ITI-007 confirm the earlier Phase 2 results that we announced in December 2013, in which ITI-007 exhibited antipsychotic efficacy in a randomized, double-blind, placebo and active controlled clinical trial in patients with schizophrenia. In this Phase 2 trial, 335 patients were randomized to receive one of four treatments: 60 mg of ITI-007, 120 mg of ITI-007, 4 mg of risperidone (active control) or placebo in a 1:1:1:1 ratio, orally once daily for 28 days. The primary endpoint for this clinical trial was change from baseline to Day 28 on the PANSS total score. In this study, ITI-007 met the trial s pre-specified primary endpoint, improving symptoms associated with schizophrenia as measured by a statistically significant and clinically meaningful decrease in the PANSS total score. The trial also met key secondary outcome measures related to efficacy on PANSS subscales and safety. We are also conducting a second Phase 3 clinical trial in schizophrenia that we initiated in the second quarter of 2015. In this trial, we are randomizing patients to two doses of ITI-007 (60 mg or 20 mg), risperidone (active control) or placebo over a 6-week treatment duration, and the primary outcome measure is change from baseline to Day 42 on the PANSS total score. Patient enrollment was completed in the second quarter of 2016, with 696 patients enrolled in the trial. We anticipate top-line results from the second Phase 3 clinical trial will be available later this year.

In addition to our two Phase 3 clinical trials, we will need to complete other clinical and non-clinical trials and manufacturing and pre-commercialization activities necessary to support the submission of a planned NDA for ITI-007 in schizophrenia, which we currently expect could occur in the first half of 2017.

ITI-007 for the Treatment of Depressive Episodes Associated with Bipolar Disorder (Bipolar Depression)

Our bipolar depression program consists of two Phase 3 multi-center, randomized, double-blind, placebo-controlled clinical trials: one to evaluate ITI-007 as a monotherapy and the other to evaluate ITI-007 as an adjunctive therapy

with lithium or valproate. In each trial, approximately 550 patients with a clinical diagnosis of Bipolar I or Bipolar II disorder and who are experiencing a current major depressive episode will be randomized to receive one of three treatments: 60 mg ITI-007, 40 mg ITI-007, or placebo in a 1:1:1 ratio orally once daily for

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6 weeks. In the ITI-007-401 trial, patients will receive ITI-007 or placebo as a monotherapy. In the ITI-007-402 trial, patients will receive ITI-007 or placebo adjunctive to their existing mood stabilizer lithium or valproate. We initiated our bipolar depression program in the third quarter of 2015.

The primary endpoint for both clinical trials is change from baseline at Day 42 on the Montgomery-Åsberg Depression Rating Scale, or MADRS, total score versus placebo. The MADRS is a well-validated 10-item checklist that measures the ability of a drug to reduce overall severity of depressive symptoms. Individual items are rated by an expert clinician on a scale of 0 to 6 in which a score of 6 represents the most depressed evaluation for each item assessed. The total score ranges from 0 to 60. Secondary endpoints include measures of social function and quality of life that may illustrate the differentiated clinical profile of ITI-007. Safety and tolerability are also assessed in both clinical trials.

ITI-007 for the Treatment of Behavioral Disturbances Associated with Dementia, Including Alzheimer s Disease

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

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

Other Indications for ITI-007

We are also pursuing clinical development of ITI-007 for the treatment of additional CNS diseases and disorders. At the lowest doses, ITI-007 has been demonstrated to act primarily as a potent 5-HT2A serotonin receptor antagonist. As the dose is increased, additional benefits are derived from the engagement of additional drug targets, including modest dopamine receptor modulation and modest inhibition of serotonin transporters. We believe that combined interactions at these receptors may provide additional benefits above and beyond selective 5-HT2A antagonism for treating agitation, aggression and sleep disturbances in diseases that include dementia, Alzheimer s disease, Huntington s disease and autism spectrum disorders, while avoiding many of the side effects associated with more robust dopamine receptor antagonism. As the dose of ITI-007 is further increased, leading to moderate dopamine

receptor modulation, inhibition of serotonin transporters, and indirect glutamate modulation, these actions complement the complete blockade of 5-HT2A serotonin receptors. At a dose of 60 mg, ITI-007 has been shown effective in treating the symptoms associated with schizophrenia, and we believe this higher dose range will be

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useful for the treatment of bipolar disorder, depressive disorders and other neuropsychiatric diseases. Within the ITI-007 portfolio, we are also developing a long-acting injectable formulation to provide more treatment options to patients suffering from mental illness. Given the encouraging tolerability data to date with oral ITI-007, we believe that a long-acting injectable option, in particular, may lend itself to being an important formulation choice for patients.

Given the potential utility for ITI-007 and follow-on compounds to treat these additional indications, we may investigate, either on our own or with a partner, agitation, aggression and sleep disturbances in additional diseases that include autism spectrum disorders; depressive disorder; intermittent explosive disorder; non-motor symptoms and motor complications associated with Parkinson s disease; and post-traumatic stress disorder. We hold exclusive, worldwide commercialization rights to ITI-007 and a family of compounds from Bristol-Myers Squibb Company pursuant to an exclusive license.

Other Product Candidates

We have a second major program called ITI-002 that has yielded a portfolio of compounds that selectively inhibits the enzyme phosphodiesterase type 1, or PDE1. We believe PDE1 helps regulate brain activity related to cognition, memory processes and movement/coordination. On February 25, 2011, we (through our wholly owned operating subsidiary, ITI) and Takeda Pharmaceutical Company Limited, or Takeda, entered into a license and collaboration agreement, or the Takeda License Agreement, under which we agreed to collaborate to research, develop and commercialize our proprietary compound ITI-214 and other selected compounds that selectively inhibit PDE1 for use in the prevention and treatment of human diseases. On October 31, 2014, we entered into an agreement with Takeda terminating the Takeda License Agreement, or the Termination Agreement, pursuant to which all rights granted under the Takeda License Agreement were returned to us. On September 15, 2015, Takeda completed the transfer of the Investigational New Drug application, or IND, for ITI-214 to us. ITI-214 is the first compound in its class to successfully advance into Phase 1 clinical trials. We intend to pursue the development of our PDE program, including ITI-214 for the treatment of several CNS and non-CNS conditions, which may include cognition in Parkinson s disease, cognition in Alzheimer s disease, cognition in schizophrenia and in other non-CNS indications. Other compounds in the PDE portfolio are also being advanced for the treatment of various indications.

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

We have assembled a management team with significant industry experience to lead the discovery and development of our product candidates. We complement our management team with a group of scientific and clinical advisors that includes recognized experts in the fields of schizophrenia and other CNS disorders, including Nobel laureate, Dr. Paul Greengard, one of our co-founders.

Additional Information

For additional information related to our business and operations, please refer to the reports incorporated herein by reference, including our Annual Report on Form 10-K for the year ended December 31, 2015, as described under the caption Incorporation of Documents by Reference on page 27 of this prospectus.

Our 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) through a reverse merger transaction on August 29, 2013. ITI was incorporated in Delaware in May 2001 to focus primarily on the development of novel drugs for

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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, and ITI continues as the operating subsidiary of the Company. As used herein, the words Intra-Cellular, ITCI, the Company, we, us, and refer to the Delaware corporation operating the business of ITI as a wholly-owned subsidiary, which business continues as the business of the Company.

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. The information contained on, or that can be accessed through, our website is not a part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

All brand names or trademarks appearing in this prospectus are the property of their respective holders. Use or display by us of other parties trademarks, trade dress, or products in this prospectus is not intended to, and does not, imply a relationship with, or endorsements or sponsorship of, us by the trademark or trade dress owners.

Offerings Under This Prospectus

Under this prospectus, we may offer shares of our common stock and preferred stock, various series of debt securities and/or warrants, rights or purchase contracts to purchase any of such securities, either individually or in units, with a total value of up to $350,000,000, from time to time at prices and on terms to be determined by market conditions at the time of the offering. This prospectus provides you with a general description of the securities we may offer. Each time we offer a type or series of securities under this prospectus, we will provide a prospectus supplement that will describe the specific amounts, prices and other important terms of the securities, including, to the extent applicable:

- designation or classification;
- aggregate principal amount or aggregate offering price;
- maturity, if applicable;
- rates and times of payment of interest or dividends, if any;
- redemption, conversion or sinking fund terms, if any;
- voting or other rights, if any; and
- conversion or exercise prices, if any.

The prospectus supplement also may add, update or change information contained in this prospectus or in documents we have incorporated by reference into this prospectus. However, no prospectus supplement will fundamentally

change the terms that are set forth in this prospectus or offer a security that is not registered and described in this prospectus at the time of its effectiveness.

We may sell the securities directly to investors or to or through agents, underwriters or dealers. We, and our agents or underwriters, reserve the right to accept or reject all or part of any proposed purchase of securities. If we offer securities through agents or underwriters, we will include in the applicable prospectus supplement:

- the names of those agents or underwriters;
- applicable fees, discounts and commissions to be paid to them;
- details regarding over-allotment options, if any; and
- the net proceeds to us.

This prospectus may not be used to consummate a sale of any securities unless it is accompanied by a prospectus supplement.

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RISK FACTORS

Investing in our securities involves significant risk. The prospectus supplement applicable to each offering of our securities will contain a discussion of the risks applicable to an investment in Intra-Cellular. Prior to making a decision about investing in our securities, you should carefully consider the specific factors discussed under the heading Risk Factors in the applicable prospectus supplement, together with all of the other information contained or incorporated by reference in the prospectus supplement or appearing or incorporated by reference in this prospectus. You should also consider the risks, uncertainties and assumptions discussed under the heading Risk Factors included in our most recent annual report on Form 10-K, as revised or supplemented by our subsequent quarterly reports on Form 10-Q or our current reports on Form 8-K that we have filed with the SEC, all of which are incorporated herein by reference, and which may be amended, supplemented or superseded from time to time by other reports we file with the SEC in the future. The risks and uncertainties we have described are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also affect our operations. The occurrence of any of these risks might cause you to lose all or part of your investment in the offered securities.

RATIO OF EARNINGS TO FIXED CHARGES

Any time debt securities are offered pursuant to this prospectus, we will provide a table setting forth our ratio of earnings to fixed charges on a historical basis in the applicable prospectus supplement, if required.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and the documents incorporated by reference in this prospectus include forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or 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, plan, potential, predict, project, targets, likely, will, would, could, should, continue, and similar 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 prospectus and incorporated by reference in this prospectus, 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 sections in our periodic reports, including our Annual Report on Form 10-K for the fiscal year ended December 31, 2015, entitled Business, Risk Factors, and Management s Discussion and Analysis of Financial Condition and Results of Operations, as well as other sections in this prospectus and the documents or reports incorporated by reference in this prospectus, 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, capital requirements and the need for additional financing;

the initiation, cost, timing, progress and results of our development activities, preclinical studies and clinical trials;

the timing of and our ability to obtain and maintain regulatory approval of our existing product candidates, any product candidates that we may develop, and any related restrictions, limitations, and/or warnings in the label of any approved product candidates;

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our plans to research, develop and commercialize our 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 our product candidates;

the size and growth of the markets for our product candidates and our ability to serve those markets;

the rate and degree of market acceptance of any future products;

the success of competing drugs that are or become available;

regulatory developments in the United States and other countries;

the performance of our third-party suppliers and manufacturers and our ability to obtain alternative sources of raw materials;

our ability to obtain additional financing;

our use of the proceeds from our securities offerings;

any restrictions on our ability to use our net operating loss carryforwards;

our exposure to investment risk, interest rate risk and capital market risk;

our expectations regarding the additional management attention and costs that will be required as we transition from an emerging growth company to a large accelerated filer ; and

our ability to attract and retain key scientific or management personnel.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important cautionary statements in this prospectus or in the documents incorporated by reference in this prospectus, particularly in the Risk Factors section, that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. For a summary of such factors, please refer to the section entitled Risk Factors in this prospectus, as updated and supplemented by the discussion of risks and uncertainties under Risk Factors contained in any supplements to this prospectus and in our most recent annual report on Form 10-K, as revised or supplemented by our subsequent quarterly reports on Form 10-Q or our current reports on Form 8-K, as well as any amendments thereto, as filed with the SEC and which are incorporated herein by reference. The information contained in this document is believed to be current as of the date of this document. We do not intend to update any of the forward-looking statements after the date of this document to conform these statements to actual results or to changes in our expectations, except as required by law.

In light of these assumptions, risks and uncertainties, the results and events discussed in the forward-looking statements contained in this prospectus or in any document incorporated herein by reference might not occur. Investors are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the date of this prospectus or the date of the document incorporated by reference in this prospectus. We are not under any obligation, and we expressly disclaim any obligation, to update or alter any forward-looking statements, whether as a result of new information, future events or otherwise. All subsequent forward-looking statements attributable to us or to any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section.

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USE OF PROCEEDS

Unless otherwise indicated in the applicable prospectus supplement, we intend to use any net proceeds from the sale of securities under this prospectus for our operations and our further development and commercialization of product candidates in our ITI-007 and PDE1 programs, as well as the development of other product candidates, and other general corporate purposes, including, but not limited to, working capital, intellectual property protection and enforcement, capital expenditures, repayment of any existing indebtedness, investments, acquisitions and collaborations. We have not determined the amounts we plan to spend on any of the areas listed above or the timing of these expenditures. As a result, our management will have broad discretion to allocate the net proceeds, if any, we receive in connection with securities offered pursuant to this prospectus for any purpose. Pending application of the net proceeds as described above, we may initially invest the net proceeds in short-term, investment-grade, interest-bearing securities or apply them to the reduction of short-term indebtedness.

PLAN OF DISTRIBUTION

We may offer securities under this prospectus from time to time pursuant to underwritten public offerings, negotiated transactions, block trades or a combination of these methods. We may sell the securities (1) through underwriters or dealers, (2) through agents or (3) directly to one or more purchasers, or through a combination of such methods. We may distribute the securities from time to time in one or more transactions at:

a fixed price or prices, which may be changed from time to time;

market prices prevailing at the time of sale;

prices related to the prevailing market prices; or

negotiated prices.

We may directly solicit offers to purchase the securities being offered by this prospectus. We may also designate agents to solicit offers to purchase the securities from time to time, and may enter into arrangements for at-the-market, equity line or similar transactions. We will name in a prospectus supplement any underwriter or agent involved in the offer or sale of the securities.

If we utilize a dealer in the sale of the securities being offered by this prospectus, we will sell the securities to the dealer, as principal. The dealer may then resell the securities to the public at varying prices to be determined by the dealer at the time of resale.

If we utilize an underwriter in the sale of the securities being offered by this prospectus, we will execute an underwriting agreement with the underwriter at the time of sale, and we will provide the name of any underwriter in the prospectus supplement which the underwriter will use to make resales of the securities to the public. In connection with the sale of the securities, we, or the purchasers of the securities for whom the underwriter may act as agent, may compensate the underwriter in the form of underwriting discounts or commissions. The underwriter may sell the securities to or through dealers, and the underwriter may compensate those dealers in the form of discounts, concessions or commissions.

With respect to underwritten public offerings, negotiated transactions and block trades, we will provide in the applicable prospectus supplement information regarding any compensation we pay to underwriters, dealers or agents in connection with the offering of the securities, and any discounts, concessions or commissions allowed by underwriters to participating dealers. Underwriters, dealers and agents participating in the distribution of the securities may be deemed to be underwriters within the meaning of the Securities Act, and any discounts and commissions received by them and any profit realized by them on resale of the securities may be deemed to be

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underwriting discounts and commissions. We may enter into agreements to indemnify underwriters, dealers and agents against civil liabilities, including liabilities under the Securities Act, or to contribute to payments they may be required to make in respect thereof.

If so indicated in the applicable prospectus supplement, we will authorize underwriters, dealers or other persons acting as our agents to solicit offers by certain institutions to purchase securities from us pursuant to delayed delivery contracts providing for payment and delivery on the date stated in each applicable prospectus supplement. Each contract will be for an amount not less than, and the aggregate amount of securities sold pursuant to such contracts shall not be less nor more than, the respective amounts stated in each applicable prospectus supplement. Institutions with whom the contracts, when authorized, may be made include commercial and savings banks, insurance companies, pension funds, investment companies, educational and charitable institutions and other institutions, but shall in all cases be subject to our approval. Delayed delivery contracts will not be subject to any conditions except that:

- the purchase by an institution of the securities covered under that contract shall not at the time of delivery be prohibited under the laws of the jurisdiction to which that institution is subject; and

- if the securities are also being sold to underwriters acting as principals for their own account, the underwriters shall have purchased such securities not sold for delayed delivery. The underwriters and other persons acting as our agents will not have any responsibility in respect of the validity or performance of delayed delivery contracts.

One or more firms, referred to as remarketing firms, may also offer or sell the securities, if a prospectus supplement so indicates, in connection with a remarketing arrangement upon their purchase. Remarketing firms will act as principals for their own accounts or as our agents. These remarketing firms will offer or sell the securities in accordance with the terms of the securities. Each prospectus supplement will identify and describe any remarketing firm and the terms of its agreement, if any, with us and will describe the remarketing firm s compensation. Remarketing firms may be deemed to be underwriters in connection with the securities they remarket. Remarketing firms may be entitled under agreements that may be entered into with us to indemnification by us against certain civil liabilities, including liabilities under the Securities Act, and may be customers of, engage in transactions with or perform services for us in the ordinary course of business.

Certain underwriters may use this prospectus and any accompanying prospectus supplement for offers and sales related to market-making transactions in the securities. These underwriters may act as principal or agent in these transactions, and the sales will be made at prices related to prevailing market prices at the time of sale. Any underwriters involved in the sale of the securities may qualify as underwriters within the meaning of Section 2(a)(11) of the Securities Act. In addition, the underwriters commissions, discounts or concessions may qualify as underwriters compensation under the Securities Act and the rules of the Financial Industry Regulatory Authority, Inc., or FINRA.

Shares of our common stock sold pursuant to the registration statement of which this prospectus is a part will be authorized for listing and trading on The NASDAQ Global Select Market. The applicable prospectus supplement will contain information, where applicable, as to any other listing, if any, on The NASDAQ Global Select Market or any securities market or other securities exchange of the securities covered by the prospectus supplement. Underwriters may make a market in our common stock, but will not be obligated to do so and may discontinue any market making at any time without notice. We can make no assurance as to the liquidity of or the existence, development or maintenance of trading markets for any of the securities.

In order to facilitate the offering of the securities, certain persons participating in the offering may engage in transactions that stabilize, maintain or otherwise affect the price of the securities. This may include over-allotments or short sales of the securities, which involve the sale by persons participating in the offering of more securities than we sold to them. In these circumstances, these persons would cover such over-allotments or short positions by making purchases in the open market or by exercising their over-allotment option. In addition, these

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persons may stabilize or maintain the price of the securities by bidding for or purchasing the applicable security in the open market or by imposing penalty bids, whereby selling concessions allowed to dealers participating in the offering may be reclaimed if the securities sold by them are repurchased in connection with stabilization transactions. The effect of these transactions may be to stabilize or maintain the market price of the securities at a level above that which might otherwise prevail in the open market. These transactions may be discontinued at any time.

The underwriters, dealers and agents may engage in other transactions with us, or perform other services for us, in the ordinary course of their business.

DESCRIPTION OF COMMON STOCK

We are authorized to issue 100,000,000 shares of common stock, par value $0.0001 per share. On August 29, 2016, we had 43,253,877 shares of common stock outstanding and approximately 122 stockholders of record.

The following summary of certain provisions of our common stock does not purport to be complete. You should refer to the section of this prospectus entitled Certain Provisions of Delaware Law and of the Company s Certificate of Incorporation and Bylaws and our restated certificate of incorporation and our restated bylaws, both of which are included as exhibits to the registration statement of which this prospectus is a part. The summary below is also qualified by provisions of applicable law.

General

Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders and do not have cumulative voting rights. An election of directors by our stockholders shall be determined by a plurality of the votes cast by the stockholders entitled to vote on the election. Holders of common stock are entitled to receive proportionately any dividends as may be declared by our board of directors, subject to any preferential dividend rights of any series of preferred stock that we may designate and issue in the future. All shares of common stock outstanding as of the date of this prospectus and, upon issuance and sale, all shares of common stock that we may offer pursuant to this prospectus, will be fully paid and nonassessable.

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

Registration Rights

On August 29, 2013, ITI entered into a registration rights agreement with investors in a private placement and also the existing stockholders of ITI who agreed to become parties to certain provisions of the agreement or who choose to become parties in the future, which initially covered 21,961,496 shares of our common stock. We assumed the registration rights agreement in connection with the reverse merger.

Resale Registration Rights

Pursuant to the registration rights agreement and subject to the rules and regulations of the SEC, we filed a registration statement covering the resale of the shares of our common stock held by the investors in the private placement that closed on August 29, 2013, and the shares of our common stock held by the former stockholders of ITI who are parties to the agreement, which we refer to as the Resale Registration Statement. The Resale Registration Statement was originally declared effective on December 18, 2013.

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Registration of these shares under the Securities Act has resulted in the shares becoming saleable under the Securities Act. Any sales of securities by holders of these shares could adversely affect the trading prices of our common stock.

We will be liable to each investor in the private placement (but not to the former stockholders of ITI who are parties to the agreement) for liquidated damages, on a 30-day basis, equal to 1.0% of the aggregate purchase price paid by the investor for the registrable shares of our common stock then held by the investor, subject to an overall cap of 5%, (i) if we suspend (subject to limited blackout periods described below) or terminate the Resale Registration Statement prior to the date which is the earlier of (x) December 18, 2016 and (y) the date on which all of the registrable shares cease to be registrable shares, or (ii) in the event one or more suspensions of the effectiveness of the Resale Registration Statement exceeds 60 days in the aggregate during any 12-month period. We will be permitted to suspend the Resale Registration Statement one or more times during any 12-month period, provided such suspensions do not exceed 30 consecutive days or 60 days in the aggregate in any 12-month period. Any suspension associated with our filing of an annual, periodic or current report, as required by the Exchange Act, will be permitted and will not be counted against the 60 day limitation. Expenses with respect to the filing and effectiveness of the Resale Registration Statement (but not selling expenses, or underwriter or agent compensation) will be paid by us, including expenses of one counsel for the selling stockholders.

Form S-3 Demand Registration Rights

Pursuant to the registration rights agreement, subject to specified limitations set forth in the registration rights agreement, the holders of at least 12% of the registrable shares of common stock then outstanding may request that we register on Form S-3 all or a portion of the registrable shares so long as the total amount of the shares being registered have an anticipated aggregate offering price, net of selling expenses, of at least $7,500,000.

Piggyback Registration Rights

Pursuant to the registration rights agreement, if we propose to register any of our common stock in a firm commitment underwritten offering, the holders of registrable shares of our common stock will be entitled to notice of the registration and have the right to require us to register all or a portion of the registrable shares then held by them, subject to our right and the right of our underwriters to reduce the number of shares proposed to be registered in view of market conditions. The requisite holders of these piggyback registration rights have waived their rights in connection with the filing of the registration statement of which this prospectus forms a part.

Expenses of Registration

We have agreed to pay all fees and expenses relating to the Resale Registration Statement, as well as all Form S-3 demand registrations and piggyback registrations, including up to $25,000 in fees of one special counsel of the investors in connection with the filing of the Resale Registration Statement.

Expiration of Registration Rights

The resale registration rights described above shall terminate upon the earlier of (1) the date on which all registrable shares have been effectively registered under the Securities Act and disposed of in accordance with the Resale Registration Statement, and (2) the third anniversary of the date that the Resale Registration Statement was declared effective, which is December 18, 2016.

Transfer Agent and Registrar

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

Stock Exchange Listing

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

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DESCRIPTION OF PREFERRED STOCK

We are authorized to issue 5,000,000 shares of preferred stock, par value $0.0001 per share. As of the date of this prospectus, no shares of our preferred stock were outstanding or designated. The following summary of certain provisions of our preferred stock does not purport to be complete. You should refer to our restated certificate of incorporation and our restated bylaws, both of which are included as exhibits to the registration statement of which this prospectus is a part. The summary below is also qualified by provisions of applicable law.

General

Our board of directors may, without further action by our stockholders, from time to time, direct the issuance of shares of preferred stock in series and may, at the time of issuance, determine the rights, preferences and limitations of each series, including voting rights, dividend rights and redemption and liquidation preferences. Satisfaction of any dividend preferences of outstanding shares of preferred stock would reduce the amount of funds available for the payment of dividends on shares of our common stock. Ho