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)**: March 4, 2015**

Intra-Cellular Therapies, Inc.

(Exact name of registrant as specified in its charter)

Commission File Number: **001-36274**

Delaware	**36-4742850**
(State or other jurisdiction of incorporation)	**(IRS Employer Identification No.)**

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

(212) 923-3344
(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))

Forward-Looking Statements

This Form 8-K contains forward-looking statements of Intra-Cellular Therapies, Inc. (the "Company" or "we") that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this Form 8-K are forward-looking statements. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," "contemplate," or the negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, among others, statements about: the Company's estimate regarding its cash, cash equivalents and investment securities as of December 31, 2014; and the Company's product candidates, development efforts, technology, intellectual property, financial condition, plans and development programs. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that the Company makes due to a number of important factors, including those risk factors attached as Exhibit 99.3 to this Form 8-K and its other filings with the Securities and Exchange Commission ("SEC"). The forward-looking statements in this Form 8-K represent the Company's views as of the date of this Form 8-K. The Company anticipates that subsequent events and developments will cause its views to change. However, while it may elect to update these forward-looking statements at some point in the future, it has no current intention of doing so except to the extent required by applicable law. You should, therefore, not rely on these forward-looking statements as representing the Company's views as of any date subsequent to the date of this Form 8-K.

ITEM 2.02 Results of Operations and Financial Condition.

On March 4, 2015, the Company filed with the Securities and Exchange Commission a preliminary prospectus supplement to its effective shelf registration statement on Form S-3 (File No. 333-198496) (the "Preliminary Prospectus Supplement") pursuant to Rule 424(b)(5) under the Securities Act of 1933, as amended, relating to a proposed public offering of shares of the Company's common stock (the "Public Offering"). The Company included the following disclosure in the Preliminary Prospectus Supplement:

While we have not finalized our full financial results for the fiscal year ended December 31, 2014, we expect to report that we had approximately $129.6 million of cash, cash equivalents and investment securities available for sale, as of December 31, 2014. This amount is preliminary, has not been audited and is subject to change upon completion of the audit of our consolidated financial statements as of and for the year ended December 31, 2014. Additional information and disclosures would be required for a more complete understanding of our financial position and results of operations as of December 31, 2014.

The information in this Item 2.02 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

ITEM 8.01 Other Events.

On March 4, 2015, the Company also issued a press release announcing the Public Offering, a copy of which is attached hereto as Exhibit 99.1 and is incorporated herein by reference. In addition, the Preliminary Prospectus Supplement for the Public Offering contains an updated summary description of the Company's business in the section entitled "Prospectus Supplement Summary," which is attached hereto as Exhibit 99.2 and incorporated herein by reference, and updated risk factors in the section entitled "Risk Factors," which is attached hereto as Exhibit 99.3 and incorporated herein by reference.

The information contained in Exhibits 99.2 and 99.3 updates and supersedes the information provided in the Company's previous periodic filings with the SEC in order to reflect recent business developments. This Current Report on Form 8-K, including the exhibits hereto, should be read in conjunction with the Company's Annual Report on Form 10-K for the year ended December 31, 2013, the Company's Quarterly Reports on Form 10-Q for the quarters ended March 31, 2014, June 30, 2014, and September 30, 2014 and the Company's Current Reports on Form 8-K since January 1, 2014.

ITEM 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press release dated March 4, 2015
99.2	Updated Business Summary
99.3	Updated Risk Factors

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. Hineline
Lawrence J. Hineline
Vice President of Finance and Chief Financial Officer

Date: March 4, 2015

Exhibit 99.1

Intra-Cellular Therapies Announces Proposed Public Offering of Common Stock

NEW YORK, March 04, 2015 (GLOBE NEWSWIRE) — Intra-Cellular Therapies, Inc. (Nasdaq: ITCI), a biopharmaceutical company, today announced that it has commenced an underwritten public offering of 4,250,000 shares of its common stock. In connection with the offering, Intra-Cellular Therapies intends to grant the underwriters a 30-day option to purchase up to an additional 15% of the shares of common stock offered in the public offering. All of the shares in the offering will be sold by Intra-Cellular Therapies.

Leerink Partners LLC, Cowen and Company, LLC and RBC Capital Markets, LLC are acting as joint book-running managers for the offering. The offering is subject to market and other conditions, and there can be no assurance as to whether or when the offering may be completed, or as to the actual size or terms of the offering.

The public offering will be made pursuant to a shelf registration statement on Form S-3 that was previously filed with and declared effective by the Securities and Exchange Commission ("SEC"). A preliminary prospectus supplement and accompanying base prospectus relating to and describing the terms of the offering has been filed with the SEC and is available on the SEC's website located at http://www.sec.gov. The offering is being made only by means of a prospectus and related prospectus supplement, copies of which may be obtained from Leerink Partners LLC, Attention: Syndicate Department, One Federal Street, 37th Floor, Boston, MA, 02110, or by phone at (800) 808-7525, ext. 6142, or by email at syndicate@leerink.com; from Cowen and Company, LLC, c/o Broadridge Financial Services, 1155 Long Island Avenue, Edgewood, NY, 11717, Attn: Prospectus Department, or by calling (631) 274-2806; or from RBC Capital Markets, Attention: Prospectus Department, Three World Financial Center, 200 Vesey Street 8th Floor, New York, NY 10281, or by phone at (877) 822-4089 or by emailing equityprospectus@rbccm.com. The final terms of the offering will be disclosed in a final prospectus supplement to be filed with the SEC.

This press release shall not constitute an offer to sell, or a solicitation of an offer to buy, nor will there be any sale of these securities in any state or other jurisdiction in which such an offer, solicitation or sale would be unlawful prior to the registration or qualification under the securities laws of any such state or other jurisdiction.

About Intra-Cellular Therapies

Intra-Cellular Therapies is developing novel drugs for the treatment of neuropsychiatric and neurodegenerative diseases and other disorders of the central nervous system. The Company is developing its lead drug candidate, ITI-007, for the treatment of schizophrenia, behavioral disturbances in dementia, bipolar disorder and other neuropsychiatric and neurological disorders. The Company is also utilizing its phosphodiesterase platform and other proprietary chemistry platforms to develop drugs for the treatment of cognitive deficits in schizophrenia and other CNS disorders. In addition, the Company is developing inhibitors against other targets for CNS indications such as Alzheimer's disease, Parkinson's disease and depression and non-CNS indications such as cardiovascular disease.

Cautionary Note Regarding Forward-Looking Statements

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that are subject to risks, uncertainties and other important factors that could cause actual results to differ materially from those indicated by such forward-looking statements, including statements with respect to Intra-Cellular's plans to consummate its proposed public offering. Intra-Cellular may use words such as "expect," "anticipate," "project," "intend," "plan," "aim," "believe," "seek," " estimate," "can," "focus," "will," and "may" and similar expressions to identify such forward-looking statements. Among the important factors that could cause actual results to differ materially from those indicated by such forward-looking statements are risks relating to, among other things, whether or not Intra-Cellular will be able to raise capital through the sale of shares of common stock, the final terms of the proposed offering, market and other conditions, the satisfaction of customary closing conditions related to the proposed public offering, Intra-Cellular's business and financial condition, and the impact of general economic, industry or political conditions in the United States or internationally. These and other risks are described in the reports filed by Intra-Cellular with the SEC, including under the caption "Risk Factors" included in Intra-Cellular's current report on Form 8-K filed with the SEC on March 4, 2015, Intra-Cellular's preliminary prospectus supplement filed with the SEC on March 4, 2015, and in other filings that Intra-Cellular makes with the SEC.

In addition, any forward-looking statement in this press release represents Intra-Cellular's views only as of the date of this press release and should not be relied upon as representing its views as of any subsequent date. Intra-Cellular disclaims any duty to update any forward-looking statement, except as required by applicable law.

Contact:

Intra-Cellular Therapies, Inc.
Juan Sanchez, M.D.
Vice President, Corporate Communications and Investor Relations
212-923-3344

Burns McClellan, Inc.
Lisa Burns/Nancy Yu (Investors)
Justin Jackson (Media)
jjackson@burnsmc.com
212-213-0006

PROSPECTUS SUPPLEMENT SUMMARY

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. We are developing our lead drug candidate, ITI-007, for the treatment of schizophrenia, behavioral disturbances in dementia, bipolar disorder and other neuropsychiatric and neurological disorders. ITI-007 is in Phase 3 clinical development as a first-in-class treatment for schizophrenia. Current medications available for the treatment of schizophrenia do not adequately address the broad array of symptoms associated with this CNS disorder. Use of these current medications also is limited by their substantial side effects. ITI-007 is designed to be effective across a wider range of symptoms, treating both the acute and residual phases of schizophrenia, with improved safety and tolerability.

ITI-007 exhibited antipsychotic efficacy in a randomized, double-blind, placebo and active controlled Phase 2 clinical trial in patients with an acutely exacerbated episode of schizophrenia. In December 2013, we announced the clinical results from this Phase 2 trial. 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 Positive and Negative Syndrome Scale, or 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 proceeding with Phase 3 development of ITI-007 for the treatment of schizophrenia. We plan to conduct two randomized, double-blind, placebo-controlled Phase 3 clinical trials of ITI-007 in patients with acutely exacerbated schizophrenia, with over 400 patients in each trial. We initiated the first Phase 3 clinical trial in schizophrenia in the fourth quarter of 2014 and, subject to finalizing the trial protocols and arrangements with clinical trial sites, we intend to initiate a second Phase 3 clinical trial in the first half of 2015. In the first Phase 3 trial, we are randomizing patients to two doses of ITI-007 (60mg or 40mg) or placebo over a 4-week treatment duration, and the primary outcome measure is change from baseline to Day 28 on the PANSS total score. We currently expect that the second Phase 3 trial will be conducted for a 6-week treatment duration. Subject to timely enrollment, we anticipate that the results of the first Phase 3 clinical trial of ITI-007 in patients with schizophrenia could be available as early as the fourth quarter of 2015. Subject to further discussions with the U.S. Food and Drug Administration, or FDA, we also plan to initiate separate additional trials in bipolar disorder in 2015. We have not yet discussed our plans to develop ITI-007 for the treatment of bipolar disorder with the FDA. We expect that the planned trials in bipolar disorder will overlap in time with the clinical conduct of the planned trials in schizophrenia. In addition to our 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 New Drug Application, or NDA, for ITI-007 in schizophrenia, which we currently expect could occur at the end of 2016 or the beginning of 2017.

In addition, in the fourth quarter of 2014, we announced the topline 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 to date 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. We plan to initiate additional clinical programs evaluating ITI-007 in patients with behavioral disturbances associated with dementia and related disorders, including Alzheimer's disease, in 2015.

We are currently conducting an open-label positron emission tomography, or PET, study of ITI-007 examining brain receptor occupancy and assessing occupancy of striatal D2 receptors. In this study, patients with stable schizophrenia will be treated with ITI-007 for 14 days. We expect topline data from this study in 2015. We believe this study will further characterize ITI-007 and provide additional insight into the molecule's unique mechanism and clinical profile.

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 useful for the treatment of bipolar disorder, major depressive disorder and other neuropsychiatric diseases.

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; major 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.

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. 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 with Takeda, 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. Takeda will complete certain ongoing activities relating to non-clinical studies and will transfer product inventory and materials to us but will not have any other ongoing involvement or funding obligations in connection with the development program. ITI-214 is the first compound in its class to successfully advance into Phase 1 clinical trials. We intend to continue the development of ITI-214 for the treatment of CNS and other disorders. Over approximately the next 12 months, we will refine our strategy for the PDE1 inhibitor program.

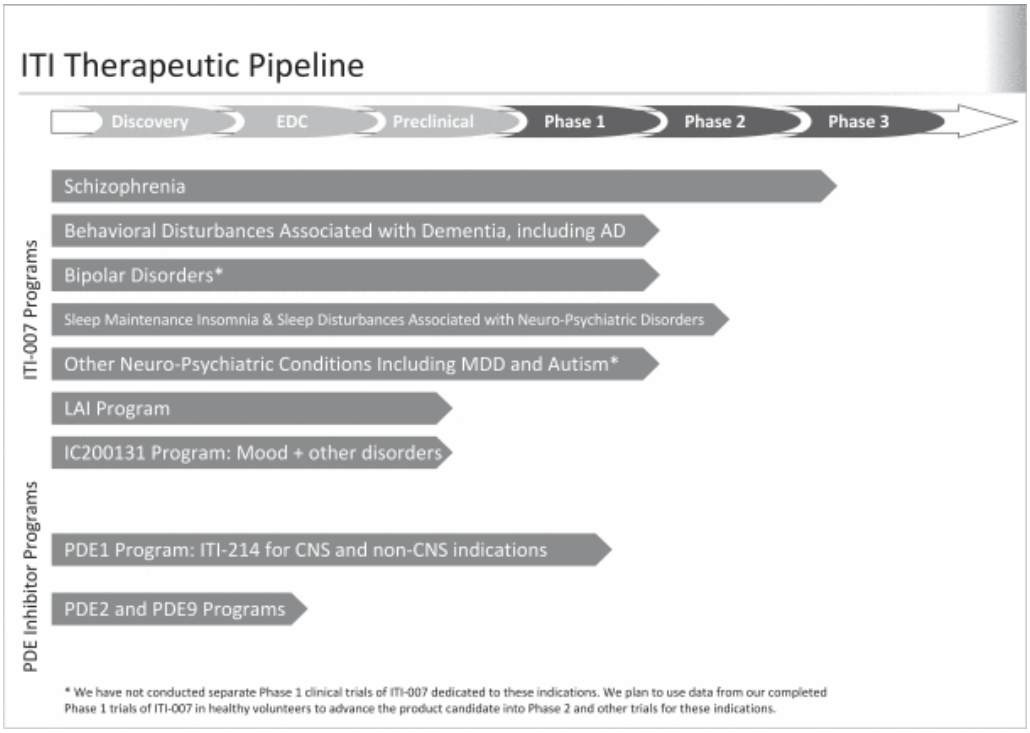
By regaining unrestricted access to ITI-214, backups and the proprietary chemistry, we can now integrate the efforts of our internal PDE1 program to include the later stage portfolio. We do not anticipate a significant increase in our operating expenses related to our PDE development programs over the next twelve months. Other compounds in the PDE1 portfolio are also being advanced for the treatment of various indications, including non-CNS therapeutic areas.

Our pipeline also includes pre-clinical programs that are focused on advancing drugs for the treatment of cognitive dysfunction, in both schizophrenia and Alzheimer's disease, and for disease modification and the treatment of neurodegenerative disorders, including Alzheimer's disease.

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.

Our Product Candidates

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



Our Strategy

Our goal is to discover and develop novel small molecule therapeutics for the treatment of CNS diseases in order to improve the lives of people suffering from such illnesses. Using our key understanding of intracellular signaling, we seek to accomplish our goal, using our in-house expert drug discovery and clinical development teams, in two ways:

- we seek to have the capability to develop first-in-class medications with novel mechanisms that have the potential to treat CNS diseases for which there are no previously marketed drugs; and
- we seek to develop drugs that either can differentiate themselves in competitive markets by addressing aspects of CNS disease which are not treated by currently marketed drugs or can be effective with fewer side effects.

The key elements of our strategy are to:

- complete the development of ITI-007 for its lead indication, treatment of schizophrenia, and for additional neuropsychiatric indications, such as bipolar disorder and residual symptoms in schizophrenia;
- expand the commercial potential of ITI-007 by investigating its usefulness in neurological areas, such as behavioral disturbances in dementia, including Alzheimer's disease and autism spectrum disorder, and in additional neuropsychiatric indications, such as sleep disorders associated with neuropsychiatric and neurological disorders and major depressive disorder;
- continue to develop PDE inhibitor compounds, such as ITI-214, for the treatment of CNS and other disorders; and
- advance earlier stage product candidates in our pipeline.

Risks Relating to Our Business

We are a biopharmaceutical company, and our business and ability to execute our business strategy are subject to a number of significant risks of which you should be aware before you decide to buy shares of our common stock. Among these important risks are the following:

- We currently do not have, and may never have, any products that generate significant revenues.
- There is no guarantee that our planned clinical trials for ITI-007 in schizophrenia or in other indications will be successful.
- Although we have discussed our clinical development plans with the FDA, the agency may ultimately determine that our Phase 3 clinical trials and non-clinical studies, even if successfully completed, are not sufficient for regulatory approval. If we are required to conduct additional clinical trials and non-clinical studies, our development of ITI-007 for schizophrenia will be more time-consuming and costly than we presently anticipate, which would have a material adverse effect on our business, results of operations and financial condition.
- If the FDA does not agree with our clinical development plans to advance ITI-007 for the treatment of schizophrenia and bipolar disorder with separate, but overlapping, well-controlled clinical trials in both indications, our development of ITI-007 for the treatment of bipolar disorder may be delayed and the costs of our development of ITI-007 would increase.
- We expect our net losses to continue for at least several years and are unable to predict the extent of future losses or when we will become profitable, if ever.
- We will require substantial additional funding, which may not be available to us on acceptable terms, or at all, and, if not so available, may require us to delay, limit, reduce or cease our operations.

- Our lead product candidate, ITI-007, is only part way through the clinical trials we anticipate needing to complete before we may be able to submit an NDA to the FDA. Clinical trials are long, expensive and unpredictable, and there is a high risk of failure.
- Delays, suspensions and terminations in our clinical trials could result in increased costs to us, delay our ability to generate product revenues and therefore may have a material adverse effect on our business, results of operations and future growth prospects.
- Safety issues with our product candidates, or with product candidates or approved products of third parties that are similar to our product candidates, could give rise to delays in the regulatory approval process, restrictions on labeling or product withdrawal after approval.
- Preliminary and interim data from our clinical studies that we may announce or publish from time to time may change as more patient data become available.
- We rely on third parties to conduct our clinical trials and perform data collection and analysis, which may result in costs and delays that prevent us from successfully commercializing our product candidates.
- Even if we successfully complete the clinical trials of one or more of our product candidates, the product candidates may fail for other reasons.
- Following regulatory approval of any of our drug candidates, we will be subject to ongoing regulatory obligations and restrictions, which may result in significant expense and limit our ability to commercialize our potential products.
- Relying on third-party manufacturers may result in delays in our clinical trials, regulatory approvals and product introductions.
- We will need to continue to manage our organization and we may encounter difficulties with our staffing and any future transitions, which could adversely affect our results of operations.
- Our ability to compete may be undermined if we do not adequately protect our proprietary rights.
- Many of our competitors have greater resources and capital than us, putting us at a competitive disadvantage. If our competitors develop and market products that are more effective than our product candidates, they may reduce or eliminate our commercial opportunity.
- Our stock price may fluctuate significantly and you may have difficulty selling your shares based on current trading volumes of our stock. In addition, numerous other factors could result in substantial volatility in the trading price of our stock.
- We have broad discretion in the use of net proceeds from this offering and may not use them effectively.
- Purchasers in this offering will experience immediate and substantial dilution in the book value of their investment.
- The price of our common stock could be subject to volatility related or unrelated to our operations.
- Management and certain members of our board of directors beneficially own a substantial amount of our outstanding equity securities and will be able to exert substantial control over us.

Recent Developments

While we have not finalized our full financial results for the fiscal year ended December 31, 2014, we expect to report that we had approximately $129.6 million of cash, cash equivalents and investment securities, available for sale, as of December 31, 2014. This amount is preliminary, has not been audited and is subject to change upon completion of the audit of our consolidated financial statements as of and for the year ended December 31, 2014. Additional information and disclosures would be required for a more complete understanding of our financial position and results of operations as of December 31, 2014.

Corporate Information

We were originally incorporated in the State of Delaware in August 2012 under the name "Oneida Resources Corp." Oneida Resources Corp. was a "shell" company registered under the Securities Exchange Act of 1934, as amended, or the Exchange Act, with no specific business plan or purpose until it began operating the business of Intra-Cellular Therapies, Inc. (now re-named ITI, Inc., or ITI) through a reverse merger transaction on August 29, 2013 (the "Merger"). ITI was incorporated in Delaware in May 2001 to focus primarily on the development of novel drugs for the treatment of neuropsychiatric and neurologic diseases and other disorders of the central nervous system. Effective upon the Merger, a wholly-owned subsidiary of the Company merged with and into ITI, and ITI continues as the operating subsidiary 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 (212) 923-3344. 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 supplement or the accompanying prospectus. We have included our website address in this prospectus supplement solely as an inactive textual reference.

Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and all amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act are available free of charge through the investor relations page of our internet website as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.

All brand names or trademarks appearing in this prospectus supplement and the accompanying prospectus are the property of their respective holders. Use or display by us of other parties' trademarks, trade dress, or products in this prospectus supplement and the accompanying 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.

RISK FACTORS

Investing in our securities involves a high degree of risk and uncertainty. In addition to the other information included or incorporated by reference in this prospectus supplement and the accompanying prospectus, you should read in their entirety and carefully consider the risks described below before making an investment decision with respect to this offering. If any of these risks actually occurs, our business, financial condition, results of operations or cash flow could be severely harmed. This could cause the trading price of our common stock to decline, and you could lose all or part of your investment.

Risks Related to Our Business

We currently do not have, and may never have, any products that generate significant revenues.

We have a limited operating history on which to evaluate our business and prospects. To date, we have not generated any product revenues from our product candidates currently in development. We cannot guarantee that any of our product candidates currently in development will ever become marketable products.

We must demonstrate that our drug candidates satisfy rigorous standards of safety and efficacy for their intended uses before the FDA and other regulatory authorities in the European Union and elsewhere will approve them for commercialization. Significant additional research, preclinical testing and clinical testing is required before we can file applications with the FDA or other regulatory authorities for premarket approval of our drug candidates. In addition, to compete effectively, our drugs must be easy to administer, cost-effective and economical to manufacture on a commercial scale. We may not achieve any of these objectives. ITI-007, our most advanced drug candidate, has just commenced its first Phase 3 clinical trial in schizophrenia in the fourth quarter of 2014 and we intend to initiate a second Phase 3 clinical trial in the first half of 2015. In addition, all rights with respect to ITI-214, which has advanced into Phase 1 clinical trials that we previously granted to Takeda were recently returned to us in connection with the termination of the Takeda License Agreement. We intend to continue the development of ITI-214 for the treatment of CNS and other disorders, and we are in the process of refining our strategy for the PDE1 inhibitor program. We cannot be certain that the clinical development of these or any other drug candidates in preclinical testing or clinical development will be successful, that we will receive the regulatory approvals required to commercialize them or that any of our other research and drug discovery programs will yield a drug candidate suitable for investigation through clinical trials. Our commercial revenues from our product candidates currently in development, if any, will be derived from sales of drugs that will not become marketable for several years, if at all.

There is no guarantee that our planned clinical trials for ITI-007 in schizophrenia or in other indications will be successful.

In our Phase 1 and Phase 2 clinical trials, our lead product candidate, ITI-007, has demonstrated improved sleep maintenance, antipsychotic efficacy, and clinical signals consistent with reduction in negative symptoms associated with schizophrenia, depression and anxiety, and other symptoms associated with impaired social function. ITI-007 exhibited antipsychotic efficacy in a randomized, double-blind, placebo and active controlled Phase 2 clinical trial in patients with an acutely exacerbated episode of schizophrenia. Our preclinical studies and initial clinical trials demonstrate that ITI-007 has shown evidence of addressing the symptoms of schizophrenia without causing cardiovascular and metabolic abnormalities, or motor impairments. Further, ITI-007 was shown effective at a dose that did not cause adverse effects displayed by existing antipsychotic drugs that tend to lead to high rates of noncompliance by the patients who most need these drugs. We are currently planning confirmatory later-stage clinical trials and recently commenced our first Phase 3 clinical trial in schizophrenia in the fourth quarter of 2014.

The historical rate of failures for product candidates in clinical development and late-stage clinical trials is high. While we plan to conduct further clinical studies in patients with schizophrenia and other indications,

including two Phase 3 clinical trials of ITI-007 in schizophrenia, one of which we commenced in the fourth quarter of 2014, there is no guarantee that we will have the same level of success in these trials as we have had in our earlier clinical trials, or be successful at all.

In addition, although we believe that ITI-007 and follow-on compounds may also have clinical utility in indications other than schizophrenia, such as behavioral disturbances in dementia, bipolar disorder, IED, non-motor disorders associated with Parkinson's disease, obsessive compulsive disorder and anxiety disorders and post-traumatic stress disorder, we have never tested ITI-007 in Phase 2 clinical trials in the patient population for these other indications, except for 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, for which we announced topline data in the fourth quarter of 2014.

If we do not successfully complete clinical development of ITI-007, we will be unable to market and sell products derived from it and to generate product revenues. Even if we do successfully complete clinical trials for ITI-007 in patients with schizophrenia, those results are not necessarily predictive of results of future pivotal trials that may be needed before we may submit an NDA to the FDA for the initial or other future indications. Of the vast number of drugs in development, only a small percentage result in the submission of an NDA to the FDA, and even less result in the NDA ultimately being approved by the FDA for commercialization.

We are advancing ITI-007 into Phase 3 clinical trials for the treatment of schizophrenia. Although we have discussed our clinical development plans with the FDA, the agency may ultimately determine that our Phase 3 clinical trials and non-clinical studies, even if successfully completed, are not sufficient for regulatory approval. If we are required to conduct additional clinical trials and non-clinical studies, our development of ITI-007 for schizophrenia will be more time-consuming and costly than we presently anticipate, which would have a material adverse effect on our business, results of operations and financial condition.

In June 2014, we held our end-of-Phase 2 meeting with the FDA to discuss our plans for initiating Phase 3 clinical trials of ITI-007 in schizophrenia. Following this meeting, we are proceeding with our Phase 3 development program, in which we plan to conduct two randomized, double-blind, placebo-controlled Phase 3 clinical trials of ITI-007 in patients with acutely exacerbated schizophrenia, with over 400 patients in each trial. We initiated the first Phase 3 clinical trial in schizophrenia in the fourth quarter of 2014 and, subject to finalizing the trial protocols and arrangements with clinical trial sites, we intend to initiate a second Phase 3 clinical trial in the first half of 2015. In the first Phase 3 trial, we are randomizing patients to two doses of ITI-007 (60mg or 40mg) or placebo over a 4-week treatment duration, and the primary outcome measure is change from baseline to Day 28 on the PANSS total score. We currently expect that the second Phase 3 trial will be conducted for a 6-week treatment duration. Subject to timely enrollment, we anticipate that the results of the first Phase 3 clinical trial of ITI-007 in patients with schizophrenia could be available as early as the fourth quarter of 2015. Even though we believe that our planned Phase 3 clinical trials and non-clinical studies for ITI-007 in schizophrenia, if successful, will be sufficient to support our NDA, the FDA may not agree with one or more aspects of our clinical trial designs, including the duration of the trials, clinical endpoints, controls, dose ranges, collection of safety data, or adequacy of our non-clinical studies. If we submit an NDA and the FDA does not agree with our clinical and non-clinical designs, our development of ITI-007 in schizophrenia and other indications may be delayed, and we may incur additional costs and devote additional resources to address any concerns the FDA may have with our trial designs. In addition, we may be required to conduct additional clinical trials or studies, which could result in additional delays and costs. There is no assurance that we will complete the Phase 3 trials and non-clinical studies within the timeframes and the costs that we currently expect, or at all, or in a manner that is acceptable to the FDA. Any delays or unplanned costs resulting from our Phase 3 clinical trials of ITI-007 in schizophrenia may have a material adverse effect on our business, results of operations and financial condition. Even if we eventually complete Phase 3 clinical testing, submit an NDA and receive approval of ITI-007, the FDA may grant approval contingent on the performance of costly additional post-approval clinical trials. The FDA may also approve ITI-007 for a more limited indication or a narrower patient population than we originally requested, and the FDA may not approve the labeling that we believe is necessary or desirable for the successful commercialization of ITI-007 or our other product candidates. Any delay

in obtaining, or inability to obtain, applicable regulatory approval for ITI-007 would delay or prevent commercialization of ITI-007 and would materially adversely impact our business, results of operations and financial condition.

If the FDA does not agree with our clinical development plans to advance ITI-007 for the treatment of schizophrenia and bipolar disorder with separate, but overlapping, well-controlled clinical trials in both indications, our development of ITI-007 for the treatment of bipolar disorder may be delayed and the costs of our development of ITI-007 would increase.

In June 2014, we had discussions with the FDA regarding our plans to initiate our Phase 3 clinical program of ITI-007 in schizophrenia. Following this meeting with the FDA, we are proceeding with Phase 3 development of ITI-007 for the treatment of schizophrenia by conducting two randomized, double-blind, placebo-controlled Phase 3 clinical trials of ITI-007 in patients with acutely exacerbated schizophrenia. Subject to further discussions with the FDA, we plan to initiate separate additional trials in bipolar disorder in 2015. We expect that the planned trials in bipolar disorder will overlap in time with the clinical conduct of the planned trials in schizophrenia. We have not yet discussed our plans to develop ITI-007 for the treatment of bipolar disorder with the FDA. The FDA may not agree with our clinical development plans for advancing ITI-007 for the treatment of bipolar disorder, including our plans to conduct separate well-controlled clinical trials of ITI-007 for the treatment of bipolar disorder that overlap with our Phase 3 clinical trials of ITI-007 for the treatment of schizophrenia. Our clinical plans for ITI-007 for the treatment of bipolar disorder may change based on any discussions with the FDA, the relative success and cost of our research, preclinical and clinical development programs, whether we are able to enter into future collaborations, and any unforeseen delays or cash needs. If the FDA does not agree with our clinical development plans for ITI-007 for the treatment of bipolar disorder, our development of ITI-007 in this indication may take longer and be more costly than we currently expect, which would have a material adverse effect on our business, financial condition and results of operations.

We expect our net losses to continue for at least several years and are unable to predict the extent of future losses or when we will become profitable, if ever.

We have experienced significant net losses since our inception. As of September 30, 2014, we had an accumulated deficit of approximately $73.1 million. We expect to incur net losses over the next several years as we advance our programs and incur significant clinical development costs. We have not received, and do not expect to receive for at least the next several years, any revenues from the commercialization of our product candidates. Substantially all of our revenues to date were from our license and collaboration agreement with Takeda and our agreements with various U.S. governmental agencies and other parties, including our research and development grants. In October 2014, we entered into the Takeda Termination Agreement, which terminated our license and collaboration agreement with Takeda, pursuant to which all rights with respect to ITI-214 that we previously granted to Takeda were returned to us. We will not, therefore, receive any further milestone payments from Takeda and we cannot be certain that we will enter into additional collaboration agreements. To obtain revenues from our product candidates, we must succeed, either alone or with others, in developing, obtaining regulatory approval for, and manufacturing and marketing drugs with significant market potential. We may never succeed in these activities, and may never generate revenues that are significant enough to achieve profitability.

We will require substantial additional funding, which may not be available to us on acceptable terms, or at all, and, if not so available, may require us to delay, limit, reduce or cease our operations.

We have consumed substantial amounts of capital since our inception. Our cash, cash equivalents and investment securities totaled $136.0 million at September 30, 2014. On August 29, 2013, immediately prior to the Merger, ITI issued approximately $60.0 million in a private placement of common stock, which included approximately $15.3 million in principal and $0.8 million in accrued interest from the conversion of ITI's then outstanding convertible promissory notes, and which resulted in net proceeds, after expenses, of approximately $40.0 million. In addition, we received net proceeds of approximately $115.4 million from the public offering of shares of our common stock in February 2014. While we believe that our existing cash, cash equivalents and

investment securities, together with interest on cash balances, will be sufficient to fund our operating expenses and capital expenditure requirements through early 2016, the amount and timing of our actual expenditures will depend upon numerous factors, including the ongoing status of our planned Phase 3 clinical trials of ITI-007 in patients with acute exacerbated schizophrenia, the process of refining our strategy for the PDE1 inhibitor program and the continued development of ITI-214 for the treatment of CNS and other disorders, and our other planned clinical and non-clinical trials. Furthermore, we anticipate that we will need to secure additional funding to complete the planned additional clinical and non-clinical trials, manufacturing and pre-commercialization activities needed for potential regulatory approval and commercialization of ITI-007 in patients with acute exacerbated schizophrenia, for further development of ITI-007 in patients with bipolar disorder and other indications, and for development of our other product candidates. If the FDA requires that we perform additional preclinical studies or clinical trials, or we experience delays or other setbacks in our clinical trials, our expenses would further increase beyond what we currently expect and the anticipated timing of any potential NDA would likely be delayed.

We intend to use substantially all of the remaining net proceeds from our public offering completed in February 2014 to fund the completion of two proposed Phase 3 clinical trials of ITI-007 in patients with acute exacerbated schizophrenia, one of which we commenced in the fourth quarter of 2014; to fund the initiation of other planned clinical and non-clinical trials, including manufacturing, needed for anticipated regulatory approval of ITI-007 in patients with acute exacerbated schizophrenia and other potential additional indications; and to fund research and preclinical development of our other product candidates. Any remaining amounts will be used for general corporate purposes, including general and administrative expenses, capital expenditures, working capital and prosecution and maintenance of our intellectual property. As such, the net proceeds from our public offering will not be sufficient to complete advanced clinical development of any of our product candidates other than ITI-007 in patients with acute exacerbated schizophrenia. Accordingly, we will continue to require substantial additional capital beyond the net proceeds from the offering to continue our clinical development and commercialization activities. In particular, we anticipate that we will need to secure additional funding to complete the planned additional clinical and non-clinical trials; manufacturing and pre-commercialization activities needed for potential regulatory approval and commercialization of ITI-007 in patients with schizophrenia; for further development of ITI-007 in patients with bipolar disorder and other indications; for further development of ITI-214 for the treatment of CNS and other disorders; and for development of our other product candidates. Because successful development of our product candidates is uncertain, we are unable to estimate the actual funds we will require to complete research and development and commercialize our products under development.

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

- the progress in, and the costs of, our preclinical studies and clinical trials and other research and development programs;
- the scope, prioritization and number of our research and development programs;
- the ability of any future collaborators and us to reach the milestones, and other events or developments, triggering payments under any future collaboration agreements or to otherwise make payments under such agreements;
- our ability to enter into new, and to maintain any existing, collaboration and license agreements;
- the extent to which any future collaborators are obligated to reimburse us for clinical trial costs under any future collaboration agreements;
- the costs involved in filing, prosecuting, enforcing and defending patent claims and other intellectual property rights;
- the costs of securing manufacturing arrangements for clinical or commercial production;

- the costs of preparing applications for regulatory approvals for our product candidates;
- the costs of establishing, or contracting for, sales and marketing capabilities if we obtain regulatory clearances to market our product candidates; and
- the costs associated with litigation.

Until we can generate significant continuing revenues, we expect to satisfy our future cash needs through our existing cash, cash equivalents and investment securities, strategic collaborations, private or public sales of our securities, debt financings, grant funding, or by licensing all or a portion of our product candidates or technology. Turmoil and volatility in the financial markets have adversely affected the market capitalizations of many biotechnology companies, and generally made equity and debt financing more difficult to obtain. This, coupled with other factors, may limit our access to additional financing. This could have a material adverse effect on our ability to access sufficient funding. We cannot be certain that additional funding will be available to us on acceptable terms, or at all. If we do obtain additional funding through equity offerings, the ownership of our existing stockholders and purchasers of shares of our common stock in any such offering will be diluted, and the terms of any financing may adversely affect the rights of our stockholders. In addition, the issuance of additional shares by us, or the possibility of such issuance, may cause the market price of our shares to decline. If funds are not available, we will be required to delay, reduce the scope of, or eliminate one or more of our research or development programs or our commercialization efforts. We also could be required to seek funds through arrangements with collaboration partners or otherwise that may require us to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us.

Our management has broad discretion over the use of our cash and we may not use our cash effectively, which could adversely affect our results of operations.

Our management has significant flexibility in applying our cash resources, including the net proceeds from our public offering completed in February 2014, and could use these resources for corporate purposes that do not increase our market value, or in ways with which our stockholders may not agree. We may use our cash resources for corporate purposes that do not yield a significant return or any return at all for our stockholders, which could adversely affect our future growth prospects.

Our lead product candidate, ITI-007, is only part way through the clinical trials we anticipate needing to complete before we may be able to submit an NDA to the FDA. Clinical trials are long, expensive and unpredictable, and there is a high risk of failure.

Preclinical testing and clinical trials are long, expensive and unpredictable processes that can be subject to delays. It may take several years to complete the preclinical testing and clinical development necessary to commercialize a drug, and delays or failure can occur at any stage. Interim results of clinical trials do not necessarily predict final results, and success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials.

In connection with clinical trials, we face risks that a product candidate may not prove to be efficacious; patients may die or suffer other adverse effects for reasons that may or may not be related to the product candidate being tested; the results may not confirm the positive results of our earlier preclinical studies and clinical trials; and the results may not meet the level of statistical significance required by the FDA or other regulatory agencies. If we do not successfully complete preclinical and clinical development, we will be unable to market and sell products derived from our product candidates and to generate product revenues. Even if we do successfully complete clinical trials, those results are not necessarily predictive of results of additional trials that may be needed before an NDA may be submitted to the FDA or the FDA may approve the NDA.

Delays, suspensions and terminations in our clinical trials could result in increased costs to us, delay our ability to generate product revenues and therefore may have a material adverse effect on our business, results of operations and future growth prospects.

The commencement of clinical trials can be delayed for a variety of reasons, including delays in: demonstrating sufficient safety and efficacy to obtain regulatory approval to commence a clinical trial; reaching agreement on acceptable terms with prospective contract research organizations and clinical trial sites; manufacturing sufficient quantities of a product candidate; obtaining clearance from the FDA to commence clinical trials pursuant to an IND; obtaining institutional review board approval to conduct a clinical trial at a prospective clinical trial site; and patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical trial sites, the availability of effective treatments for the relevant disease and the eligibility criteria for the clinical trial.

Once a clinical trial has begun, it may be delayed, suspended or terminated due to a number of factors, including: ongoing discussions with regulatory authorities regarding the scope or design of our clinical trials or requests by them for supplemental information with respect to our clinical trial results; failure to conduct clinical trials in accordance with regulatory requirements; lower than anticipated screening or retention rates of patients in clinical trials; serious adverse events or side effects experienced by participants; and insufficient supply or deficient quality of product candidates or other materials necessary for the conduct of our clinical trials.

Many of these factors may also ultimately lead to denial of regulatory approval of a current or potential product candidate. If we experience delays, suspensions or terminations in a clinical trial, our costs will increase, the commercial prospects for the related product candidate will be harmed, and our ability to generate product revenues will be delayed.

Safety issues with our product candidates, or with product candidates or approved products of third parties that are similar to our product candidates, could give rise to delays in the regulatory approval process, restrictions on labeling or product withdrawal after approval.

Problems with product candidates or approved products marketed by third parties that utilize the same therapeutic target or that belong to the same therapeutic class as our product candidates could adversely affect the development, regulatory approval and commercialization of our product candidates. In 2012, the FDA released draft guidance recommending that prospective suicidality assessments be performed in clinical trials of any drug being developed for a psychiatric indication. Our development programs are focused on psychiatric indications. Our PDE1 program is a novel target and may have unexpected safety effects that do not appear until late in clinical development or after commercial approval. To date, we have not experienced any treatment-related serious adverse effects, or SAEs, in clinical trials for any of our product candidates; however, some approved products marketed by third parties for psychiatric indications that utilize different therapeutic targets or are in a different therapeutic class have experienced SAEs. As we continue the development and clinical trials of our product candidates, there can be no assurance that our product candidates will not experience any SAEs.

Discovery of previously unknown class effect problems may prevent or delay clinical development and commercial approval of product candidates or result in restrictions on permissible uses after their approval, including withdrawal of the medicine from the market. Many drugs acting on the CNS include boxed warnings and precautions related to suicidal behavior or ideation, driving impairment, somnolence/sedation and dizziness, discontinuation, weight gain, non-insulin dependent (type II) diabetes, cardiovascular side effects, sleep disturbances, and motor disturbances. If we or others later identify undesirable side effects caused by the mechanisms of action or classes of our product candidates or specific product candidates:

- we may be required to conduct additional clinical trials or implement a Risk Evaluation and Mitigation Strategies program prior to approval;
- regulatory authorities may not approve our product candidates or, as a condition of approval, require specific warnings and contraindications;

- regulatory authorities may withdraw their approval of the product and require us to take our drug off the market;
- we may have limitations on how we promote our drugs;
- sales of products may decrease significantly;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product or could substantially increase our commercialization costs and expenses, which, in turn, could delay or prevent us from generating significant revenues from its sale.

Finally, if the FDA determines that a drug may present a risk of substance abuse, it can recommend to the Drug Enforcement Administration that the drug be scheduled under the Controlled Substances Act. Any failure or delay in commencing or completing clinical trials or obtaining regulatory approvals for our product candidates would delay commercialization of our product candidates, and severely harm our business and financial condition.

If we seek to enter into strategic alliances for our drug candidates, but fail to enter into and maintain successful strategic alliances, we may have to reduce or delay our drug candidate development or increase our expenditures.

An important element of a biotechnology company's strategy for developing, manufacturing and commercializing its drug candidates may be to enter into strategic alliances with pharmaceutical companies or other industry participants to advance its programs and enable it to maintain its financial and operational capacity. We may face significant competition in seeking appropriate alliances. If we seek such alliances, we may not be able to negotiate alliances on acceptable terms, if at all. In addition, these alliances may be unsuccessful. On October 31, 2014, we entered into the Termination Agreement with Takeda, which terminated the Takeda License Agreement, pursuant to which all rights granted under the Takeda License Agreement were returned to us. If we seek such alliances and then fail to create and maintain suitable alliances, we may have to limit the size or scope of, or delay, one or more of our drug development or research programs. If we elect to fund drug development or research programs on our own, we will have to increase our expenditures and will need to obtain additional funding, which may be unavailable or available only on unfavorable terms.

To the extent we are able to enter into collaborative arrangements or strategic alliances, we will be exposed to risks related to those collaborations and alliances.

Biotechnology companies at our stage of development sometimes become dependent upon collaborative arrangements or strategic alliances to complete the development and commercialization of drug candidates, particularly after the Phase 2 stage of clinical testing. If we elect to enter into collaborative arrangements or strategic alliances, these arrangements may place the development of our drug candidates outside our control, may require us to relinquish important rights or may otherwise be on terms unfavorable to us.

Dependence on collaborative arrangements or strategic alliances would subject us to a number of risks, including the risk that:

- we may not be able to control the amount and timing of resources that our collaborators may devote to the drug candidates;
- our collaborators may experience financial difficulties;
- we may be required to relinquish important rights, such as marketing and distribution rights;

- business combinations or significant changes in a collaborator's business strategy may also adversely affect a collaborator's willingness or ability to complete its obligations under any arrangement;
- a collaborator could independently move forward with a competing drug candidate developed either independently or in collaboration with others, including our competitors; and
- collaborative arrangements are often terminated or allowed to expire, which would delay the development and may increase the cost of developing our drug candidates.

Preliminary and interim data from our clinical studies that we may announce or publish from time to time may change as more patient data become available.

From time to time, we may announce or publish preliminary or interim data from our clinical studies. Preliminary and interim results of a clinical trial are not necessarily predictive of final results. Preliminary and interim data are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. As a result, preliminary and interim data should be viewed with caution until the final data are available. Material adverse changes in the final data compared to the interim data could significantly harm our business prospects.

We rely on third parties to conduct our clinical trials and perform data collection and analysis, which may result in costs and delays that prevent us from successfully commercializing our product candidates.

Although we design and manage our current preclinical studies and clinical trials, we do not now have the ability to conduct clinical trials for our product candidates on our own. In addition to our collaborators, we rely on contract research organizations, medical institutions, clinical investigators, and contract laboratories to perform data collection and analysis and other aspects of our clinical trials. In addition, we also rely on third parties to assist with our preclinical studies, including studies regarding biological activity, safety, absorption, metabolism, and excretion of product candidates.

Our preclinical activities or clinical trials may be delayed, suspended, or terminated if: the quality or accuracy of the data obtained by the third parties on whom we rely is compromised due to their failure to adhere to our clinical protocols or regulatory requirements or if for other reasons, these third parties do not successfully carry out their contractual duties or fail to meet regulatory obligations or expected deadlines, or these third parties need to be replaced.

If the third parties on whom we rely fail to perform, our development costs may increase, our ability to obtain regulatory approval, and consequently, to commercialize our product candidates may be delayed or prevented altogether. We currently use several contract research organizations to perform services for our preclinical studies and clinical trials. While we believe that there are numerous alternative sources to provide these services, in the event that we seek such alternative sources, we may not be able to enter into replacement arrangements without delays or incurring additional expenses.

Even if we successfully complete the clinical trials of one or more of our product candidates, the product candidates may fail for other reasons.

Even if we successfully complete the clinical trials for one or more of our product candidates, the product candidates may fail for other reasons, including the possibility that the product candidates will:

- fail to receive the regulatory approvals required to market them as drugs;
- be subject to proprietary rights held by others requiring the negotiation of a license agreement prior to marketing;
- be difficult or expensive to manufacture on a commercial scale;
- have adverse side effects that make their use less desirable; or

- fail to compete with product candidates or other treatments commercialized by our competitors.

If we are unable to receive the required regulatory approvals, secure our intellectual property rights, minimize the incidence of any adverse side effects or fail to compete with our competitors' products, our business, financial condition, and results of operations could be materially and adversely affected.

Following regulatory approval of any of our drug candidates, we will be subject to ongoing regulatory obligations and restrictions, which may result in significant expense and limit our ability to commercialize our potential products.

With regard to our drug candidates, if any, approved by the FDA or by another regulatory authority, we are held to extensive regulatory requirements over product manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion and record keeping. Regulatory approvals may also be subject to significant limitations on the indicated uses or marketing of the drug candidates. Potentially costly follow-up or post-marketing clinical studies may be required as a condition of approval to further substantiate safety or efficacy, or to investigate specific issues of interest to the regulatory authority. Previously unknown problems with the drug candidate, including adverse events of unanticipated severity or frequency, may result in restrictions on the marketing of the drug, and could include withdrawal of the drug from the market.

In addition, the law or regulatory policies governing pharmaceuticals may change. New statutory requirements may be enacted or additional regulations may be enacted that could prevent or delay regulatory approval of our drug candidates. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action, either in the United States or elsewhere. If we are not able to maintain regulatory compliance, we might not be permitted to market our drugs and our business could suffer.

Our product candidates may not gain acceptance among physicians, patients, or the medical community, thereby limiting our potential to generate revenues, which will undermine our future growth prospects.

Even if our product candidates are approved for commercial sale by the FDA or other regulatory authorities, the degree of market acceptance of any approved product candidate by physicians, health care professionals and third-party payors, and our profitability and growth will depend on a number of factors, including:

- our ability to provide acceptable evidence of safety and efficacy;
- pricing and cost effectiveness, which may be subject to regulatory control;
- our ability to obtain sufficient third-party insurance coverage or reimbursement;
- effectiveness of our or our collaborators' sales and marketing strategy;
- relative convenience and ease of administration;
- prevalence and severity of any adverse side effects; and
- availability of alternative treatments.

If any product candidate that we develop does not provide a treatment regimen that is at least as beneficial as the current standard of care or otherwise does not provide some additional patient benefit over the current standard of care, that product will not achieve market acceptance and we will not generate sufficient revenues to achieve profitability.

The failure to attract and retain skilled personnel and key relationships could impair our drug development and commercialization efforts.

We are highly dependent on our senior management and key clinical development, scientific and technical personnel. Competition for these types of personnel is intense. The loss of the services of any member of our

senior management, clinical development, scientific or technical staff may significantly delay or prevent the achievement of drug development and other business objectives and could have a material adverse effect on our business, operating results and financial condition. We also rely on consultants and advisors to assist us in formulating our strategy. All of our consultants and advisors are either self-employed or employed by other organizations, and they may have conflicts of interest or other commitments, such as consulting or advisory contracts with other organizations, that may affect their ability to contribute to us. We intend to expand and develop new drug candidates, and will need additional funding to grow our business. We will need to hire additional employees in order to continue our research and clinical trials and to market our drugs when approved. This strategy will require us to recruit additional executive management and clinical development, regulatory, scientific, technical and sales and marketing personnel. There is currently intense competition for skilled executives and employees with relevant clinical development, scientific, technical and sales and marketing expertise, and this competition is likely to continue. The inability to attract and retain sufficient clinical development, scientific, technical and managerial personnel, due to intense competition and our limited resources, would limit or delay our product development efforts, which would adversely affect the development of our drug candidates and commercialization of our potential drugs and growth of our business.

We may not be able to continue or fully exploit our partnerships with outside scientific and clinical advisors, which could impair the progress of our clinical trials and our research and development efforts.

We work with scientific and clinical advisors at academic and other institutions who are experts in the field of CNS disorders. They advise us with respect to our clinical trials. These advisors are not our employees and may have other commitments that would limit their future availability to us. If a conflict of interest arises between their work for us and their work for another entity, we may lose their services, which may impair our reputation in the industry and delay the development or commercialization of our product candidates.

Relying on third-party manufacturers may result in delays in our clinical trials, regulatory approvals and product introductions.

We have no manufacturing facilities and do not have extensive experience in the manufacturing of drugs or in designing drug-manufacturing processes. We have contracted with third-party manufacturers to produce, in collaboration with us, our product candidates, including ITI-007, for clinical trials. If any of our product candidates are approved by the FDA or other regulatory agencies for commercial sale, we may need to amend our contracts with our current manufacturers or contract with other third parties to manufacture them in larger quantities. While we believe that there are alternative sources available to manufacture our product candidates, in the event that we seek such alternative sources, we may not be able to enter into replacement arrangements without delays or additional expenditures. We cannot estimate these delays or costs with certainty but, if they were to occur, they could cause a delay in our development and commercialization efforts. We have not entered into a long-term agreement with our current third-party manufacturers or with any alternate suppliers. Although we intend to do so prior to any commercial launch of a product that is approved by the FDA in order to ensure that we maintain adequate supplies of commercial drug product, we may be unable to enter into such agreements or do so on commercially reasonable terms, which could delay a product launch or subject our commercialization efforts to significant supply risk.

Manufacturers of our product candidates are obliged to operate in accordance with FDA-mandated current good manufacturing practices, or cGMPs. In addition, the facilities used by our contract manufacturers or other third party manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we request regulatory approval from the FDA. A failure of any of our current or future contract manufacturers to establish and follow cGMPs and to document their adherence to such practices may lead to significant delays in clinical trials or in obtaining regulatory approval of product candidates or the ultimate launch of products based on our product candidates into the market. Failure by our current or future third-party manufacturers or us to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of the government to grant pre-market

approval of drugs, delays, suspension or withdrawal of approvals, seizures or recalls of products, operating restrictions, and criminal prosecutions.

We will need to continue to manage our organization and we may encounter difficulties with our staffing and any future transitions, which could adversely affect our results of operations.

We will need to manage our operations and facilities effectively in order to advance our drug development programs (including ITI-007 and ITI-214), facilitate any future collaborations, and pursue other development activities. It is possible that our infrastructure may be inadequate to support our future efforts and growth. In particular, we may have to develop internal sales, marketing, and distribution capabilities if we decide to market any drug that we may successfully develop. We may not successfully manage our operations and, accordingly, may not achieve our research, development, and commercialization goals.

Our ability to generate product revenues will be diminished if our products do not receive coverage from payors or sell for inadequate prices, or if patients are unable to obtain adequate levels of reimbursement.

Patients who are prescribed medicine for the treatment of their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Adequate coverage and reimbursement from governmental health care programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. Even if we obtain coverage for any approved products, the resulting reimbursement payment rates might not be adequate or may require co-payments that patients find unacceptably high. Patients are unlikely to use any products we may market unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of those products.

In addition, the market for any products for which we may receive regulatory approval will depend significantly on access to third-party payors' drug formularies, or lists of medications for which third-party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payors may refuse to include a particular branded drug in their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or other alternative is available.

Third-party payors, whether foreign or domestic, governmental or commercial, are developing increasingly sophisticated methods of controlling health care costs. In addition, in the United States, no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage will be obtained. If we are unable to obtain coverage of, and adequate payment levels for, our products from third-party payors, physicians may limit how much or under what circumstances they will prescribe or administer them and patients may decline to purchase them. This in turn could affect our ability to successfully commercialize any approved products and thereby adversely impact our profitability, results of operations, financial condition, and future success.

In the future, if we have products that are approved, health care legislation may make it more difficult to receive revenues from those products.

In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory proposals in recent years to change the health care system in ways that could impact our ability to sell our products profitably. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively, PPACA, became law in the United States. PPACA substantially changed the way health care is financed by both governmental and private

insurers and significantly affects the health care industry. Among the provisions of PPACA of importance to our potential product candidates are the following:

- imposition of an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government health care programs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, retroactive to January 1, 2010, to 23% and 13% of the average manufacturer price for most branded and generic drugs, respectively;
- expansion of health care fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals beginning in 2014 and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the Federal Poverty Level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- new requirements to report certain financial arrangements with physicians and teaching hospitals, including reporting any "payments or transfers of value" made or distributed to prescribers, teaching hospitals and other health care providers and reporting any ownership and investment interests held by physicians and their immediate family members and applicable group purchasing organizations during the preceding calendar year, with data reporting to the Centers for Medicare & Medicaid Services to be required by March 31, 2014 and by the 90th day of each subsequent calendar year;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Many of the details regarding the implementation of PPACA are yet to be determined and, at this time, it remains unclear what the full effect that PPACA will have on our business. At this time, it remains unclear whether there will be any further changes made to PPACA, whether in part or in its entirety. Some states have indicated that they intend not to implement certain sections of PPACA, and some members of the U.S. Congress are still working to repeal PPACA. We cannot predict whether these challenges will continue or other proposals will be made or adopted, or what impact these efforts may have on us.

In addition, in many foreign countries, particularly the countries of the European Union, the pricing of prescription drugs is subject to government control. In some non-U.S. jurisdictions, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the

company placing the medicinal product on the market. We may face competition from lower-priced products in foreign countries that have placed price controls on pharmaceutical products. In addition, there may be importation of foreign products that compete with any products we may market, which could negatively impact our profitability.

We expect that PPACA, as well as other health care reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we may receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other health care reforms may prevent us from being able to generate revenue, attain profitability, or commercialize any products for which we receive regulatory approval.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market any products we may develop, we may not be able to generate product revenue.

We do not currently have an organization for the sales, marketing or distribution of pharmaceutical products. In order to market any products that may be approved by the FDA, we must build our sales, marketing, managerial, and related capabilities or make arrangements with third parties to perform these critical commercial services. If we are unable to establish adequate sales, marketing, and distribution capabilities, whether independently or with third parties, we may not be able to generate product revenue and may not become profitable.

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

As of September 30, 2014, we had net operating loss carryforwards of approximately $65.1 million to reduce future federal and state taxable income through 2034. Since we had net operating loss carryforwards as of December 31, 2014 and 2013, no excess tax benefits for the tax deductions related to share-based awards were recognized in the statements of operations. The net operating loss carryforwards of approximately $65.1 million as of September 30, 2014 will begin to expire in the year 2030 if unused. The use of our net operating loss carryforwards may be restricted due to changes in our ownership.

Security breaches, loss of data and other disruptions could compromise sensitive information related to our business, prevent us from accessing critical information or expose us to liability, which could adversely affect our business and our reputation.

In the ordinary course of our business, we, our clinical research organizations and other third parties on which we rely collect and store sensitive data, including legally protected patient health information, personally identifiable information about our employees, intellectual property, and proprietary business information. We manage and maintain our applications and data utilizing on-site systems. These applications and data encompass a wide variety of business critical information including research and development information and business and financial information.

The secure processing, storage, maintenance and transmission of this critical information is vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure may be vulnerable to attacks by hackers, viruses, breaches, interruptions due to employee error, malfeasance or other disruptions, lapses in compliance with privacy and security mandates, or damage from natural disasters, terrorism, war and telecommunication and electrical failures. Any such event could compromise our networks and the information stored there could be accessed by unauthorized parties, publicly disclosed, lost or stolen. We have measures in place that are designed to detect and respond to such security incidents and breaches of privacy and security mandates. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal

information, such as the Health Insurance Portability and Accountability Act of 1996, government enforcement actions and regulatory penalties. Unauthorized access, loss or dissemination could also disrupt our operations, including our ability to conduct research and development activities, process and prepare company financial information, manage various general and administrative aspects of our business and damage our reputation, any of which could adversely affect our business. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. In addition, there can be no assurance that we will promptly detect any such disruption or security breach, if at all. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed.

Risks Related to Our Intellectual Property

Our ability to compete may be undermined if we do not adequately protect our proprietary rights.

Our commercial success depends on obtaining and maintaining proprietary rights to our product candidates and technologies and their uses, as well as successfully defending these rights against third-party challenges. We will only be able to protect our product candidates, proprietary technologies, and their uses from unauthorized use by third parties to the extent that valid and enforceable patents, or effectively protected trade secrets, cover them. We have patent rights under issued patents in many cases covering our ITI-007 and ITI-002 development programs. Nonetheless, the issued patents and patent applications covering our primary technology programs remain subject to uncertainty and continuous monitoring and action by us due to a number of factors, including:

- we may not have been the first to make the inventions covered by our pending patent applications or issued patents;
- we may not have been the first to file patent applications for our product candidates or the technologies we rely upon;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- our disclosures in patent applications may not be sufficient to meet the statutory requirements for patentability;
- any or all of our pending patent applications may not result in issued patents;
- we may not seek or obtain patent protection in all countries that will eventually provide a significant business opportunity;
- any patents issued to us or our collaborators may not provide a basis for commercially viable products, may not provide us with any competitive advantages or may be challenged by third parties;
- our proprietary technologies may not be patentable;
- others may design around our patent claims to produce competitive products which fall outside of the scope of our patents;
- others may identify prior art which could invalidate our patents; and
- changes to patent laws that limit the exclusivity rights of patent holders.

Even if we have or obtain patents covering our product candidates or technologies, we may still be barred from making, using and selling our product candidates or technologies because of the patent rights of others. Others have or may have filed, and in the future are likely to file, patent applications covering compounds, assays, genes, gene products and therapeutic products that are similar or identical to ours. There are many issued U.S. and foreign patents relating to genes, nucleic acids, polypeptides, chemical compounds or therapeutic products, and some of these may encompass reagents utilized in the identification of candidate drug compounds

or compounds that we desire to commercialize. Numerous U.S. and foreign issued patents and pending patent applications owned by others exist in the area of central nervous system disorders and the other fields in which we are developing products. These could materially affect our ability to develop our product candidates or sell our products. Because patent applications can take many years to issue, there may be currently pending applications, unknown to us, that may later result in issued patents that our product candidates or technologies may infringe. These patent applications may have priority over patent applications filed by us.

We regularly conduct searches to identify patents or patent applications that may prevent us from obtaining patent protection for our proprietary compounds or that could limit the rights we have claimed in our patents and patent applications. Disputes may arise regarding the ownership or inventorship of our inventions. It is difficult to determine how such disputes would be resolved. Others may challenge the validity of our patents. If our patents are found to be invalid, we will lose the ability to exclude others from making, using or selling the inventions claimed therein.

Some of our academic institutional licensors, research collaborators and scientific advisors have rights to publish data and information to which we have rights. If we cannot maintain the confidentiality of our technology and other confidential information in connection with our collaborations, then our ability to receive patent protection or protect our proprietary information will be impaired. Additionally, any employee whose employment with us terminates, whether voluntarily by the employee or by us in connection with restructurings or otherwise, may seek future employment with our competitors. Although each of our employees is required to sign a confidentiality agreement with us at the time of hire, we cannot guarantee that the confidential nature of our proprietary information will be maintained in the course of such future employment. In addition, technology that we may license-in may become important to some aspects of our business. We generally will not control the patent prosecution, maintenance or enforcement of in-licensed technology.

Confidentiality agreements with employees and others may not adequately prevent disclosure of our trade secrets and other proprietary information and may not adequately protect our intellectual property, which could limit our ability to compete.

Because we operate in the highly technical field of drug discovery and development of small molecule drugs, we rely in part on trade secret protection in order to protect our proprietary technology and processes. However, trade secrets are difficult to protect. We enter into confidentiality and intellectual property assignment agreements with our corporate partners, employees, consultants, outside scientific collaborators, sponsored researchers, and other advisors. These agreements generally require that the other party keep confidential and not disclose to third parties any confidential information developed by the party or made known to the party by us during the course of the party's relationship with us. These agreements also generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, these agreements may not be honored and may not effectively assign intellectual property rights to us. Enforcing a claim that a party illegally obtained and is using our trade secrets is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets. The failure to obtain or maintain trade secret protection could adversely affect our competitive position.

A dispute concerning the infringement or misappropriation of our proprietary rights or the proprietary rights of others could be time consuming and costly, and an unfavorable outcome could harm our business.

There is significant litigation in our industry regarding patent and other intellectual property rights. While we are not currently subject to any pending intellectual property litigation, and are not aware of any such threatened litigation, we may be exposed to future litigation by third parties based on claims that our product candidates, technologies or activities infringe the intellectual property rights of others. If our drug development activities are found to infringe any such patents, we may have to pay significant damages or seek licenses to such patents. We may need to resort to litigation to enforce a patent issued to us, protect our trade secrets or determine the scope and validity of third-party proprietary rights. From time to time, we may hire scientific personnel

formerly employed by other companies involved in one or more areas similar to the activities conducted by us. Either we or these individuals may be subject to allegations of trade secret misappropriation or other similar claims as a result of their prior affiliations. If we become involved in litigation, it could consume a substantial portion of our managerial and financial resources, regardless of whether we win or lose. We also may not be able to afford the costs of litigation.

The patent applications of pharmaceutical and biotechnology companies involve highly complex legal and factual questions, which, if determined adversely to us, could negatively impact our patent position.

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions. The U.S. Patent and Trademark Office's, or USPTO's, standards are uncertain and could change in the future. Consequently, the issuance and scope of patents cannot be predicted with certainty. Patents, if issued, may be challenged, invalidated or circumvented. U.S. patents and patent applications may also be subject to interference proceedings, and U.S. patents may be subject to reexamination proceedings in the USPTO (and foreign patents may be subject to opposition or comparable proceedings in the corresponding foreign patent office), which proceedings could result in either loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. Similarly, opposition or invalidity proceedings could result in loss of rights or reduction in the scope of one or more claims of a patent in foreign jurisdictions. In addition, such interference, reexamination and opposition proceedings may be costly. Accordingly, rights under any issued patents may not provide us with sufficient protection against competitive products or processes.

In addition, changes in or different interpretations of patent laws in the United States and foreign countries may permit others to use our discoveries or to develop and commercialize our technology and products without providing any compensation to us or may limit the number of patents or claims we can obtain. In particular, there have been proposals to shorten the exclusivity periods available under U.S. patent law that, if adopted, could substantially harm our business. The product candidates that we are developing are protected by intellectual property rights, including patents and patent applications. If any of our product candidates becomes a marketable product, we will rely on our exclusivity under patents to sell the compound and recoup our investments in the research and development of the compound. If the exclusivity period for patents is shortened, then our ability to generate revenues without competition will be reduced and our business could be materially adversely impacted. The laws of some countries do not protect intellectual property rights to the same extent as U.S. laws, and those countries may lack adequate rules and procedures for defending our intellectual property rights. For example, some countries, including many in Europe, do not grant patent claims directed to methods of treating humans and, in these countries, patent protection may not be available at all to protect our product candidates. In addition, U.S. patent laws may change, which could prevent or limit us from filing patent applications or patent claims to protect our products and/or technologies or limit the exclusivity periods that are available to patent holders. For example, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was recently signed into law and includes a number of significant changes to U.S. patent law. These include changes to transition from a "first-to-invent" system to a "first-to-file" system and to the way issued patents are challenged. These changes may favor larger and more established companies that have more resources to devote to patent application filing and prosecution. The USPTO has been in the process of implementing regulations and procedures to administer the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act may affect our ability to obtain, enforce or defend our patents. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will ultimately have on the cost of prosecuting our patent applications, our ability to obtain patents based on our discoveries and our ability to enforce or defend our issued patents.

If we fail to obtain and maintain patent protection and trade secret protection of our product candidates, proprietary technologies and their uses, we could lose our competitive advantage and competition we face would increase, reducing our potential revenues and adversely affecting our ability to attain or maintain profitability.

Risks Related to Our Industry

We will be subject to stringent regulation in connection with the marketing of any products derived from our product candidates, which could delay the development and commercialization of our products.

The pharmaceutical industry is subject to stringent regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Neither we nor our collaborators can market a pharmaceutical product in the United States until it has completed rigorous preclinical testing and clinical trials and an extensive regulatory clearance process implemented by the FDA. Satisfaction of regulatory requirements typically takes many years, depends upon the type, complexity and novelty of the product, and requires substantial resources. Even if regulatory approval is obtained, it may impose significant restrictions on the indicated uses, conditions for use, labeling, advertising, promotion, and/or marketing of such products, and requirements for post-approval studies, including additional research and development and clinical trials. These limitations may limit the size of the market for the product or result in the incurrence of additional costs. Any delay or failure in obtaining required approvals could have a material adverse effect on our ability to generate revenues and continue our business.

Outside the United States, the ability to market a product is contingent upon receiving approval from the appropriate regulatory authorities. The requirements governing the conduct of clinical trials, marketing authorization, pricing, and reimbursement vary widely from country to country. Only after the appropriate regulatory authority is satisfied that adequate evidence of safety, quality, and efficacy has been presented will it grant a marketing authorization. Approval by the FDA does not automatically lead to the approval by regulatory authorities outside the United States and, similarly, approval by regulatory authorities outside the United States will not automatically lead to FDA approval.

Many of our competitors have greater resources and capital than us, putting us at a competitive disadvantage. If our competitors develop and market products that are more effective than our product candidates, they may reduce or eliminate our commercial opportunity.

Competition in the pharmaceutical and biotechnology industries is intense and increasing. We face competition from pharmaceutical and biotechnology companies, as well as numerous academic and research institutions and governmental agencies, both in the United States and abroad. Some of these competitors have products or are pursuing the development of drugs that target the same diseases and conditions that are the focus of our drug development programs.

For example, our potential products for the treatment of schizophrenia would compete with, among other branded products, Abilify®, marketed jointly by Bristol-Myers Squibb and Otsuka Pharmaceutical, Fanapt®, marketed by Novartis Pharmaceuticals, Seroquel XR®, marketed by AstraZeneca, Invega®, marketed by Janssen, and Latuda®, marketed by Sunovion. In addition, our products will compete with, among other generic antipsychotic drugs, haloperidol, risperidone, quetiapine, olanzapine and clozapine.

Many of our competitors and their collaborators have significantly greater experience than we do in the following:

- identifying and validating targets;
- screening compounds against targets;
- preclinical studies and clinical trials of potential pharmaceutical products; and
- obtaining FDA and other regulatory approvals.

In addition, many of our competitors and their collaborators have substantially greater capital and research and development resources, manufacturing, sales and marketing capabilities, and production facilities. Smaller companies also may prove to be significant competitors, particularly through proprietary research discoveries and

collaboration arrangements with large pharmaceutical and established biotechnology companies. Many of our competitors have products that have been approved or are in advanced development and may develop superior technologies or methods to identify and validate drug targets and to discover novel small molecule drugs. Our competitors, either alone or with their collaborators, may succeed in developing drugs that are more effective, safer, more affordable, or more easily administered than ours and may achieve patent protection or commercialize drugs sooner than us. Our competitors may also develop alternative therapies that could further limit the market for any drugs that we may develop. Our failure to compete effectively could have a material adverse effect on our business.

Any claims relating to improper handling, storage, or disposal of biological, hazardous, and radioactive materials used in our business could be costly and delay our research and development efforts.

Our research and development activities involve the controlled use of potentially harmful hazardous materials, including volatile solvents, biological materials such as blood from patients that have the potential to transmit disease, chemicals that cause cancer, and various radioactive compounds. Our operations also produce hazardous waste products. We face the risk of contamination or injury from the use, storage, handling or disposal of these materials. We are subject to federal, state and local laws and regulations governing the use, storage, handling, and disposal of these materials and specified waste products. The cost of compliance with these laws and regulations could be significant, and current or future environmental regulations may impair our research, development, or production efforts. If one of our employees were accidentally injured from the use, storage, handling, or disposal of these materials, the medical costs related to his or her treatment would be covered by our workers' compensation insurance policy. However, we do not carry specific biological or hazardous waste insurance coverage and our general liability insurance policy specifically excludes coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be subject to criminal sanctions or fines or be held liable for damages, our operating licenses could be revoked, and we could be required to suspend or modify our operations and our research and development efforts.

Consumers may sue us for product liability, which could result in substantial liabilities that exceed our available resources and damage our reputation.

Researching, developing, and commercializing drug products entail significant product liability risks. Liability claims may arise from our and our collaborators' use of products in clinical trials and the commercial sale of those products. Consumers may make these claims directly and our collaborators or others selling these products may seek contribution from us if they receive claims from consumers. We have obtained limited product liability insurance coverage for our clinical trials. Our product liability insurance coverage for clinical trials is currently limited to an aggregate of $30 million. As such, our insurance coverage may not reimburse us or may not be sufficient to reimburse us for any expenses or losses we may suffer. Although we currently have product liability insurance that covers our clinical trials, we will need to increase and expand this coverage as we commence larger scale trials and if our product candidates are approved for commercial sale. This insurance may be prohibitively expensive or may not fully cover our potential liabilities. Inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the commercialization of products that we or our collaborators develop. Product liability claims could have a material adverse effect on our business and results of operations. Our liability could exceed our total assets if we do not prevail in a lawsuit from any injury caused by our drug products.

Risks Related to Owning Our Common Stock

Our stock price may fluctuate significantly and you may have difficulty selling your shares based on current trading volumes of our stock. In addition, numerous other factors could result in substantial volatility in the trading price of our stock.

Since January 31, 2014, shares of our common stock have been listed on the NASDAQ Global Select Market, and from December 20, 2013 to January 30, 2014, shares of our common stock were quoted for trading on the OTC Markets—OTCQB tier, or OTCQB, in very limited volume. In the 12 months preceding March 2, 2015, the price per share of our common stock has ranged from a high of $30.72 to a low of $12.67. Prior to December 20, 2013, our common stock was not publicly-traded. We cannot predict the extent to which investor interest in our company will continue to result in an active trading market on the NASDAQ Global Select Market or any other exchange in the future. We have several stockholders, including affiliated stockholders, who hold substantial blocks of our stock. Sales of large numbers of shares by any of our large stockholders could adversely affect our trading price, particularly given our small historic trading volumes. If stockholders holding shares of our common stock sell, indicate an intention to sell, or if it is perceived that they will sell, substantial amounts of their common stock in the public market, the trading price of our common stock could decline.

In addition, the trading price of our common stock may be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include:

- actual or anticipated quarterly variation in our results of operations or the results of our competitors;
- announcements of medical innovations or new products by our competitors;
- issuance of new or changed securities analysts' reports or recommendations for our stock;
- developments or disputes concerning our intellectual property or other proprietary rights;
- commencement of, or our involvement in, litigation;
- market conditions in the biopharmaceutical industry;
- timing and announcement of regulatory approvals;
- any future sales of our common stock or other securities in connection with raising additional capital or otherwise;
- any major change to the composition of our board of directors or management; and
- general economic conditions and slow or negative growth of our markets.

The stock market in general, and market prices for the securities of biotechnology companies like ours in particular, have from time to time experienced volatility that often has been unrelated to the operating performance of the underlying companies. These broad market and industry fluctuations may adversely affect the market price of our common stock, regardless of our operating performance. In several recent situations where the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our stockholders were to bring a lawsuit against us, the defense and disposition of the lawsuit could be costly and divert the time and attention of our management and harm our operating results.

Raising additional capital may cause dilution to existing stockholders, restrict our operations or require us to relinquish rights.

We will need to satisfy our future cash needs through public or private sales of our equity securities, sales of debt securities, the incurrence of debt from commercial lenders, strategic collaborations, licensing a portion or all of our product candidates and technology and, to a lesser extent, grant funding. We filed a universal shelf registration statement on Form S-3 with the SEC, which was declared effective on September 15, 2014, on which

we registered for sale up to $150,000,000 of securities of any combination of common stock, preferred stock, debt securities, warrants, rights, purchase contracts and/or units from time to time and at prices and on terms that we may determine. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our existing stockholders will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of our stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring debt, making capital expenditures or declaring dividends. If we raise additional funds through collaboration and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or grant licenses on terms that are not favorable to us.

The price of our common stock could be subject to volatility related or unrelated to our operations.

The market price of our common stock could fluctuate substantially due to a variety of factors, including market perception of our ability to meet our growth projections and expectations, quarterly operating results of other companies in the same industry, trading volume in our common stock, changes in general conditions in the economy and the financial markets or other developments affecting our business and the business of others in our industry. In addition, the stock market itself is subject to extreme price and volume fluctuations. This volatility has had a significant effect on the market price of securities issued by many companies for reasons related and unrelated to their operating performance and could have the same effect on our common stock.

Management and certain members of our board of directors beneficially own a substantial amount of our outstanding equity securities and will be able to exert substantial control over us.

Our executive officers and directors beneficially own a substantial percentage of the outstanding equity securities of the Company. Accordingly, if they act as a group, the executive officers and directors of the Company will be able to make all business decisions, including with respect to such matters as amendments to the Company's charter, other fundamental corporate transactions, such as mergers, asset sales and the sale of the Company, and otherwise will be able to direct the Company's business and affairs.

We will incur increased costs and demands upon management as a result of complying with the laws and regulations affecting public companies, which could harm our operating results.

As a public company, we have incurred and will incur significant legal, accounting and other expenses, including costs associated with public company reporting requirements. We also have incurred and will incur costs associated with current corporate governance requirements, including requirements under Section 404 and other provisions of the Sarbanes-Oxley Act, as well as rules implemented by the SEC or the NASDAQ Global Select Market or any other stock exchange or inter-dealer quotations system on which our common stock may be listed in the future. The expenses incurred by public companies for reporting and corporate governance purposes have increased dramatically in recent years. We expect these rules and regulations to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. We are unable currently to estimate these costs with any degree of certainty. We also expect that these new rules and regulations may make it difficult and expensive for us to retain our director and officer liability insurance, and if we are able to retain such insurance, we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage available to privately-held companies. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our board of directors or as our executive officers.

If we fail to maintain proper and effective internal controls, our ability to produce accurate and timely financial statements could be impaired, which could harm our operating results, our ability to operate our business and investors' views of us.

We are required to comply with Section 404 of the Sarbanes-Oxley Act. Section 404 of the Sarbanes-Oxley Act requires public companies to conduct an annual review and evaluation of their internal controls and, for

public companies that are not emerging growth companies, attestations of the effectiveness of internal controls by independent auditors. Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that will need to be evaluated frequently. Our failure to maintain the effectiveness of our internal controls in accordance with the requirements of the Sarbanes-Oxley Act could have a material adverse effect on our business. We could lose investor confidence in the accuracy and completeness of our financial reports, which could have an adverse effect on the price of our common stock. In addition, if our efforts to comply with new or changed laws, regulations, and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

We are an emerging growth company and the reduced disclosure requirements applicable to emerging growth companies could make our common stock less attractive to investors.

We are an emerging growth company under the Jumpstart Our Business Startups Act, or JOBS Act, enacted in 2012. For as long as we continue to be an emerging growth company, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies, which may include, but are not limited to, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, exemptions from the requirements of holding a nonbinding advisory stockholder vote on executive compensation and any golden parachute payments not previously approved, and exemption from the requirement of auditor attestation in the assessment of our internal control over financial reporting. If we do take advantage of these exemptions, the information that we provide stockholders may be different than what is available with respect to other public companies. We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. However, we have irrevocably elected not to avail ourselves of this extended transition period for complying with new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

We will remain an emerging growth company until the earliest of (1) the end of the fiscal year in which the market value of our common stock that is held by non-affiliates exceeds $700 million as of the end of the second fiscal quarter, (2) the end of the fiscal year in which we have total annual gross revenues of $1 billion or more during such fiscal year, (3) the date on which we issue more than $1 billion in non-convertible debt in a three-year period or (4) the end of the fiscal year following the fifth anniversary of the date of the first sale of our common stock pursuant to an effective registration statement filed under the Securities Act of 1933, as amended, or the Securities Act. Our first registration statement filed under the Securities Act was declared effective on December 18, 2013. Decreased disclosures in our SEC filings due to our status as an “emerging growth company” may make it harder for investors to analyze our results of operations and financial prospects.

If securities or industry analysts do not publish, or cease publishing, research or reports about us, our business or our market, or if they change their recommendations regarding our stock adversely, our stock price and trading volume could decline.

As the trading market for our common stock develops, the trading market for our common stock is and will be influenced by whether industry or securities analysts publish or continue to publish research and reports about us, our business, our market or our competitors and, to the extent analysts do publish such reports, what they publish in those reports. We may not continue to have or to obtain analyst coverage in the future. Any analysts that do cover us may make adverse recommendations regarding our stock, adversely change their recommendations from time to time, and/or provide more favorable relative recommendations about our competitors. If any analyst who covers us

or may cover us in the future were to cease coverage of our company or fail to regularly publish reports on us, or if analysts fail to cover us or publish reports about us at all, we could lose, or never gain, visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

Provisions of the Delaware law, our restated certificate of incorporation and our restated bylaws may delay or prevent a takeover which may not be in the best interests of our stockholders.

The provisions of Delaware law and our restated certificate of incorporation and restated bylaws could discourage or make it more difficult to accomplish a proxy contest or other change in our management or the acquisition of control by a holder of a substantial amount of our voting stock. It is possible that these provisions could make it more difficult to accomplish, or could deter, transactions that stockholders may otherwise consider to be in their best interests or in our best interests. These provisions are intended to enhance the likelihood of continuity and stability in the composition of our board of directors and in the policies formulated by the board of directors and to discourage certain types of transactions that may involve an actual or threatened change of our control. These provisions are designed to reduce our vulnerability to an unsolicited acquisition proposal and to discourage certain tactics that may be used in proxy fights. Such provisions also may have the effect of preventing changes in our management.

We do not anticipate paying cash dividends in the foreseeable future.

We currently intend to retain any future earnings for funding growth. We do not anticipate paying any dividends in the foreseeable future. As a result, you should not rely on an investment in our securities if you require dividend income. Capital appreciation, if any, of our shares may be your sole source of gain for the foreseeable future. Moreover, you may not be able to re-sell your shares at or above the price you paid for them.