Intra-Cellular Therapies, Inc.
Form POS AM
March 31, 2014
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As filed with the Securities and Exchange Commission on March 31, 2014

Registration No. 333-191238

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Post-Effective Amendment No. 1

to

FORM S-1

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

Intra-Cellular Therapies, Inc.

(Exact name of registrant as specified in its charter)

Delaware	2834	36-4742850
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

3960 Broadway

New York, New York 10032

(212) 923-3344

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

Sharon Mates, Ph.D.

Chairman, President and Chief Executive Officer

Intra-Cellular Therapies, Inc.

3960 Broadway

New York, New York 10032

(212) 923-3344

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

Copies to:

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One Financial Center

Boston, MA 02111

(617) 542-6000

Approximate date of commencement of proposed sale to the public: From time to time after the effective date of this Registration Statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. x

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

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

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

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

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

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

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EXPLANATORY NOTE

This Post-Effective Amendment No. 1 to the Registration Statement on Form S-1 (File No. 333-191238) (the Registration Statement) of Intra-Cellular Therapies, Inc. (the Company) is being filed pursuant to the undertakings in Item 17 of the Registration Statement to update and supplement the information contained in the Registration Statement, as originally declared effective by the Securities and Exchange Commission (the SEC) on December 18, 2013, to (i) include the information contained in the Company s Annual Report on Form 10-K for the fiscal year ended December 31, 2013 that was filed with the SEC on March 25, 2014 and (ii) to update certain other information in the Registration Statement.

No additional securities are being registered under this Post-Effective Amendment No. 1. All applicable registration fees were paid at the time of the original filing of the Registration Statement.

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The information in this preliminary prospectus is not complete and may be changed. The selling stockholders named in this prospectus may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and the selling stockholders named in this prospectus are not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Subject to Completion, Dated March 31, 2014

PROSPECTUS

19,169,155 Shares of Common Stock

This prospectus relates to the offering and resale by the selling stockholders identified herein of up to 19,169,155 shares of our common stock, par value $0.0001 per share. These shares were privately issued to the selling stockholders on August 29, 2013 in exchange for shares of Intra-Cellular Therapies, Inc., a Delaware corporation, which is now our wholly-owned subsidiary and which has assumed the name ITI, Inc. We will not receive any proceeds from the sale of these shares by the selling stockholders. The selling stockholders may sell the shares as set forth herein under Plan of Distribution. For a list of the selling stockholders, see the section entitled Selling Stockholders on page 106. We have borne and will continue to bear the costs relating to the registration of these shares.

Our common stock is listed on The NASDAQ Global Select Market under the symbol ITCI. On March 28, 2014, the last reported sale price of our common stock on The NASDAQ Global Select Market was $18.59 per share. The selling stockholders may sell all or a portion of their shares through public or private transactions at prevailing market prices or at privately negotiated prices.

We may amend or supplement this prospectus from time to time by filing amendments or supplements as required. You should read the entire prospectus and any amendments or supplements carefully before you make your investment decision.

We are an emerging growth company as defined under the federal securities laws, and, as such, are eligible for reduced public company reporting requirements. See Prospectus Summary Implications of Being an Emerging Growth Company.

Investment in our common stock involves risks. See Risk Factors beginning on page 10 of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is , 2014

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ABOUT THIS PROSPECTUS

You should rely only on the information contained in this prospectus or contained in any prospectus supplement or free writing prospectus filed with the Securities and Exchange Commission. Neither we nor the selling stockholders have authorized anyone to provide you with additional information or information different from that contained in this prospectus filed with the Securities and Exchange Commission. The selling stockholders are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of shares of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

For investors outside the United States: Neither we nor the selling stockholders have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside the United States.

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PROSPECTUS SUMMARY

The following summary highlights selected information contained elsewhere in this prospectus. This summary is not complete and does not contain all the information that should be considered before investing in our common stock. Before making an investment decision, investors should carefully read the entire prospectus, paying particular attention to the risks referred to under the headings Risk Factors and Cautionary Statement Regarding Forward-Looking Statements and our financial statements and the notes to those financial statements.

As used in this prospectus, unless the context requires otherwise, the terms Company, we, our and us refer to Intra-Cellular Therapies, Inc. and our wholly-owned operating subsidiary, ITI, Inc.

Overview

We are a biopharmaceutical company focused on the discovery and clinical development of innovative, small molecule drugs that address underserved medical needs in neuropsychiatric and neurological disorders by targeting intracellular signaling mechanisms within the central nervous system, or CNS. Our lead product candidate, ITI-007, is in 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. Additional data from the Phase 2 trial are set forth below in the section of this prospectus entitled Description of Our Business Our Clinical Programs ITI-007 Program ITI-007 for the treatment of exacerbated and residual schizophrenia Phase 2 Clinical Trial (ITI-007-005). In the second quarter of 2014, we plan to request a meeting with the U.S. Food and Drug Administration, or FDA, to discuss the existing ITI-007 safety and efficacy data and our future clinical development plans for ITI-007, including our plans to conduct separate, but overlapping, well-controlled clinical trials in schizophrenia and bipolar disorder. The Phase 3 clinical trial design for ITI-007 in schizophrenia will be the primary focus of the first meeting. Additional meetings may be requested, as needed, to discuss in greater detail our plans for bipolar disorder, and other elements of our regulatory strategy, including additional therapeutic indications, as the program progresses.

Subject to discussions with the FDA, we intend to initiate Phase 3 clinical trials and additional supporting trials in patients with acute exacerbated schizophrenia in the second half of 2014 and 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. We currently anticipate conducting two placebo-controlled Phase 3 clinical trials of ITI-007 in patients with acute exacerbated schizophrenia, with approximately 300 to 400 patients per trial. We expect that these trials would include a four-week to six-week treatment duration. Subject to our discussions with the FDA, our finalization of the protocols for the Phase 3 clinical trials and timely enrollment, we anticipate that

the results of these Phase 3 clinical trials of ITI-007 in

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patients with acute exacerbated schizophrenia could be available as soon as the fourth quarter of 2015. 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 patients with acute exacerbated schizophrenia, which we currently expect could occur at the end of 2016 or the beginning of 2017.

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 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.

In March 2014, we announced the initiation of 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 commencement 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. We expect that initial data from the trial will be available in the second half of 2014.

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 that has yielded a portfolio of compounds that selectively inhibits the enzyme phosphodiesterase 1, or PDE1. PDE1 helps regulate brain activity related to cognition, memory processes and movement/coordination. We have licensed the lead compound in this portfolio, ITI-214, and other compounds in this portfolio, to Takeda Pharmaceutical Company Limited, or Takeda. ITI-214 is the first compound in its class to successfully advance into Phase 1 clinical trials and is being developed for the treatment of cognitive impairment associated with schizophrenia, or CIAS, and other disorders. The results of our first Phase 1 clinical trial in 70 subjects in a randomized, double-blind, placebo-controlled study indicate that ITI-214 was safe and well-tolerated across a broad range of single oral doses. Other compounds in the PDE1 portfolio outside the Takeda collaboration are being advanced for the treatment of other indications, including non-CNS therapeutic areas.

Our pipeline also includes pre-clinical programs that are focused on advancing drug candidates 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.

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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 Clinical Programs

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

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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 acute symptoms in 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 with our collaboration partner, Takeda, PDE inhibitor compounds, such as ITI-214, for CNS indications such as CIAS; 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 acute schizophrenia or in other indications will be successful.

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 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.

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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.

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.

For additional information about the risks we face, please see the section of this prospectus entitled Risk Factors.

Implications of Being an Emerging Growth Company

As a company with less than $1.0 billion in revenue during our last fiscal year, we qualify as an emerging growth company as defined in the Jumpstart Our Business Startups Act, or JOBS Act, enacted in April 2012. An emerging growth company may take advantage of reduced reporting requirements that are otherwise applicable to public companies. These provisions include, but are not limited to:

being required to provide only two years of audited financial statements in addition to any required unaudited interim financial statements, with correspondingly reduced disclosure in the Management s Discussion and Analysis of Financial Condition and Results of Operations section of this prospectus;

not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or Sarbanes-Oxley Act;

reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements; and

exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We may take advantage of these provisions for up to five years after the first sale of our common equity securities pursuant to an effective registration statement under the Securities Act. Our first registration statement

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filed under the Securities Act became effective on December 18, 2013. However, if certain events occur prior to the end of such five year period, including if we become a large accelerated filer, our annual gross revenues exceed $1 billion or we issue more than $1 billion of non-convertible debt in any three year period, we would cease to be an emerging growth company prior to the end of such five year period.

We may choose to take advantage of some but not all of these reduced burdens. We have taken advantage of certain of the reduced disclosure obligations, which include providing only two years of audited financial statements and correspondingly reduced financial disclosures and reduced executive compensation disclosure in the registration statement of which this prospectus forms a part and may elect to take advantage of other reduced burdens in future filings. As a result, the information that we provide to our stockholders may be different than you might receive from other public reporting companies in which you hold equity interests.

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 are also a smaller reporting company as defined in Rule 12b-2 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and have elected to take advantage of certain of the scaled disclosure available to smaller reporting companies.

Reverse Merger

On August 29, 2013, Oneida Resources Corp., which we refer to as the Company, we, our and us, completed a reverse merger transaction in which ITI, Inc., a Delaware corporation and wholly-owned subsidiary of the Company, or Merger Sub, merged with and into Intra-Cellular Therapies, Inc., a Delaware corporation, which we refer to as ITI, with ITI remaining as the surviving entity and a wholly-owned operating subsidiary of the Company. This transaction is referred to throughout this prospectus as the Merger. In the Merger, each outstanding share of capital stock of ITI was exchanged for 0.5 shares of our common stock, and we assumed each outstanding option and outstanding warrant of ITI. Following the Merger and the redemption of all of our then outstanding shares at the closing of the Merger, the former shareholders of ITI owned 100% of the shares of our outstanding capital stock. In connection with the Merger, ITI changed its name to ITI, Inc. and we changed our name to Intra-Cellular Therapies, Inc.

Public Offering in February 2014

On February 5, 2014, we completed our initial public offering of 7,063,300 shares of our common stock at a price of $17.50 per share for aggregate gross proceeds of approximately $123.6 million, and net proceeds of approximately $115.4 million.

Our Corporate Information

We were originally incorporated in the State of Delaware in August 2012 under the name Oneida Resources Corp. Prior to the Merger, Oneida Resources Corp. was a shell company registered under the Exchange Act with no specific business plan or purpose until it began operating the business of ITI through the Merger transaction on August 29, 2013. 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. See Description of the Merger for

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additional information concerning the Merger. As used herein, the words the Company, we, us, and our refer to the Delaware corporation operating the business of ITI as a wholly-owned subsidiary, which business continues as the business of the Company.

Our corporate headquarters and laboratory are located at 3960 Broadway, New York, New York, 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. Our filings with the Securities and Exchange Commission, or SEC, will be available free of charge through the website as soon as reasonably practicable after being electronically filed with or furnished to the SEC. Information contained in our website does not constitute a part of this prospectus or our other filings with the SEC.

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

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THE OFFERING

Common stock offered by selling stockholders	19,169,155 shares
Common stock outstanding	29,222,746 shares
Use of proceeds	We will not receive any proceeds from the sale of the shares of common stock offered by the selling stockholders.
Offering price	The selling stockholders may sell all or a portion of their shares through public or private transactions at prevailing market prices or at privately negotiated prices.
Risk factors	You should read the Risk Factors section of this prospectus for a discussion of factors to consider carefully before deciding to invest in shares of our common stock.
NASDAQ Global Select Market symbol	ITCI

The number of shares of common stock outstanding is based on an aggregate of 29,222,746 shares outstanding as of March 15, 2014, and excludes:

- 1,528,125 shares of common stock issuable upon exercise of outstanding options as of March 15, 2014, at a weighted average exercise price of $3.24 per share, of which 1,182,139 shares were vested as of such date;
- 1,822 shares of common stock issuable upon the exercise of a warrant outstanding as of March 15, 2014, at an exercise price of $6.0264 per share; and
- 1,509,390 shares of common stock reserved for future issuance under our 2013 Equity Incentive Plan, or the 2013 Plan, as of March 15, 2014, plus (i) up to an additional maximum of 1,400,125 shares which may be issued solely after the cancellation or expiration of any unexercised stock options that we assumed in the Merger, and (ii) any future increases in the number of shares of common stock reserved for issuance under the 2013 Plan pursuant to evergreen provisions.

Unless otherwise indicated in this prospectus, all share and per share figures reflect the exchange of each share of ITI common stock and each share of ITI preferred stock then outstanding for 0.5 shares of our common stock upon the

effective time of the Merger, or the Effective Time, on August 29, 2013.

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SUMMARY FINANCIAL DATA

The following tables summarize our financial data for the periods presented and should be read together with the sections of this prospectus entitled Risk Factors and Management s Discussion and Analysis of Financial Condition and Results of Operations, and our financial statements and related notes appearing elsewhere in this prospectus. The following summary statements of operations for the years ended December 31, 2012 and 2013 and the balance sheet data as of December 31, 2013 have been derived from our audited consolidated financial statements and footnotes included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results we expect in the future.

	Years Ended December 31,	
	2013	**2012**
	(Audited)	*(Audited)*
Statements of Operations:		
Revenues	$ 2,737,002	$ 3,117,991
Costs and expenses:		
Research and development	23,027,578	15,486,476
General and administrative	5,976,276	4,034,925
Total costs and expenses	29,003,854	19,521,401
Loss from operations	(26,266,852)	(16,403,410)
Interest expense	(612,963)	(193,498)
Interest income	29,617	39,002
Income taxes	(18,000)	(32,921)
Net (loss) income	(26,868,198)	(16,590,827)
Net (loss) income per common share:		
Basic & Diluted	$ (1.56)	$ (2.96)
Weighted average number of common shares:		
Basic & Diluted	17,260,768	5,607,539

	December 31, 2013
	(Audited)
Balance Sheet data:	
Cash and cash equivalents	$ 35,150,924
Total assets	38,449,312
Total liabilities	6,834,037
Accumulated deficit	(57,564,497)
Total stockholders equity	31,615,275

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RISK FACTORS

Investing in our common stock involves a high degree of risk. In addition to the information, documents or reports included or incorporated by reference in this prospectus and, if applicable, any prospectus supplement or other offering materials, you should carefully consider the risks described below in addition to the other information contained in this prospectus, before making an investment decision. Our business, financial condition or results of operations could be harmed by any of these risks. As a result, you could lose some or all of your investment in our common stock. The risks and uncertainties described below are not the only ones we face. Additional risks not currently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business operations.

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 U.S. Food and Drug Administration, or 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 completed a Phase 2 clinical trial and ITI-214 is currently in Phase 1 clinical trials. 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 acute 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.

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 acute schizophrenia and other indications, 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. We may need to conduct additional clinical trials before we are able to advance ITI-007 into Phase 3 clinical trials in patients with acute schizophrenia.

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In addition, although we believe that ITI-007 and follow-on compounds may also have clinical utility in indications other than acute schizophrenia, such as behavioral disturbances in dementia, bipolar disorder, intermittent explosive disorder, or 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 and in March 2014 we announced the initiation of a Phase 1/2 clinical trial of ITI-007 in healthy geriatric subjects and in patients with dementia, including Alzheimer s disease.

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 acute schizophrenia, those results are not necessarily predictive of results of future pivotal trials that may be needed before we may submit a New Drug Application, or 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.

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 may be delayed and the costs of our development of ITI-007 would increase.

Subject to discussions with the FDA, we intend to initiate Phase 3 clinical trials and additional supporting trials in patients with acute exacerbated schizophrenia in the second half of 2014 and 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. With the recent completion of the ITI-007-005 Phase 2 clinical trial in schizophrenia, in the second quarter of 2014 we plan to request a meeting with the FDA to discuss the existing ITI-007 safety and efficacy data and our future clinical development plans for ITI-007, including our plans to conduct separate, but overlapping, well-controlled clinical trials in schizophrenia and bipolar disorder. The Phase 3 clinical trial design for ITI-007 in schizophrenia will be the primary focus of the first meeting. Additional meetings may be requested, as needed, to discuss in greater detail our plans for bipolar disorder, and other elements of our regulatory strategy, including additional therapeutic indications, as the program progresses. We currently anticipate conducting two placebo-controlled Phase 3 clinical trials of ITI-007 in patients with acute exacerbated schizophrenia, with approximately 300 to 400 patients per trial. We expect that these trials would include a four to six-week treatment duration. Subject to our discussions with the FDA, our finalization of the protocols for the Phase 3 clinical trials and timely enrollment, we anticipate that the results of these Phase 3 clinical trials of ITI-007 in patients with acute exacerbated schizophrenia could be available as soon as the fourth quarter of 2015. However, the FDA may not agree with our clinical development plans for advancing ITI-007, including our plans to conduct separate, but overlapping, well-controlled clinical trials in schizophrenia and bipolar disorder. 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 NDA for ITI-007 in patients with acute exacerbated schizophrenia, which we currently expect could occur at the end of 2016 or the beginning of 2017. Our clinical plans 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, our development of ITI-007 may be delayed and the costs of our development of ITI-007 could increase, which would have a material adverse effect on our business, financial condition and results of operations.

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

We have experienced significant net losses since our inception. As of December 31, 2013, we had an accumulated deficit of approximately $57.6 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. We anticipate that our collaborations, which provide us with research funding and potential milestone payments, will continue to be our primary sources of revenues for the next several years. We cannot be certain that the milestones required to trigger payments under our existing collaborations will be achieved or 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 $37.2 million at December 31, 2013. 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, our Phase 1/2 clinical trial of ITI-007 in healthy geriatric subjects and in patients with dementia, including Alzheimer s disease, 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 net proceeds from our recently completed public offering to fund the completion of two proposed Phase 3 clinical trials of ITI-007 in patients with acute exacerbated schizophrenia; 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; to fund the completion of proposed Phase 1/2 and Phase 2 clinical trials of ITI-007 for the treatment of patients with behavioral disturbances in dementia, including Alzheimer s disease; 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 recently completed 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

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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 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. 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 our collaborators and us to reach the milestones, and other events or developments, triggering payments under our collaboration agreements or to otherwise make payments under these agreements;
- our ability to enter into new, and to maintain existing, collaboration and license agreements;
- the extent to which our collaborators are obligated to reimburse us for clinical trial costs under our 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 recently completed public offering, and could use these resources for corporate purposes that do not increase

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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 Investigational New Drug Application, or 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.

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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

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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. 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.

We are currently party to a license and collaboration agreement with Takeda. 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.

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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.

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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.

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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 contract with our current manufacturer or contract with another third party 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 manufacturer 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, ITI-214 and those compounds covered by our collaboration with Takeda), achieve milestones under our license and collaboration agreement with Takeda, facilitate additional 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.

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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;

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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 December 31, 2013, we had net operating loss carryforwards of approximately $49.3 million to reduce future federal and state taxable income through 2034. Since we had net operating loss carryforwards as of December 31, 2013 and 2012, no excess tax benefits for the tax deductions related to share-based awards were

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recognized in the statements of operations. The net operating loss carryforwards of approximately $49.3 million as of December 31, 2013 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, including as a result of our recent public offering in February 2014.

Our business and operations would suffer in the event of system failures.

Despite the implementation of security measures, our internal computer systems, and those of our clinical research organizations and other third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. 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. 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.

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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 all 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

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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.

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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 acute 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.

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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 $10 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.

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Risks Relating 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. As of March 31, 2014, the price per share of our common stock has ranged from a high of $21.26 to a low of $10.00. 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 lead to the development of 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. Moreover, if there is no active trading market or if the volume of trading is limited, holders of our common stock may have difficulty selling their shares.

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.

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The resale of shares covered by the registration statement of which this prospectus forms a part and the resale of shares of common stock issued in our recently completed public offering could adversely affect the market price of our common stock in the public market, which result would in turn negatively affect our ability to raise additional equity capital.

The sale, or availability for sale, of our common stock in the public market may adversely affect the prevailing market price of our common stock and may impair our ability to raise additional capital by selling equity or equity-linked securities. We filed the registration statement of which this prospectus forms a part with the SEC, which was originally declared effective on December 18, 2013, to register the resale of 21,961,496 shares of our common stock, which represents substantially all of the shares of our common stock issued in connection with the Merger. The registration statement permits the resale of these shares at any time, subject to applicable lock-up restrictions described in the Certain Relationships and Related Person Transactions Agreements with Stockholders Lock-Up Provisions in Registration Rights Agreement section of this prospectus. In addition, we recently issued 7,063,300 shares of common stock in our public offering which closed on February 5, 2014. The resale of a substantial number of shares of our common stock in the public market could adversely affect the market price for our common stock and make it more difficult for you to sell shares of our common stock at times and prices that you feel are appropriate. Furthermore, we expect that, because there are a large number of shares registered pursuant to the registration statement of which this prospectus forms a part, the selling stockholders will continue to offer shares covered by the registration statement for a significant period of time, the precise duration of which cannot be predicted. Accordingly, the adverse market and price pressures resulting from an offering pursuant to the registration statement may continue for an extended period of time and continued negative pressure on the market price of our common stock could have a material adverse effect on our ability to raise additional equity capital.

A significant portion of our total outstanding shares of common stock is restricted from immediate resale but may be sold into the market in the near future. This could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur in the future. These sales, or the perception in the market that the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock. Our directors, executive officers and certain stockholders own an aggregate of approximately 16,437,038 shares of our common stock that are subject to a lock-up agreement with us contained in the Registration Rights Agreement and/or a separate lock-up agreement with the underwriters in our recently completed public offering pursuant to which these persons have agreed, subject to specified exceptions, not to sell, transfer, dispose of, contract to sell, sell any option or contract to purchase, or otherwise transfer or dispose of, directly or indirectly, without the written consent of the underwriters, any shares of our common stock or any securities convertible into or exercisable or exchangeable for shares of our common stock prior to April 30, 2014. Once these lock-up provisions expire, these shares, which are registered on the registration statement of which this prospectus forms a part, can be freely sold in the public market, which could cause the market price of our common stock to drop significantly.

At any time when the registration statement of which this prospectus forms a part may not be available, the liquidity and price of our common stock could significantly decline and it may be difficult for you to sell your shares, if at all.

Although we filed a registration statement of which this prospectus forms a part with the SEC, which was originally declared effective on December 18, 2013, to register the resale of 21,961,496 shares of our common stock, which represents substantially all of the shares of our common stock issued in connection with the Merger, and the registration statement permits the resale of these shares at any time, subject to applicable lock-up restrictions, such

registration may not be available at all times. We are not currently eligible to register the resale of our common stock included in the registration statement on Form S-3, and, therefore, have registered the resale of these securities on Form S-1. As a result, under certain circumstances, we must update the registration

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statement for the resale of such shares of our common stock by filing post-effective amendments to the registration statement that will not be effective until each is declared effective by the SEC. Between the time it is determined that the registration statement must be updated by a post-effective amendment and the time the SEC declares the applicable post-effective amendment effective, the registration statement will not be available for use and the price of our common stock could decline during that time. The SEC has broad discretion to determine whether any registration statement (including any post-effective amendment) will be declared effective and may delay or deny the effectiveness of any registration statement or post-effective amendment filed by us for a variety of reasons. Therefore, at any time when the registration statement may not be available, the liquidity and price of our common stock could significantly decline and it may be difficult for you to sell your shares, if at all.

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 will incur significant legal, accounting and other expenses, including costs associated with public company reporting requirements. We will also 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

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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 JOBS Act. 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

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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.

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CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and the documents incorporated by reference in this prospectus include forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act that relate to future events or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to differ materially from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. Words such as, but not limited to, believe, expect, anticipate, estimate, intend, may, plan, potential, pr targets, likely, will, would, could, should, continue, and similar expressions or phrases, or the negative of t expressions or phrases, are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Although we believe that we have a reasonable basis for each forward-looking statement contained in this prospectus, we caution you that these statements are based on our projections of the future that are subject to known and unknown risks and uncertainties and other factors that may cause our actual results, level of activity, performance or achievements expressed or implied by these forward-looking statements, to differ. The sections in this prospectus entitled Description of Our Business, Risk Factors, and Management s Discussion and Analysis of Financial Condition and Results of Operations as well as other sections in this prospectus, discuss some of the factors that could contribute to these differences. These forward-looking statements include, among other things, statements about:

- the accuracy of our estimates regarding expenses, future revenues and capital requirements;
- the initiation, cost, timing, progress and results of our development activities, preclinical studies and clinical trials;
- the timing of and our ability to obtain and maintain regulatory approval of our existing product candidates, any product candidates that we may develop, and any related restrictions, limitations, and/or warnings in the label of any approved product candidates;
- our plans to research, develop and commercialize our future product candidates;
- our collaborators election to pursue research, development and commercialization activities;
- our ability to obtain future reimbursement and/or milestone payments from our collaborators;
- our ability to attract collaborators with development, regulatory and commercialization expertise;
- our ability to obtain and maintain intellectual property protection for our product candidates;

our ability to successfully commercialize our product candidates;

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

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

the success of competing drugs that are or become available;

regulatory developments in the United States and other countries;

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

our ability to obtain additional financing;

our use of the proceeds from our public offering in February 2014 and our private placement in August 2013;

our expectations regarding the time during which we will be an emerging growth company under the JOBS Act;

the accuracy of our estimates regarding expenses, future revenues, capital requirements and the need for additional financing; and

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

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We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important cautionary statements in this prospectus, particularly in the Risk Factors section, that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

You should read this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement of which this prospectus forms a part, completely and with the understanding that our actual future results may be materially different from what we expect. The forward-looking statements contained in this prospectus are made as of the date of this prospectus, and we do not assume, and specifically disclaim, any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

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DESCRIPTION OF THE MERGER

Pursuant to an Agreement and Plan of Merger dated August 23, 2013, or the Merger Agreement, by and among Oneida Resources Corp., which we refer to as the Company, we, our and us; ITI, Inc., a Delaware corporation and wholly-owned subsidiary of the Company, or Merger Sub; and Intra-Cellular Therapies, Inc., a Delaware corporation, which we refer to as ITI; Merger Sub merged with and into ITI, with ITI remaining as the surviving entity and a wholly-owned operating subsidiary of the Company. This transaction is referred to throughout this prospectus as the Merger. The Merger was effective on August 29, 2013, upon the filing of a Certificate of Merger with the Secretary of State of the State of Delaware. As part of the Merger, ITI changed its name to ITI, Inc.

Immediately following the Merger, a newly organized wholly-owned subsidiary of the Company named Intra-Cellular Therapies, Inc. , or Name Change Merger Sub, merged with and into the Company, leaving the Company as the surviving corporation. We refer to this transaction as the Name Change Merger. In connection with the Name Change Merger, we relinquished our corporate name Oneida Resources Corp. and assumed in its place the name Intra-Cellular Therapies, Inc. The Name Change Merger and name change became effective on August 29, 2013, upon the filing of a Certificate of Ownership and Merger with the Secretary of State of the State of Delaware.

At the effective time of the Merger, or the Effective Time, the legal existence of Merger Sub ceased and each share of ITI common stock and each share of ITI preferred stock that was issued and outstanding immediately prior to the Effective Time was automatically exchanged for 0.5 shares of our common stock, which we refer to as the Exchange. We issued an aggregate of 22,134,647 shares of our common stock upon such exchange of the outstanding shares of ITI common stock and preferred stock. In addition, at the Effective Time, we assumed ITI s 2003 Equity Incentive Plan, as amended, or the 2003 Equity Incentive Plan, and all options to purchase ITI common stock then outstanding under the 2003 Equity Incentive Plan, and such options became exercisable for an aggregate of 1,462,380 shares of our common stock, subject to the vesting and other terms of such options. The vesting of such options was not accelerated as a result of the Merger. At the Effective Time, we also assumed the outstanding warrant to purchase ITI common stock, and such warrant became exercisable for 1,822 shares of our common stock.

Immediately following the Effective Time, pursuant to the terms of a Redemption Agreement dated August 29, 2013, or the Redemption Agreement, by and among the Company and its then-current sole stockholder, we completed the closing of a redemption of 5,000,000 shares of our common stock, or the Redemption, from our then-current sole stockholder in consideration of $60,000, plus professional costs related to the transaction that were approximately $20,000. The 5,000,000 shares constituted all of the issued and outstanding shares of our capital stock, on a fully-diluted basis, immediately prior to the Merger.

Upon completion of the Merger and the Redemption, the former stockholders of ITI held 100% of the outstanding shares of our capital stock. Unless otherwise indicated in this prospectus, all share and per share figures reflect the exchange of each share of ITI common stock and each share of ITI preferred stock then outstanding for 0.5 shares of our common stock at the Effective Time.

As a condition to the Merger, we entered into an Indemnity Agreement with our former sole officer and director, or the Indemnity Agreement, pursuant to which we agreed to indemnify such former officer and director for actions taken by him in his official capacities relating to the consideration, approval and consummation of the Merger and certain related transactions.

The Merger was accounted for as a capital transaction. Upon the effectiveness of the Merger, the Company s business became the operation of ITI and its business. Immediately following the Effective Time, our board of directors, which immediately prior to the Effective Time consisted of Samir N. Masri as our sole director, appointed Sharon Mates,

Ph.D., who was Chairman, President and Chief Executive Officer of ITI, as

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our Chairman, President and Chief Executive Officer, to serve on our board of directors with Mr. Masri. At the Effective Time, Mr. Masri resigned from all of his positions as an officer of the Company. In addition, immediately following the Effective Time, our board of directors appointed Lawrence J. Hineline, who was the Vice President of Finance, Chief Financial Officer and Secretary of ITI, as our Vice President of Finance, Chief Financial Officer and Secretary; Allen A. Fienberg, Ph.D., who was the Vice President of Business Development of ITI, as our Vice President of Business Development; Lawrence P. Wennogle, Ph.D., who was the Vice President, Drug Discovery of ITI, as our Vice President, Drug Discovery; and Kimberly E. Vanover, Ph.D., who was the Vice President, Clinical Development of ITI, as our Vice President, Clinical Development. On September 9, 2013, which was the eleventh day following the date that we filed with the SEC and transmitted to our sole stockholder prior to the Merger, a Schedule 14f-1 reporting a change in the majority of our directors, Christopher Alafi, Ph.D., Richard Lerner, M.D., Joel S. Marcus and Sir Michael Rawlins, M.D., FRCP, FMedSci, were appointed to our board of directors to serve on our board of directors with Dr. Mates, and Mr. Masri resigned from our board of directors as of such date. Each of Dr. Mates, Dr. Alafi, Dr. Lerner, Mr. Marcus, and Sir Michael were directors of ITI immediately prior to the Merger. In addition, in January 2014, Rory B. Riggs and Robert L. Van Nostrand joined our board of directors.

Prior to the Merger, ITI sold to accredited investors approximately $60.0 million of its shares of common stock, or 18,889,307 shares at a price of $3.1764 per share, which included $15.3 million in principal and $0.8 million in accrued interest from the conversion of ITI s then outstanding convertible promissory notes, or Notes. We refer to this transaction as the Private Placement and the number of shares stated in the preceding sentence does not reflect the Exchange in the Merger. The price per share in the Private Placement, as adjusted for the Exchange in the Merger, would be $6.3528 per share of our post-Merger common stock. Also, ITI granted the investors in the Private Placement registration rights requiring ITI or any successor to register those shares of ITI common stock (which were exchanged for shares of our common stock, along with the rest of the outstanding shares of ITI capital stock, except for dissenting shares, at the Effective Time) for public resale, as described in more detail below. The then existing stockholders of ITI who agreed to become parties to the registration rights agreement also became entitled to such registration rights, subject to specified differences in the agreement between the rights of new investors and existing stockholders. The existing Second Amended and Restated Investor Rights Agreement, by and among ITI and the investors listed therein, dated as of October 25, 2007, as amended, was terminated at the Effective Time. The Private Placement closed immediately prior to the filing of a Certificate of Merger with the Secretary of State of the State of Delaware, on August 29, 2013.

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DESCRIPTION OF OUR BUSINESS

Overview

We are a biopharmaceutical company focused on the discovery and clinical development of innovative, small molecule drugs that address underserved medical needs in neuropsychiatric and neurological disorders by targeting intracellular signaling mechanisms within the central nervous system, or CNS. Our lead product candidate, ITI-007, is in 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. Additional data from the Phase 2 trial are set forth below in the section entitled Our Clinical Programs ITI-007 Program ITI-007 for the treatment of exacerbated and residual schizophrenia Phase 2 Clinical Trial (ITI-007-005). In the second quarter of 2014, we plan to request a meeting with the FDA to discuss the existing ITI-007 safety and efficacy data and our future clinical development plans for ITI-007, including our plans to conduct separate, but overlapping, well-controlled clinical trials in schizophrenia and bipolar disorder. The Phase 3 clinical trial design for ITI-007 in schizophrenia will be the primary focus of the first meeting. Additional meetings may be requested, as needed, to discuss in greater detail our plans for bipolar disorder, and other elements of our regulatory strategy, including additional therapeutic indications, as the program progresses.

Subject to discussions with the FDA, we intend to initiate Phase 3 clinical trials and additional supporting trials in patients with acute exacerbated schizophrenia in the second half of 2014 and 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. We currently anticipate conducting two placebo-controlled Phase 3 clinical trials of ITI-007 in patients with acute exacerbated schizophrenia, with approximately 300 to 400 patients per trial. We expect that these trials would include a four-week to six-week treatment duration. Subject to our discussions with the FDA, our finalization of the protocols for the Phase 3 clinical trials and timely enrollment, we anticipate that the results of these Phase 3 clinical trials of ITI-007 in patients with acute exacerbated schizophrenia could be available as soon as the fourth quarter of 2015. 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 NDA for ITI-007 in patients with acute exacerbated schizophrenia, which we currently expect could occur at the end of 2016 or the beginning of 2017.

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

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dementia, Alzheimer 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.

In March 2014, we announced the initiation of 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 commencement 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. We expect that initial data from the trial will be available in the second half of 2014.

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 that has yielded a portfolio of compounds that selectively inhibits the enzyme phosphodiesterase 1, or PDE1. PDE1 helps regulate brain activity related to cognition, memory processes and movement/coordination. We have licensed the lead compound in this portfolio, ITI-214, and other compounds in this portfolio, to Takeda Pharmaceutical Company Limited, or Takeda. ITI-214 is the first compound in its class to successfully advance into Phase 1 clinical trials and is being developed for the treatment of cognitive impairment associated with schizophrenia, or CIAS, and other disorders. The results of our first Phase 1 clinical trial in 70 subjects in a randomized, double-blind, placebo-controlled study indicate that ITI-214 was safe and well-tolerated across a broad range of single oral doses. Other compounds in the PDE1 portfolio outside the Takeda collaboration are being advanced for the treatment of other indications, including non-CNS therapeutic areas.

Our pipeline also includes pre-clinical programs that are focused on advancing drug candidates 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.

We were originally incorporated in the State of Delaware in August 2012 under the name Oneida Resources Corp. Prior to a reverse merger that occurred on August 29, 2013, or the Merger, Oneida Resources Corp. was a shell company registered under the Securities Exchange Act of 1934, or the Exchange Act, with no specific business plan or purpose until it began operating the business of ITI, Inc., or ITI, through the Merger transaction on August 29, 2013. 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 CNS. Effective upon the Merger, a wholly-owned subsidiary of the Company merged with and into ITI, and ITI continues as the operating subsidiary of the Company. As used herein, the words the Company, we, us, and our refer to the current Delaware corporation operating the business of ITI as a wholly-owned subsidiary, which business continues as the business of the Company.

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Our corporate headquarters and laboratory are located at 3960 Broadway, New York, New York, 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. Our filings with the SEC will be available free of charge through the website as soon as reasonably practicable after being electronically filed with or furnished to the SEC. Information contained in our website does not constitute a part of this prospectus or our other filings with the SEC.

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

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 acute symptoms in 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 with our collaboration partner, Takeda, PDE inhibitor compounds, such as ITI-214, for CNS indications such as CIAS; and

- advance earlier stage product candidates in our pipeline.

Our Drug Discovery Platform and Capabilities

Based on the pioneering efforts of ITI co-founder and Nobel laureate, Dr. Paul Greengard, we have developed a detailed understanding of intracellular signaling pathways and intracellular targets. We have used that knowledge to develop several state of the art technology platforms, including one called CNSProfile™. This technology monitors the phosphoprotein changes elicited by major psychotropic drug classes and subclasses, and generates a unique molecular signature for drug compounds. By monitoring how the levels of these phosphoproteins change *in vivo*, we identify intracellular signaling pathways through which several major drug classes operate. Along with what we believe to be state of the art drug discovery efforts, we have used, and may continue to use, this information as a tool to validate our selection of preclinical candidate molecules.

During the years ended December 31, 2013 and 2012, we incurred $23.0 and $15.5 million in research and development expenses, respectively.

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Given the nature of our research and development and business activities, we do not expect that compliance with federal, state and local environmental laws will result in material costs to the Company or have a significant negative effect on our operations.

Disease and Market Overview

Our programs for small molecule therapeutics are designed to address various CNS diseases that we believe are underserved or unmet by currently available therapies and that represent large potential commercial market opportunities for us. Background information on the CNS diseases and related commercial markets that may be addressed by our programs is set forth below.

Schizophrenia

Schizophrenia is a disabling and chronic mental illness that is characterized by multiple symptoms during an acute phase of the disorder that can include so-called positive symptoms, such as hearing voices, grandiose beliefs and suspiciousness or paranoia. These symptoms can be accompanied by additional, harder to treat symptoms, such as social withdrawal, blunted emotional response and speech deficits, collectively referred to as negative symptoms, difficulty concentrating and disorganized thoughts, or cognitive impairment, depression and insomnia. Such residual symptoms often persist even after the acute positive symptoms subside, and contribute substantially to the social and employment disability associated with schizophrenia. Current antipsychotic medications provide some relief for the symptoms associated with the acute phase of the disorder, but they do not effectively treat the residual phase symptoms associated with chronic schizophrenia. Currently available medications used to treat acute schizophrenia are limited in their use due to side effects that can include movement disorders, weight gain, metabolic disturbances, and cardiovascular disorders. Indeed, the side effects associated with current antipsychotic medications often make some of the residual phase symptoms, such as negative symptoms and social function, worse. There is an unmet medical need for new therapies that have improved side effect and efficacy profiles.

According to the National Institute of Mental Health, over 1% of the world s population suffers from schizophrenia, and more than 3 million Americans suffer from the illness in any given year. Worldwide sales of antipsychotic drugs used to treat schizophrenia and other CNS related disorders exceeded $40 billion in 2012. These drugs have been increasingly used by physicians to address a range of disorders in addition to schizophrenia, including bipolar disorder and a variety of psychoses and related conditions in elderly patients. Despite their commercial success, current antipsychotic drugs have substantial limitations, including inadequate efficacy and severe side effects.

The first-generation, or typical, antipsychotics that were introduced in the late-1950s block dopamine receptors. While typical antipsychotics are effective against positive symptoms of schizophrenia in many patients, these drugs often induce disabling motor disturbances, and they fail to address or worsen most of the negative symptoms and cognitive disturbances associated with schizophrenia.

Most schizophrenia patients in the United States are treated today with second-generation, or atypical, antipsychotics, which induce fewer motor disturbances than typical antipsychotics, but still fail to address most of the negative symptoms of schizophrenia and other symptoms associated with social function impairment. Many patients with schizophrenia have deficits in social function. Social function is the ability to recognize, understand, process and use external cues to solve problems, maintain work performance, and conduct interpersonal relationships. Deficits in social function often remain after positive symptoms, such as hallucinations and delusions, have resolved in these patients. In addition, currently prescribed treatments do not effectively address or may exacerbate cognitive disturbances associated with schizophrenia. It is believed that the efficacy of atypical antipsychotics is due to their interactions with dopamine and 5-HT2A receptors. The side effects induced by the atypical agents may include weight

gain, non-insulin dependent (type II) diabetes, cardiovascular side effects, sleep disturbances, and motor disturbances. We believe that these side effects generally arise either from non-essential receptor interactions or from excessive dopamine blockade.

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The limitations of currently available antipsychotics result in poor patient compliance. A landmark study funded by the National Institute of Mental Health, the Clinical Antipsychotic Trials of Intervention Effectiveness, also referred to as CATIE, which was published in The New England Journal of Medicine in September 2005, found that 74% of patients taking typical or atypical antipsychotics discontinued treatment within 18 months because of side effects or lack of efficacy. We believe there is a large underserved medical need for new therapies that have improved side effect and efficacy profiles.

Behavioral Disturbances in Dementia, Including Alzheimer s Disease

It has been estimated that 44.4 million people worldwide were living with dementia in 2013, including over 5.0 million patients with Alzheimer s disease in the United States. This number is expected to nearly double to 75.6 million by 2030 and to 135.5 million by 2050. While the diagnostic criteria for Alzheimer s disease and other dementias mostly focus on the related cognitive deficits, it is often the behavioral and psychiatric symptoms that are most troublesome for caregivers and lead to poor quality of life for patients. Several behavioral symptoms are quite prevalent in patients with dementia, including patients with Alzheimer s disease. Rates of depression in Alzheimer s disease are estimated to be up to 87%, although most estimates are between 30% and 50%. Agitation and aggression are present in approximately 60% of patients. Sleep disturbances, particularly as an increased likelihood of day-night reversal, are present in up to approximately 60% of patients. In view of the potential multiple effects of ITI-007 on aggression, agitation, sleep disorders and depression, and its safety profile to date, we believe that ITI-007 may provide a novel therapy for treating the behavioral disturbances accompanying dementia, including Alzheimer s disease.

The FDA has not approved any drug to treat the behavioral symptoms of dementia, including Alzheimer s disease. As symptoms progress and become more severe, physicians often resort to off-label use of antipsychotic medications in these patients. Current antipsychotic drugs are associated with a number of side effects, which can be problematic for elderly patients with dementia. In addition, antipsychotic drugs may exacerbate the cognitive disturbances associated with dementia. We believe there is a large unmet medical need for a safe and effective therapy to treat the behavioral symptoms in patients with dementia, including Alzheimer s disease.

Bipolar Disorder

Bipolar disorder, commonly referred to as manic-depressive illness, is characterized by extreme shifts in mood. Individuals with bipolar disorder may experience intense feelings of over-excitement, irritability, and impulsivity with grandiose beliefs and racing thoughts, referred to as a manic episode. Symptoms of depression may include feeling tired, hopeless and sad, with difficulty concentrating and thoughts of suicide. Some people experience both types of symptoms in the same mixed episode. Severe symptoms of bipolar disorder can be associated with hallucinations or delusions, otherwise referred to as psychosis.

Bipolar disorder affects 4.4% of the adult United States population, or approximately 13 million adults, with a worldwide prevalence of 2.4%. In 2012, therapeutics used to treat bipolar disorder had global sales of approximately $6 billion.

Bipolar disorder is often treated with antipsychotic medications alone or in combination with mood stabilizers. The side effects and safety risks associated with antipsychotic drugs in patients with bipolar disorder are similar to those experienced by patients with schizophrenia. Moreover, a large national research program conducted from 1998 to 2005 called the Systematic Treatment Enhancement Program for Bipolar Disorder, or STEP-BD, followed 4,360 patients with bipolar disorder long term and showed that about half of patients who were treated for bipolar disorder still experienced lingering and recurrent symptoms, indicating a clear need for improved treatments.

Alzheimer s Disease

Alzheimer s disease is a progressive neurodegenerative disorder that slowly destroys memory and thinking skills, and eventually even the ability to carry out simple tasks. Its symptoms include cognitive dysfunction,

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memory abnormalities, progressive impairment in activities of daily living, and a host of behavioral and neuropsychiatric symptoms. Alzheimer s disease primarily affects older people and, in most cases, symptoms first appear after age 60. Alzheimer s disease gets worse over time and is fatal.

The market for Alzheimer s disease therapeutics is categorized into two segments: acetylcholinesterase inhibitors and NMDA receptor antagonists, which include Aricept®, Namenda®, Exelon® and Ebixa®. Acetylcholinesterase inhibitors, which account for 40% of the total worldwide market, had total sales of $4.1 billion in 2011. In 2012, global sales of CNS therapeutics for dementia and Alzheimer s disease reached $8 billion.

According to the Alzheimer s Association, 5.2 million people in the United States are living with Alzheimer s disease, and it is currently the fifth leading cause of death for people age 65 and older. It has been estimated that 44.4 million people worldwide were living with dementia in 2013. This number is expected to nearly double to 65.7 million by 2030 and to 115.4 million by 2050. While the diagnostic criteria for Alzheimer s disease mostly focus on the related cognitive deficits, it is often the behavioral and psychiatric symptoms that are most troublesome for caregivers and lead to poor quality of life for patients. These symptoms include agitation, aggressive behaviors, depression, sleep disorders, and psychosis. Studies have suggested that approximately 60% of patients with Alzheimer s disease experience agitation/aggression, up to 87% of patients experience depression, approximately 60% of patients experience sleep disturbances, particularly as an increased likelihood of day-night reversal, and approximately 20% to 51% of Alzheimer s disease patients may develop psychosis at some point in the disease process, commonly consisting of hallucinations and delusions. The diagnosis of Alzheimer s disease psychosis is associated with more rapid cognitive and functional decline and institutionalization. Sleep disturbances increase the likelihood of day-night reversion, increased agitation and increased caregiver stress that strongly influences decisions for nursing home placement.

The FDA has not approved any drug to treat the behavioral symptoms of Alzheimer s disease. As symptoms progress and become more severe, physicians often resort to off-label use of antipsychotic medications in these patients. Current antipsychotic drugs are associated with a number of side effects, which can be problematic for elderly patients with Alzheimer s disease. In addition, antipsychotic drugs may exacerbate the cognitive disturbances associated with Alzheimer s disease. Current antipsychotic drugs also have a boxed warning for use in elderly patients with dementia-related psychosis due to increased mortality and morbidity. There is a large unmet medical need for a safe and effective therapy to treat the behavioral symptoms in patients with Alzheimer s disease.

Parkinson s Disease

Parkinson s disease is a chronic and progressive neurodegenerative disorder that involves malfunction and death of neurons in a region of the brain that controls movement. This neurodegeneration creates a shortage of an important brain signaling chemical, or neurotransmitter, known as dopamine, thereby rendering patients unable to direct or control their movements in a normal manner. Parkinson s disease is characterized by well-known motor symptoms, including tremors, limb stiffness, slowness of movements, and difficulties with posture and balance, as well as by non-motor symptoms, which include sleep disturbances, mood disorders, cognitive impairment and psychosis. Parkinson s disease progresses slowly in most people and the severity of symptoms tends to worsen over time.

Parkinson s disease is the second most common neurodegenerative disorder after Alzheimer s disease. According to the National Parkinson Foundation, about 1 million people in the United States and from approximately 4 to 6 million people worldwide suffer from this disease. Parkinson s disease is more common in people over 60 years of age, and the prevalence of this disease is expected to increase significantly as the average age of the population increases. Parkinson s disease patients are commonly treated with dopamine replacement therapies, such as levodopa, commonly referred to as L-DOPA, which is metabolized to dopamine, and dopamine agonists, which are molecules that mimic

the action of dopamine. Sales of therapeutics such as L-DOPA and dopamine agonists used to treat the motor symptoms of the disease reached $2.5 billion in 2012.

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Non-motor symptoms can be particularly distressing and even more troublesome to patients with Parkinson s disease than the primary motor disturbances. Non-motor symptoms substantially contribute to the burden of Parkinson s disease and deeply affect the quality of life of patients and their caregivers. Non-motor symptoms of Parkinson s disease are associated with increased caregiver stress and burden, nursing home placement, and increased morbidity and mortality.

Treatment of non-motor symptoms associated with Parkinson s disease poses a challenge to physicians. Current dopamine replacement drugs used to treat the motor symptoms of Parkinson s disease do not help, and sometimes worsen, the non-motor symptoms. No drugs are currently approved by the FDA for treating the broad non-motor symptoms associated with Parkinson s disease, and this remains a large unmet medical need.

Depression

Major depressive disorder, or MDD, is a brain disorder that can be associated with symptoms of sadness, hopelessness, helplessness, feelings of guilt, irritability, loss of interest in formerly pleasurable activities, cognitive impairment, disturbed sleep patterns, and suicide ideation or behavior. Different people may experience different symptoms, but everyone with major depression experiences symptoms that are severe enough to interfere with everyday functioning, such as the ability to concentrate at work or school, social interactions, eating and sleeping. Sometimes the depressive episode can be so severe it is accompanied by psychosis (hallucinations and delusions). According to the National Institute of Mental Health, approximately 3% of teenagers and approximately 7% of adults experience MDD each year. Worldwide sales of antidepressant drugs reached $11.9 billion in 2011. The antidepressant market is primarily composed of selective serotonin reuptake inhibitors such as Lexapro® (marketed by Forest Laboratories and Lundbeck) and selective norepinephrine reuptake inhibitors, or SNRIs, such as Cymbalta® (marketed by Eli Lilly). Antipsychotics such as Seroquel® (marketed by Astrazeneca) and Abilify® (marketed jointly by Bristol-Myers Squibb and Otsuka Pharmaceutical) are also used as adjunctive treatments with antidepressant treatment. The National Institute of Mental Health-funded Sequenced Treatment Alternatives to Relieve Depression, or STAR*D, study showed that only one-third of treated patients experience complete remission of depressive symptoms. Nearly two-thirds of patients were considered treatment-resistant.

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Our Clinical Programs

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:

ITI-007 Program

Our lead product candidate, ITI-007, possesses mechanisms of action that we believe have the potential to yield a first-in-class antipsychotic therapy. In our pre-clinical and clinical trials to date, ITI-007 combines potent serotonin 5-HT2A receptor antagonism, dopamine receptor phosphoprotein modulation, or DPPM, glutamatergic modulation and serotonin reuptake inhibition into a single drug candidate for the treatment of acute and residual schizophrenia. At dopamine D2 receptors, ITI-007 has been demonstrated to have dual properties and to act as both a post-synaptic antagonist and a pre-synaptic partial agonist. ITI-007 has also been demonstrated to stimulate phosphorylation of glutamatergic NMDA NR2B, or GluN2B, receptors in a mesolimbic specific manner. We believe that this regional selectivity in brain areas thought to mediate the efficacy of antipsychotic drugs, together with serotonergic, glutamatergic, and dopaminergic interactions, may result in antipsychotic efficacy for positive, negative, affective and cognitive symptoms associated with schizophrenia. The serotonin reuptake inhibition could allow for antidepressant activity for the treatment of schizoaffective disorder, co-morbid depression, and/or as a stand-alone treatment for major depressive disorder. We believe ITI-007 may also be useful for the treatment of bipolar disorder and other psychiatric and neurodegenerative disorders, particularly behavioral disturbances associated with dementia, autism and other CNS diseases.

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We believe these features of ITI-007 may be able to improve the quality of life of patients with schizophrenia and enhance social function to allow them to integrate more fully into their families and their workplaces. In addition, ITI-007 may be shown to treat disorders at either low-doses (*e.g.,* sleep, aggression and agitation) or high-doses (*e.g.*, acute exacerbated and residual schizophrenia, bipolar disorders, and mood disorders).

Phase 1 studies to support multiple clinical indications

We have conducted a series of Phase 1 safety studies of ITI-007 in Europe and the United States during the period from 2007 to 2011. All of the studies conducted to date in the United States have been conducted under an Investigational New Drug, or IND, filed in 2007 by ITI. Data from these studies are being used to support the clinical development of ITI-007 in multiple indications, including acute exacerbated schizophrenia, sleep disorders in neuropsychiatric and neurodegenerative disease, major depressive disorders, bipolar disorders, behavioral disturbances in dementia and Alzheimer s disease, autism, posttraumatic stress disorder, or PTSD, and intermittent explosive disorder, or IED. We have completed the following three Phase 1 trials in healthy volunteers:

A Phase 1, double-blind placebo controlled, single ascending dose study in 40 healthy volunteers in Europe in 2007. ITI-007 was generally well tolerated at all doses. Most adverse events, or AEs, were mild to moderate and all treatment related AEs resolved. The most frequent AE was headache.

A Phase 1, placebo controlled multiple ascending dose study in 25 healthy volunteers in Europe from 2007 to 2008. ITI-007 was generally well tolerated at all doses. Most AEs were mild to moderate and all treatment related AEs resolved.

A Phase 1, open-label positron emission tomography, or PET, study to demonstrate receptor occupancy, safety, tolerability and pharmacokinetics after single oral dose administration of ITI-007 in 16 healthy male volunteers. This study was conducted in the United States from 2007 to 2009. ITI-007 was well tolerated, all AEs were of mild or moderate intensity and all treatment related AEs resolved. Dose related increases in receptor occupancy at dopamine D2 receptors in the striatum were demonstrated after ITI-007 administration. Brain occupancy at 5-HT2A and serotonin reuptake transporters also was demonstrated after singles doses of ITI-007.

We continued Phase 1 development of ITI-007 in patients with schizophrenia in order to advance ITI-007 in this target therapeutic indication. Specifically, we conducted the following additional studies:

A Phase1b/2, placebo controlled multiple ascending dose study in 45 patients with stable schizophrenia in the United States during 2009 to 2010. ITI-007 was generally well tolerated at all doses. All AEs were mild to moderate and all treatment related AEs resolved. The overall percentage of patients reporting treatment related AEs was similar for those treated with ITI-007 (83.3% to 100%, across dose groups) and placebo (72.7%). The majority of the treatment related AEs that occurred at the commencement of the study decreased in terms of frequency and/or severity with repeated administration. We observed signs consistent with clinical efficacy in stable patients with schizophrenia in this study.

A Phase 1, randomized study to determine the tolerability, safety and pharmacokinetics of ITI-007 using different dosing regimens in 11 patients with schizophrenia. This study was conducted in the United States in 2011. In this study, we showed that administration of ITI-007 in a capsule dosage form taken with food reduced the incidence of treatment related AEs and all treatment related AEs resolved. The most commonly reported treatment related AE in this study was somnolence, commonly known as drowsiness.

ITI-007 for the treatment of exacerbated and residual schizophrenia

In multiple clinical trials of ITI-007 in patients with schizophrenia, the drug candidate has demonstrated clinical signals consistent with reductions in psychosis, depression and insomnia. Reductions in psychosis are

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consistent with the potential to treat acute schizophrenia, whereas reductions in depression and insomnia are consistent with the potential to treat residual phase schizophrenia. ITI-007 has been shown to be safe and well-tolerated across a wide range of doses in these studies. Further, at doses that have demonstrated clinical activity, ITI-007 has caused fewer adverse effects than those typically associated with antipsychotic drug treatment, such as impaired motor function. These adverse side effects can be a major cause of patient noncompliance with current antipsychotic therapies and can lead to poorer social function.

Phase 2 Clinical Trial (ITI-007-005)

ITI-007 exhibited antipsychotic efficacy in ITI-007-005, 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. Patients received study treatment orally once daily in the morning for 28 days. Of those randomized, 311 patients were included in the intent-to-treat primary analysis. Subject participation lasted approximately 7 to 8 weeks, including a one week screening period, a four week treatment period followed by stabilization on standard of care, and a safety follow up visit approximately two weeks after stabilization. The primary endpoint for this clinical trial was change from baseline to Day 28 on the PANSS total score. The PANSS is a well-validated 30-item rating scale that measures the ability of a drug to reduce schizophrenia symptom severity. The PANSS measures positive symptoms, such as delusions, suspiciousness, and hallucinations; negative symptoms, such as blunted affect, social and emotional withdrawal, and stereotyped thinking; and general psychopathology, such as anxiety, tension, depression, and active social avoidance.

Secondary endpoints in this trial included weekly assessments of the PANSS total score as well as its subscales (Positive Symptom Subscale, Negative Symptom Subscale, and General Psychopathology Subscale) and the Negative Symptom Factor (based on a subset of PANSS questions), individual item response on the PANSS, and the Calgary Depression Scale for Schizophrenia. Safety and tolerability were also assessed.

In December 2013, we announced that topline results from the ITI-007-005 study indicated that 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.

Many patients with schizophrenia have deficits in social function. Social function is the ability to recognize, understand, process and use external cues to solve problems, maintain work performance and conduct interpersonal relationships. Deficits in social function often remain after positive symptoms, such as hallucinations and delusions, have resolved in these patients. In the Phase 2 trial, ITI-007 exhibited a differentiating response profile across a broad range of symptoms that we believe is consistent with improvements in these social functioning deficits. The study also showed that ITI-007 was well-tolerated at the tested doses. ITI-007 demonstrated a favorable safety profile in the study without characteristic antipsychotic drug side effects or any serious adverse events.

ITI-007 at a dose of 60 mg demonstrated a statistically significant improvement in psychosis ($p = 0.017$) on the trial s pre-specified primary endpoint, which was change from baseline on the PANSS total score, compared to placebo. The primary statistical analysis was pre-specified and used a Mixed-Effect Model Repeated Measure method for handling missing data in the intent-to-treat, or ITT, study population and a Bonferroni procedure to correct for multiple two-sided comparisons (each dose of ITI-007 compared to placebo). The trial s pre-specified sensitivity analysis on the primary endpoint used the analysis of covariance, or ANCOVA, model and last observation carried forward, or LOCF, method for handling missing data for the ITT population and confirmed the positive outcome with statistically

significant improvements compared to placebo in patients receiving the 60 mg dose of ITI-007 ($p = 0.011$). ITI-007 at a dose of 60 mg also significantly improved the positive symptom subscale ($p < 0.05$) and the general psychopathology subscale ($p < 0.05$) on the PANSS after 28 days of treatment using the ANCOVA-LOCF on the ITT population.

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The improvement in the PANSS total score in the 120 mg dose group did not reach statistical significance. We believe that it is possible that sedation, the most frequent side effect in the 120 mg dose group, interfered with the ability to detect an efficacy signal at this dose administered once daily in the morning. Approximately 32.5% of subjects randomized to 120 mg of ITI-007 experienced sedation/somnolence, compared to 21% of subjects randomized to risperidone, 17% of subjects randomized to 60 mg of ITI-007, and 13% randomized to placebo. We believe that nighttime administration may be more appropriate for testing the effectiveness of the 120 mg dose of ITI-007 in this patient population. In the trial, the 60 mg dose of ITI-007 was effective when administered once daily in the morning.

Consistent with preliminary indications from the interim analysis and with the drug s pharmacological profile, ITI-007 at a dose of 60 mg significantly improved certain items on the negative symptom and general psychopathology subscales consistent with improved social function. The study was statistically powered only on the primary endpoint. ITI-007 did significantly improve many secondary endpoints, although the study was not designed for significance on secondary endpoints and was not powered to detect statistical differences in subgroup analyses. Additional secondary endpoints, including depression, continue to be analyzed, and we expect that data will be presented at upcoming scientific conferences.

A high percentage (74%) of randomized subjects completed trial participation. Only 19% of subjects discontinued from study treatment during the 28 day study treatment period, and an additional 7% of subjects completed study treatment but were lost to follow up.

In the Phase 2 trial, ITI-007 was well-tolerated. The most frequent adverse event was sedation, as described above. There were no serious adverse events related to ITI-007. There were no clinically meaningful changes in safety measures with ITI-007. Notably, ITI-007 demonstrated a favorable metabolic profile with no increase of blood levels of glucose, insulin, cholesterol or triglycerides over a four week treatment period. Moreover, in contrast to risperidone, 60 mg of ITI-007 was effective with no difference from placebo on weight change parameters, prolactin levels, extrapyramidal symptoms (EPS) or akathisia. ITI-007 was not associated with EPS as measured by the Simpson-Angus Scale, Barnes Akathisia Rating Scale, or Abnormal Involuntary Movement Scale. There was no increase in suicidal ideation or behavior with ITI-007.

Proposed Phase 3 Clinical Trials and Regulatory Plans

Subject to discussions with the FDA, we intend to initiate Phase 3 clinical trials and additional supporting trials in patients with acute exacerbated schizophrenia in the second half of 2014 and 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. With the recent completion of the ITI-007-005 Phase 2 clinical trial in schizophrenia, in the second quarter of 2014 we plan to request a meeting with the FDA to discuss the existing ITI-007 safety and efficacy data and our future clinical development plans for ITI-007, including our plans to conduct separate, but overlapping, well-controlled clinical trials in schizophrenia and bipolar disorder. The Phase 3 clinical trial design for ITI-007 in schizophrenia will be the primary focus of the first meeting. Additional meetings may be requested, as needed, to discuss in greater detail our plans for bipolar disorder, and other elements of our regulatory strategy, including additional therapeutic indications, as the program progresses. We currently anticipate conducting two placebo-controlled Phase 3 clinical trials of ITI-007 in patients with acute exacerbated schizophrenia, with approximately 300 to 400 patients per trial. We expect that these trials would include a four-week to six-week treatment duration to support the primary antipsychotic efficacy endpoint as well as a longer treatment duration extension phase for safety. Subject to our discussions with the FDA, our finalization of the protocols for the Phase 3 clinical trials and timely enrollment, we anticipate that the results of these Phase 3 clinical trials of ITI-007 in patients with acute exacerbated schizophrenia could be available as soon as the fourth quarter of 2015. However, the FDA may

not agree with our clinical development plans for advancing ITI-007, including our plans to conduct separate, but overlapping, well-controlled clinical trials in schizophrenia and bipolar disorder. In addition to our Phase 3 clinical trials, we will

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need to complete other clinical and non-clinical trials and manufacturing and pre-commercialization activities necessary to support the submission of a planned NDA for ITI-007 in patients with acute exacerbated schizophrenia, which we currently expect could occur at the end of 2016 or the beginning of 2017. Our clinical plans 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, our development of ITI-007 may be delayed and the costs of our development of ITI-007 could increase, which would have a material adverse effect on our business, financial condition and results of operations.

ITI-007 for the treatment of behavioral disturbances associated with dementia, including Alzheimer s disease

Behavioral disturbances are common in dementia and Alzheimer s disease. These disturbances are a major component of the burden to caregivers, and often lead to institutionalization. Although currently available treatments for patients with dementia mainly address cognitive disturbances, behavioral disturbances are considerably more problematic and likely more amenable to drug treatment. Several behavioral symptoms are quite prevalent in patients with dementia, including patients with Alzheimer s disease. In March 2014, we announced the initiation of 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 commencement 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. We plan to conduct the ITI-007-200 trial in two parts. Part 1 is a randomized, double-blind, placebo-controlled multiple ascending dose evaluation of ITI-007 in healthy geriatric subjects. In each cohort in Part 1, we anticipate that 10 subjects will be randomized to receive ITI-007 (N=8) or placebo (N=2) for seven days. In Part 2, we anticipate that twelve patients with dementia will be randomized to receive ITI-007 (N=9) or placebo (N=3) for seven days. The number of cohorts in each part may be adjusted based on results. Safety, tolerability and pharmacokinetic data will be determined. Exploratory pharmacodynamic endpoints will be included to assess feasibility of measuring agitation, sedation, sleep and cognition in potential future trials. We expect that initial data from the trial will be available in the second half of 2014.

ITI-007 for the treatment of bipolar disorder

The pharmacological profile of ITI-007 offers the potential to treat bipolar mania, depression, and mixed symptoms at doses similar to those targeted for the treatment of schizophrenia. We believe that ITI-007 may be effective alone or in combination with mood stabilizers. Given that many patients with bipolar disorder also experience disturbed sleep and cognitive impairment similar to that observed in schizophrenia, we believe that ITI-007 may treat a wide array of symptoms in patients with bipolar disorder, including improvement of cognition and sleep. We expect that data from our completed Phase 1 studies and data from our Phase 2 trial in acute exacerbated schizophrenia will be used to advance ITI-007 directly into well-controlled clinical trials for the treatment of bipolar disorder. Based on the successful completion of our Phase 2 trial in acute exacerbated schizophrenia, subject to discussions with the FDA, we intend to initiate Phase 3 clinical trials and additional supporting trials in patients with acute exacerbated schizophrenia in the second half of 2014 and 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. With the recent completion of the ITI-007-005 Phase 2 clinical trial in schizophrenia, in the second quarter of 2014 we plan to request a meeting with the FDA to discuss the existing ITI-007 safety and efficacy data and our future clinical development plans for ITI-007, including our plans to conduct separate, but overlapping, well-controlled clinical trials in schizophrenia and bipolar disorder. The Phase 3 clinical trial design for ITI-007 in schizophrenia will be the primary focus of the first meeting. Additional meetings may be requested, as needed, to discuss in greater detail our plans for bipolar disorder, and other elements of our regulatory strategy, including additional therapeutic

indications, as the program progresses.

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The FDA may 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 clinical plans may change based on any discussions with the FDA. If the FDA does not agree with our clinical development plans for ITI-007, our development of ITI-007 may be delayed and the costs of our development of ITI-007 would increase, which may have an adverse effect on our business, financial condition and results of operations.

ITI-007 for the treatment of sleep disturbances associated with neurologic and psychiatric disorders

A Phase 2 double-blind, placebo controlled cross-over clinical trial conducted in 19 patients at low doses was completed in 2008 and conducted in Europe. The primary outcome measure was slow wave sleep as determined by polysomnography. ITI-007 demonstrated a dose-related statistically significant increase in slow wave sleep. Secondary measures were consistent with improvement of sleep maintenance in patients with primary insomnia, indicated by decreased waking after sleep onset, increased total sleep time, and no increase in latency to sleep onset. At these low doses ITI-007 did not induce sleep, but rather helped maintain sleep once sleep had been initiated. In addition, ITI-007 was not associated with next day cognitive impairment, or hang-over effects. We believe that ITI-007 may be particularly useful in the treatment of sleep disorders that accompany neuropsychiatric and neurologic disorders, including schizophrenia, autism spectrum disorder, or ASD, Parkinson s disease and dementia. Previous work has suggested that selective 5-HT2A receptor antagonists increase deep, slow wave sleep in both humans and animals. We believe, however, that other neuropharmacological mechanisms, in addition to 5-HT2A receptor antagonism, such as engaging some dopamine modulation, may be beneficial for the successful treatment of sleep maintenance insomnia, or SMI, in humans. We believe that ITI-007 represents a new approach to the treatment of sleep maintenance insomnia because of its unique pharmacology and neuropharmacological interactions beyond selective 5-HT2A receptor antagonism. We believe that ITI-007 offers a potentially new approach to the treatment of sleep maintenance disorders, particularly in those disorders that accompany neuropsychiatric and neurologic disorders. Many of these disorders are accompanied by profound sleep deficits, which impair daytime functioning including cognition, exacerbate disease symptoms and increase the cost of care. We are presently exploring clinical designs to incorporate the examination of sleep disturbances in one or more of these indications. There is no assurance that any such design would be sufficient for an FDA approval for this indication.

ITI-007 for the treatment of sleep and behavioral disturbances associated with autism spectrum disorder

Sleep problems are common in patients with ASD and are not adequately treated by currently available interventions. Approximately two thirds of children and adolescents with ASD experience sleep problems, higher than the rate of sleep problems in age-matched developmentally typical children. Moreover, individuals with ASD suffer from behavioral disturbances, including aggression, irritability, anxiety and depression. With its multiple pathway mechanism of action, we believe that ITI-007 could address the multi-faceted behavioral symptoms associated with ASD. 5-HT2A receptor antagonism is predicted to increase slow wave sleep, improve sleep maintenance and reduce aggression. D2 receptor modulation is predicted to improve sleep maintenance and reduce irritability and aggression. Serotonin reuptake inhibition is predicted to reduce anxiety and depression. Accordingly, we believe that ITI-007 could improve sleep maintenance, reduce behavioral disturbances and enhance social interaction in patients with ASD. We believe that our completed Phase 1 studies support advancing ITI-007 into Phase 2 trials in this patient population, and we are presently exploring the feasibility of such trials.

ITI-007 for the treatment of depression and other mood disorders

As a potent 5-HT2A receptor antagonist and serotonin reuptake inhibitor, we believe that ITI-007 could improve symptoms of depression with fewer side effects than selective serotonin reuptake inhibitors, or SSRIs. Dopamine modulation by ITI-007 may reduce irritability and aggression that can accompany many mood disorders. As such,

ITI-007 may be effective for the treatment of mood disorders including MDD, PTSD, and IED. We are presently exploring the feasibility of clinical studies in these indications.

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ITI-002 (PDE1) Program

We have a second major program, called our ITI-002 program that has generated a portfolio of compounds that have demonstrated the ability to modulate CNS pathways that are critical to controlling cognition and motor behavior through the inhibition of an important intracellular enzyme, PDE1. In March 2011, we entered into a license and collaboration agreement with Takeda to develop and commercialize selected PDE1 inhibitors in our ITI-002 program for the treatment of CIAS and other disorders, including Parkinson s disease, cognitive impairment in Alzheimer s disease, and Attention Deficit Hyperactivity Disorder. Cognitive deficits are believed to underlie much of the significant functional impairments observed in patients with schizophrenia. One of these portfolio compounds, ITI-214, has advanced into Phase 1 clinical studies. In the first quarter of 2013, we announced the completion by Takeda of a single ascending dose Phase 1 study in 70 healthy volunteers in the United States under an IND filed by Takeda in 2012. Takeda will be solely responsible for development, manufacturing and commercialization of PDE1 inhibitors. The results of this randomized, double-blind, placebo-controlled Phase 1 study indicated that ITI-214 was safe and well-tolerated across a broad range of single oral doses. Moreover, the study demonstrated a favorable pharmacokinetic profile of ITI-214 consistent with once-a-day dosing. We believe that this study represents a significant milestone as the first use of a potent and highly specific PDE1 inhibitor in humans. We have worked closely with Takeda since 2011 to advance ITI-214 into clinical development and to optimize select backup/follow-on compounds for treating other CNS diseases, including Parkinson s disease, cognitive impairment in Alzheimer s disease and attention deficit and hyperactivity disorders. We believe that inhibition of PDE1 may also be beneficial in a number of therapeutic indications outside of CNS diseases, such as pulmonary arterial hypertension, heart failure, muscular dystrophy and inflammatory disease. We are pursuing additional ITI-002 PDE1 inhibitor compounds outside the scope of the Takeda collaboration for the treatment of cardiovascular and other disorders.

Additional PDE Programs

There are multiple forms and isoforms of PDE with distinct roles in intracellular signaling. We have developed strong internal expertise in the design and synthesis of inhibitors specific for individual PDE isoforms. Based on our understanding of the expression and functions of these isoforms in the CNS, we have identified PDE2 and PDE9 as compelling targets for drug discovery. We believe that inhibitors of these PDEs may be useful in treating neurodegeneration and bioenergetic failure in a variety of CNS diseases.

Alzheimer s disease ITI-012 (Casein Kinase 1 Inhibitors) and ITI-009 (gSAP Inhibitors)

We are pursuing early stage drug discovery programs targeting two different pathways thought to be involved in the pathogenesis of Alzheimer s disease. The first program targets the enzyme casein kinase 1, or CK1, the misregulation of which in Alzheimer s disease may provoke misfolding of a neuronal protein, tau, which has been linked to cellular loss in the brains of patients with Alzheimer s disease. We are currently optimizing our CK1 inhibitors in anticipation of advancing them into preclinical development. We have a second program targeting the protein Gamma Secretase Activating Protein, or gSAP. We have demonstrated in preclinical models that inhibiting gSAP lowers the level of a toxic protein located in the brain called Abeta. Scientists in the field of dementia and Alzheimer s disease believe that inhibiting the accumulation of Abeta may slow the onset of Alzheimer s disease. The discovery of gSAP was made by ITI in collaboration with Dr. Paul Greengard, Nobel laureate and ITI co-founder. The preclinical characterization of this class of molecules is ongoing. We believe that these compounds have the potential to provide novel, disease-modifying treatments for Alzheimer s disease and related disorders.

Intellectual Property

Our Patent Portfolio

As of March 1, 2014, we owned or controlled approximately 60 patent families filed in the United States and other major markets worldwide, including approximately 31 issued or allowed U.S. patents, 50 pending U.S.

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patent applications, 102 issued foreign patents, and 344 pending foreign patent applications, directed to novel compounds, formulations, methods of treatment, synthetic methods, and platform technologies.

Our ITI-007 program on novel compounds for neuropsychiatric and neurodegenerative diseases includes patents exclusively in-licensed from Bristol-Myers Squibb on families of compounds, including the ITI-007 lead molecule. We have extensively characterized this lead and filed additional patent applications on polymorphs, formulations, additional indications, derivatives and additional compounds. The ITI-007 lead molecule has composition of matter protection through 2025 and additional Orange Book-listable protection to 2034. Additionally, we expect to have data exclusivity in the European Union for up to 11 years from commercial launch. We also have a follow-on program, directed to compounds structurally related to the ITI-007 lead, but having composition of matter protection beyond 2031.

Our program on PDE1 inhibitors for cognition and dopamine-mediated disorders, such as Parkinson s disease, includes patent protection for the lead molecule, ITI-214, as well as a wide range of filings on other proprietary compounds and indications. Certain PDE1 inhibitors are being developed under a joint development agreement with Takeda, under which we received an upfront cash payment and are eligible to receive payments for development and sales, as well as royalty payments. We also have an option to co-promote with Takeda in the U.S., and we retain certain rights to PDE1 inhibitor compounds and uses outside the scope of that collaboration. The ITI-214 lead molecule has composition of matter protection to 2029, with possible extensions and additional Orange Book-listable protection to 2034. Additionally, we expect to have data exclusivity in the European Union for up to 11 years from commercial launch. We are also evaluating potential follow-on compounds for ITI-214 which would have patent protection beyond 2030.

We have also filed patent applications on novel proprietary targets and lead compounds for Alzheimer s disease, which would provide compound protection beyond 2028 or beyond 2034, depending on which compound is ultimately selected for development.

License Agreement

The Bristol-Myers Squibb License Agreement

On May 31, 2005 we entered into a worldwide, exclusive License Agreement with Bristol-Myers Squibb Company, or BMS, pursuant to which we hold a license to certain patents and know-how of BMS relating to ITI-007 and other specified compounds. The agreement was amended on November 3, 2010. The licensed rights are exclusive, except BMS retains rights in specified compounds in the fields of obesity, diabetes, metabolic syndrome and cardiovascular disease. However, BMS has no right to use, develop or commercialize ITI-007 and other specified compounds in any field of use. We have the right to grant sublicenses of the rights conveyed by BMS. We are obliged under the license to use commercially reasonable efforts to develop and commercialize the licensed technology. We are also prohibited from engaging in the clinical development or commercialization of specified competitive compounds.

Under the agreement, we made an upfront payment of $1.0 million to BMS. Under the agreement, we may be obliged to make milestone payments to BMS for each licensed product of up to an aggregate of approximately $14.8 million, which includes a milestone payment of $1.25 million that we made during the fourth quarter of 2013 in connection with our recently completed Phase 2 trial. We are also obliged to make tiered single digit percentage royalty payments on sales of licensed products. We are obliged to pay to BMS a percentage of non-royalty payments made in consideration of any sublicense.

The agreement extends, and royalties are payable, on a country-by-country and product-by-product basis, through the later of ten years after first commercial sale of a licensed product in such country, expiration of the last licensed patent

covering a licensed product, its method of manufacture or use, or the expiration of other government grants providing market exclusivity, subject to certain rights of the parties to terminate the

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agreement on the occurrence of certain events. On termination of the agreement, we may be obliged to convey to BMS rights in developments relating to a licensed compound or licensed product, including regulatory filings, research results and other intellectual property rights.

Collaboration Agreement

The Takeda Pharmaceutical License and Collaboration Agreement

On February 25, 2011, we entered into a license and collaboration agreement with Takeda Pharmaceutical Company Limited 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. As part of the agreement, we assigned to Takeda certain patents owned by us that claim ITI-214 and granted Takeda an exclusive license to develop and commercialize compounds identified in the conduct of the research program that satisfy specified criteria. However, we have retained rights to all compounds that do not meet the specified criteria and we continue to develop PDE1 inhibitors outside the scope of the agreement.

Under the terms of the agreement, we have conducted a research program with an initial term of three years to identify and characterize compounds that meet certain specified criteria sufficient for further development by Takeda. This research program ended in February 2014. We were responsible for our expenses incurred in the conduct of certain research activities specified in the research plan. Takeda agreed to reimburse us for expenses we incurred in conducting additional research activities.

Takeda is obliged to use commercially reasonable efforts to develop and commercialize licensed compounds at its expense, and has agreed to reimburse us for the costs and expenses of development activities we may perform. We formed a joint steering committee with Takeda to coordinate and oversee activities on which we collaborate under the agreement. We have the option to co-promote any licensed product in the United States by assuming responsibility for a certain percentage of the detailing activity with respect to that product.

We fulfilled our responsibility under the agreement to supply Takeda with ITI-214 for nonclinical activities and Phase 1 clinical trials at our expense. Takeda is responsible, at its expense, for the manufacture and supply of compounds that it develops and commercializes under the agreement for all other activities.

Upon execution of the agreement, Takeda made a nonrefundable payment to us. We are eligible to receive payments of approximately $500 million in the aggregate upon achievement of certain development milestones and up to an additional $250 million in the aggregate upon achievement of certain sales-based milestones, along with tiered royalty payments ranging from the high single digits to the low teens in percent based on net sales by Takeda.

The agreement extends, on a country-by-country and product-by-product basis, through the later of expiration of the last licensed patent covering a licensed product, its method of manufacture or use, the expiration of other government grants providing market exclusivity or ten years after first commercial sale of a licensed product in such country, subject to rights of the parties to sooner terminate the agreement on certain events and the right of Takeda to unilaterally terminate the agreement upon a specified number of days prior notice. Upon the termination of the agreement, Takeda is obliged to assign to us the patents covering ITI-214 assigned to Takeda upon the execution of the agreement, to grant us a license to develop and commercialize licensed compounds developed by Takeda and to transfer to us certain materials, information and regulatory materials reasonably necessary for us to continue the development and commercialization of those compounds.

Manufacturing

We do not own or operate manufacturing facilities for the production of any of our product candidates, nor do we have plans to develop our own manufacturing operations in the foreseeable future. We currently rely on

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one third-party contract manufacturer for all of our required raw materials, active pharmaceutical ingredient, or API, and finished product for our preclinical research and clinical trials, including the Phase 2 trial for ITI-007 for the treatment of schizophrenia and the Phase1/2 clinical trial of ITI-007 in healthy geriatric subjects and in patients with dementia, including Alzheimer s disease. We believe that we would be able to contract with another third-party contract manufacturer to obtain API if our existing source of API was no longer available, but there is no assurance that API would be available from another third-party manufacturer on acceptable terms, on the timeframe that our business would require, or at all. We do not have long-term agreements with our existing third-party contract manufacturer. We also do not have any current contractual relationships for the manufacture of commercial supplies of any of our product candidates if they are approved. As ITI-007 and any of our other product candidates continue to progress towards potential regulatory approval, we intend to enter into agreements with a third-party contract manufacturer and one or more back-up manufacturers for the commercial production of those products. Development and commercial quantities of any products that we develop will need to be manufactured in facilities, and by processes, that comply with the requirements of the FDA and the regulatory agencies of other jurisdictions in which we are seeking approval. We currently employ internal resources to manage our manufacturing contractors.

Sales and Marketing

We currently have no marketing, sales or distribution capabilities. In order to commercialize any of our product candidates, we must develop these capabilities internally or through collaboration with third parties. In selected therapeutic areas where we feel that our product candidates can be commercialized by a specialty sales force that calls on a limited and focused group of physicians, we may plan to participate in the commercialization of our product candidates in the United States. In therapeutic areas that require a large sales force selling to a large and diverse prescribing population, we may elect to commercialize through, or in collaboration with, strategic partners. We may choose to commercialize our products in markets outside of the United States by establishing one or more strategic alliances in the future.

Competition

We face, and will continue to face, intense competition from pharmaceutical and biotechnology companies, as well as numerous academic and research institutions and governmental agencies, both in the United States and abroad. We compete, or will compete, with existing and new products being developed by our competitors. Some of these competitors are pursuing the development of pharmaceuticals that target the same diseases and conditions that our research and development programs target.

Even if we are successful in developing our product candidates, the resulting products would compete with a variety of established drugs in the areas of our targeted CNS therapeutic indications. Our potential products for the treatment of schizophrenia and bipolar disorder 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 product candidates, if approved, will compete with, among other generic antipsychotic products, haloperidol, risperidone, quetiapine, olanzapine and clozapine.

In addition, the companies described above and other competitors may have a variety of drugs in development or awaiting FDA approval that could reach the market and become established before we have a product to sell. Our competitors may also develop alternative therapies that could further limit the market for any drugs that we may develop. Many of our competitors are using technologies or methods different or similar to ours to identify and validate drug targets and to discover novel small molecule drugs. Many of our competitors and their collaborators have significantly greater experience than we do in the following:

identifying and validating targets;

screening compounds against targets;

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preclinical and clinical trials of potential pharmaceutical products; and

obtaining FDA and other regulatory clearances.

In addition, many of our competitors and their collaborators have substantially greater advantages in the following areas:

capital resources;

research and development resources;

manufacturing capabilities; and

sales and marketing.

Smaller companies also may prove to be significant competitors, particularly through proprietary research discoveries and collaborative arrangements with large pharmaceutical and established biotechnology companies. Many of our competitors have products that have been approved by the FDA or are in advanced development. We face competition from other companies, academic institutions, governmental agencies and other public and private research organizations for collaborative arrangements with pharmaceutical and biotechnology companies, in recruiting and retaining highly qualified scientific and management personnel and for licenses to additional technologies. Our competitors, either alone or with their collaborators, may succeed in developing technologies or drugs that are more effective, safer, and more affordable or more easily administered than ours and may achieve patent protection or commercialize drugs sooner than us. Developments by others may render our product candidates or our technologies obsolete. Our failure to compete effectively could have a material adverse effect on our business.

Government Regulation

United States FDA Process

The research, development, testing, manufacture, labeling, promotion, advertising, import and export, distribution and marketing, among other things, of drug products are extensively regulated by governmental authorities in the United States and other countries. In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or the FDCA, and its implementing regulations. Failure to comply with the applicable U.S. requirements may subject us to administrative or judicial sanctions, such as FDA refusal to approve pending NDAs, warning letters, fines, civil penalties, product recalls, product seizures, total or partial suspension of production or distribution, injunctions and/or criminal prosecution.

Drug Approval Process. None of our drug product candidates may be marketed in the United States until the drug has received FDA approval. Such approval can take many years to obtain and may be rejected by the FDA at a number of steps. The steps required before a drug may be marketed in the United States generally include the following:

completion of extensive pre-clinical laboratory tests, animal studies, and formulation studies in accordance with the FDA s Good Laboratory Practice, or GLP, regulations;

submission to the FDA of an IND for human clinical testing, which must become effective before human clinical trials may begin;

performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the drug for each proposed indication;

submission to the FDA of an NDA after completion of all clinical trials;

satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the API and finished drug product are produced and tested to assess compliance with cGMPs;

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satisfactory completion of FDA inspections of clinical trial sites to assure that data supporting the safety and effectiveness of product candidates has been generated in compliance with Good Clinical Practices; and

FDA review and approval of the NDA prior to any commercial marketing or sale of the drug in the United States.

The development and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, if at all.

Pre-clinical tests include laboratory evaluation of product chemistry, toxicity and formulation, as well as animal studies. The conduct of the pre-clinical tests and formulation of the compounds for testing must comply with federal regulations and requirements. The results of the pre-clinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND, which must become effective before human clinical trials may begin. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions about the conduct of the trial, such as whether human research subjects will be exposed to an unreasonable health risk. In such a case, the IND sponsor and the FDA must resolve any outstanding FDA concerns or questions before clinical trials can proceed. We cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin.

Clinical trials involve administration of the investigational drug to human subjects under the supervision of qualified investigators. Clinical trials are conducted under protocols detailing the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol must be provided to the FDA as part of a separate submission to the IND. Further, an Institutional Review Board, or IRB, for each medical center proposing to conduct the clinical trial must review and approve the study protocol and informed consent information for study subjects for any clinical trial before it commences at that center, and the IRB must monitor the study until it is completed. There are also requirements governing reporting of on-going clinical trials and clinical trial results to public registries. Study subjects must sign an informed consent form before participating in a clinical trial.

Clinical trials necessary for product approval typically are conducted in three sequential phases, but the phases may overlap.

Phase 1 usually involves the initial introduction of the investigational drug into a limited population, typically healthy humans, to evaluate its short-term safety, dosage tolerance, metabolism, pharmacokinetics and pharmacologic actions, and, if possible, to gain an early indication of its effectiveness.

Phase 2 usually involves trials in a limited patient population to (i) evaluate dosage tolerance and appropriate dosage; (ii) identify possible adverse effects and safety risks; and (iii) evaluate preliminarily the efficacy of the drug for specific targeted indications. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.

Phase 3 trials, commonly referred to as pivotal studies, are undertaken in an expanded patient population at multiple, geographically dispersed clinical trial centers to further evaluate clinical efficacy and test further for safety by using the drug in its final form. There can be no assurance that Phase 1, Phase 2 or Phase 3 testing will be completed successfully within any specified period of time, if at all. Furthermore, we, the

FDA or an IRB may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Moreover, the FDA may approve an NDA for a product candidate, but require that the sponsor conduct additional clinical trials to further assess the drug after NDA approval under a post-approval commitment. Post-approval trials are typically referred to as Phase 4 clinical trials.

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During the development of a new drug, sponsors are given an opportunity to meet with the FDA at certain points. These points may be prior to submission of an IND, at the end of Phase 2, and before an NDA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and the FDA to reach an agreement on the next phase of development. Sponsors typically use the end of Phase 2 meeting to discuss their Phase 2 clinical results and present their plans for the pivotal Phase 3 clinical trial that they believe will support approval of the new drug. A sponsor may request a Special Protocol Assessment, or SPA, to reach an agreement with the FDA that the protocol design, clinical endpoints, and statistical analyses are acceptable to support regulatory approval of the product candidate with respect to effectiveness in the indication studied. If such an agreement is reached, it will be documented and made part of the administrative record, and it will be binding on the FDA except in limited circumstances, such as if the FDA identifies a substantial scientific issue essential to determining the safety or effectiveness of the product after clinical studies begin, or if the sponsor fails to follow the protocol that was agreed upon with the FDA. There is no guarantee that a study will ultimately be adequate to support an approval even if the study is subject to an SPA.

Concurrent with clinical trials, companies usually complete additional animal safety studies and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and the manufacturer must develop methods for testing the quality, purity and potency of the final drugs. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

Assuming successful completion of the required clinical testing, the results of pre-clinical studies and of clinical studies, together with other detailed information, including information on the manufacture and composition of the drug, are submitted to the FDA in the form of an NDA requesting approval to market the product for one or more indications. An NDA must be accompanied by a significant user fee, which is waived for the first NDA submitted by a qualifying small business.

The testing and approval process requires substantial time, effort and financial resources. The FDA will review the NDA and may deem it to be inadequate to support approval, and we cannot be sure that any approval will be granted on a timely basis, if at all. The FDA may also refer the application to the appropriate advisory committee, typically a panel of clinicians, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendations of the advisory committee, but it typically follows such recommendations.

Before approving an NDA, the FDA inspects the facility or the facilities at which the drug and/or its active pharmaceutical ingredient is manufactured and will not approve the product unless the manufacturing is in compliance with cGMPs. If the FDA evaluates the NDA and the manufacturing facilities are deemed acceptable, the FDA may issue an approval letter, or in some cases a Complete Response Letter. The approval letter authorizes commercial marketing of the drug for specific indications. As a condition of NDA approval, the FDA may require post-marketing testing and surveillance to monitor the drug s safety or efficacy, or impose other conditions. A Complete Response Letter indicates that the review cycle of the application is complete and the application is not ready for approval. A Complete Response Letter may require additional clinical data and/or additional clinical trial(s), and/or other significant, expensive and time-consuming requirements related to clinical trials, pre-clinical studies or manufacturing. Even if such additional information is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data from clinical trials is not always conclusive and the FDA may interpret data differently than we or our collaborators interpret data. Alternatively, the FDA could also approve the NDA with a

Risk Evaluation and Mitigation Strategy to mitigate risks of the drug, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries or other risk minimization tools. Once the FDA approves a drug, the FDA may withdraw product approval if on-going regulatory requirements are not met or if

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safety problems occur after the product reaches the market. In addition, the FDA may require testing, including Phase 4 clinical trials, and surveillance programs to monitor the safety effects of approved products that have been commercialized, and the FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs or other information.

Post-Approval Requirements. After a drug has been approved by the FDA for sale, the FDA may require that certain post-approval requirements be satisfied, including the conduct of additional clinical studies. In addition, certain changes to an approved product, such as adding new indications, making certain manufacturing changes, or making certain additional labeling claims, are subject to further FDA review and approval. Before a company can market products for additional indications, it must obtain additional approvals from the FDA, typically a new NDA. Obtaining approval for a new indication generally requires that additional clinical studies be conducted. A company cannot be sure that any additional approval for new indications for any product candidate will be approved on a timely basis, or at all.

If post-approval conditions are not satisfied, the FDA may withdraw its approval of the drug. In addition, holders of an approved NDA are required to (i) report certain adverse reactions to the FDA and maintain pharmacovigilance programs to proactively look for these adverse events; (ii) comply with certain requirements concerning advertising and promotional labeling for their products; and (iii) continue to have quality control and manufacturing procedures conform to cGMPs after approval. The FDA periodically inspects the sponsor s records related to safety reporting and/or manufacturing facilities, which includes assessment of on-going compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. We intend to use third-party manufacturers to produce our products in clinical and commercial quantities, and future FDA inspections may identify compliance issues at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct. In addition, discovery of problems with a product after approval may result in restrictions on a product, manufacturer or holder of an approved NDA, including recall of the product from the market or withdrawal of approval of the NDA for that drug.

Patent Term Restoration and Marketing Exclusivity. Depending upon the timing, duration and specifics of FDA approval of the use of our drugs, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product s approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA, plus the time between the submission date of an NDA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension and the extension must be requested prior to expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we intend to apply for restorations of patent term for some of our currently owned or licensed patents to add patent life beyond their current expiration date, depending on the expected length of clinical trials and other factors involved in the submission of the relevant NDA.

Data and market exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent data exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application, or ANDA, or a 505(b)(2) NDA submitted by another company for another version of such drug

where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of marketing

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exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, for new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA; however, an applicant submitting a full NDA would be required to conduct, or obtain a right of reference to all of the pre-clinical studies, adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Foreign Regulation

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we must obtain approval by the comparable regulatory authorities of foreign countries before we can commence clinical trials and approval of foreign countries or economic areas, such as the European Union, before we may market products in those countries or areas. The approval process and requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from place to place, and the time may be longer or shorter than that required for FDA approval.

In the European Economic Area, or EEA, which is comprised of the 27 member states of the European Union, or Member States, plus Norway, Iceland and Liechtenstein, medicinal products can only be commercialized after obtaining a Marketing Authorization, or MA. There are two types of MAs:

Community MAs These are issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use, or CHMP, of the European Medicines Agency, or EMA, and are valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, and medicinal products indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA; for products that constitute a significant therapeutic, scientific or technical innovation; or for products that are in the interest of public health in the European Union.

National MAs These are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, and are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA, this National MA can be recognized in another Member State through the Mutual Recognition Procedure. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure. Under the Decentralized Procedure, an identical dossier is submitted to the competent authorities of each of the Member States in which the MA is sought, one of which is selected by the applicant as the Reference Member State. The competent authority of the Reference Member State prepares a draft assessment report, a draft summary of the product characteristics, or SPC, and a draft of the labeling and package leaflet, which are sent to the other Member States (referred to as the Member States Concerned) for their approval. If the Member States Concerned raise no objections, based on a potential serious risk to public health, to the

assessment, SPC, labeling or packaging proposed by the Reference Member State, the product is subsequently granted a National MA in all the Member States (i.e., in the Reference Member State and the Member States Concerned).

Under the above described procedures, before granting the MA, the EMA or the competent authorities of the Member States of the EEA assess the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy. As in the United States, it may be possible in foreign countries to obtain a period of market and/or data exclusivity that would have the effect of postponing the entry into the

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marketplace of a competitor s generic product. For example, if any of our products receive marketing approval in the EEA, we expect they will benefit from eight years of data exclusivity and ten years of marketing exclusivity. An additional non-cumulative one-year period of marketing exclusivity is possible if during the data exclusivity period (the first eight years of the 10-year marketing exclusivity period), we obtain an authorization for one or more new therapeutic indications that are deemed to bring a significant clinical benefit compared to existing therapies. The data exclusivity period begins on the date of the product s first marketing authorization in the European Union and prevents generics from relying on the marketing authorization holder s pharmacological, toxicological and clinical data for a period of eight years. After eight years, a generic product application may be submitted and generic companies may rely on the marketing authorization holder s data. However, a generic cannot launch until two years later (or a total of 10 years after the first marketing authorization in the European Union of the innovator product), or three years later (or a total of 11 years after the first marketing authorization in the European Union of the innovator product) if the marketing authorization holder obtains marketing authorization for a new indication with significant clinical benefit within the eight-year data exclusivity period. In Japan, our products may be eligible for eight years of data exclusivity. There can be no assurance that we will qualify for such regulatory exclusivity, or that such exclusivity will prevent competitors from seeking approval solely on the basis of their own studies.

When conducting clinical trials in the European Union, we must adhere to the provisions of the European Union Clinical Trials Directive and the laws and regulations of the European Union Member States implementing them. These provisions require, among other things, that the prior authorization of an Ethics Committee and the competent Member State authority is obtained before commencing the clinical trial.

Pricing and Reimbursement

In the United States and internationally, sales of products that we market in the future, and our ability to generate revenues on such sales, are dependent, in significant part, on the availability of adequate coverage and reimbursement from third-party payors, such as state and federal governments, managed care providers and private insurance plans. Private insurers, such as health maintenance organizations and managed care providers, have implemented cost-cutting and reimbursement initiatives and likely will continue to do so in the future. These include establishing formularies that govern the drugs and biologics that will be offered and the out-of-pocket obligations of member patients for such products. We may need to conduct pharmacoeconomic studies to demonstrate the cost-effectiveness of our products for formulary coverage and reimbursement. Even with such studies, our products may be considered less safe, less effective or less cost-effective than existing products, and third-party payors may not provide coverage and reimbursement for our product candidates, in whole or in part.

In addition, particularly in the United States and increasingly in other countries, we are required to provide discounts and pay rebates to state and federal governments and agencies in connection with purchases of our products that are reimbursed by such entities. It is possible that future legislation in the United States and other jurisdictions could be enacted to potentially impact reimbursement rates for the products we are developing and may develop in the future and could further impact the levels of discounts and rebates paid to federal and state government entities. Any legislation that impacts these areas could impact, in a significant way, our ability to generate revenues from sales of products that, if successfully developed, we bring to market.

Political, economic and regulatory influences are subjecting the health care industry in the United States to fundamental changes. There have been, and we expect there will continue to be, legislative and regulatory proposals to change the health care system in ways that could significantly affect our future business. For example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively, the PPACA, enacted in March 2010, substantially changes the way health care is financed by both governmental and private insurers. Among other cost containment measures, PPACA establishes:

an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents;

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a new Medicare Part D coverage gap discount program, in which pharmaceutical manufacturers who wish to have their drugs covered under Part D must offer discounts to eligible beneficiaries during their coverage gap period, or the donut hole; and

a new formula that increases the rebates a manufacturer must pay under the Medicaid Drug Rebate Program.

In addition, other legislative changes have been proposed and adopted in the United States since the PPACA was enacted, which, among other things, potentially reduce Medicare payments to providers by up to 2% per fiscal year.

Sales and Marketing

The FDA regulates all advertising and promotion activities for products under its jurisdiction prior to and after approval, including standards and regulations for direct-to-consumer advertising, dissemination of off-label information, industry-sponsored scientific and educational activities and promotional activities involving the Internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved label. Further, if there are any modifications to the drug, including changes in indications, labeling, or manufacturing processes or facilities, we may be required to submit and obtain FDA approval of a new or supplemental NDA, which may require us to collect additional data or conduct additional pre-clinical studies and clinical trials. Failure to comply with applicable FDA requirements may subject a company to adverse publicity, enforcement action by the FDA, corrective advertising, consent decrees and the full range of civil and criminal penalties available to the FDA.

Physicians may prescribe legally available drugs for uses that are not described in the drug s labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties, and often reflect a physician s belief that the off-label use is the best treatment for the patient. The FDA does not regulate the behavior of physicians in their choice of treatments, but FDA regulations do impose stringent restrictions on manufacturers communications regarding off-label uses. Failure to comply with applicable FDA requirements may subject a company to adverse publicity, enforcement action by the FDA, corrective advertising, consent decrees and the full range of civil and criminal penalties available to the FDA.

Outside the United States, our ability to market a product is contingent upon obtaining marketing authorization from the appropriate regulatory authorities. The requirements governing marketing authorization, pricing and reimbursement vary widely from country to country.

We may also be subject to various federal and state laws pertaining to health care fraud and abuse, including anti-kickback laws and false claims laws. Anti-kickback laws make it illegal for a prescription drug manufacturer to solicit, offer, receive, or pay any remuneration in exchange for, or to induce, the referral of business, including the purchase or prescription of a particular drug. Due to the breadth of the statutory provisions, the absence of guidance in the form of regulations, and very few court decisions addressing industry practices, it is possible that our practices might be challenged under anti-kickback or similar laws. False claims laws prohibit anyone from knowingly and willingly presenting, or causing to be presented, for payment to third-party payors (including Medicare and Medicaid) claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. Our activities relating to the sale and marketing of our products may be subject to scrutiny under these laws.

Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including fines and civil monetary penalties, the possibility of exclusion from federal health care programs (including Medicare and Medicaid) and corporate integrity agreements, which impose, among other things, rigorous operational and monitoring requirements on companies. Similar sanctions and penalties also may be imposed upon executive

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officers and employees, including criminal sanctions against executive officers under the so-called responsible corporate officer doctrine, even in situations where the executive officer did not intend to violate the law and was unaware of any wrongdoing. Given the penalties that may be imposed on companies and individuals if convicted, allegations of such violations often result in settlements even if the company or individual being investigated admits no wrongdoing. Settlements often include significant civil sanctions, including fines and civil monetary penalties, and corporate integrity agreements. If the government was to allege or convict us or our executive officers of violating these laws, our business could be harmed. In addition, private individuals have the ability to bring similar actions. Our activities could be subject to challenge for the reasons discussed above and due to the broad scope of these laws and the increasing attention being given to them by law enforcement authorities. Further, there are an increasing number of state laws that require manufacturers to make reports to states on pricing and marketing information. Many of these laws contain ambiguities as to what is required to comply with the laws. Given the lack of clarity in laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent state authorities.

Employees

As of March 1, 2014, we employed 22 employees, 21 of whom were full-time. To successfully develop our drug candidates, we must be able to attract and retain highly skilled personnel. We anticipate hiring additional employees for research and development, clinical and regulatory affairs and general and administrative activities over the next few years. In addition, we intend to use clinical research organizations and third parties to perform our clinical studies and manufacturing.

Properties

Our headquarters are located at 3960 Broadway, New York, New York 10032, where we occupy approximately 11,600 square feet of office and laboratory space. The term of the lease expires September 30, 2014, and we have the option to extend the term of the lease for six additional months, until March 31, 2015. We also lease office space in Towson, Maryland on a month to month basis.

On March 31, 2014, we entered into a long-term lease for approximately 12,000 square feet of useable laboratory and office space located at 430 East 29th Street, New York, New York 10016, which we expect to occupy as our headquarters on or about February 2015. The lease has a term of five years.

Legal Proceedings

We are not currently a party to any material legal proceedings.

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MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion of the financial condition and results of our operations and our wholly-owned subsidiary should be read in conjunction with the financial statements and the notes to those statements appearing elsewhere in this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. You should read the Risk Factors section of this prospectus for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a biopharmaceutical company focused on the discovery 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. Our lead product candidate, ITI-007, is in Phase 2 clinical trials as a first-in-class treatment for schizophrenia. Results from the Phase 2 trial are included in the Description of Our Business Our Clinical Programs ITI-007 Program section of this prospectus. Subject to discussions with the U.S. Food and Drug Administration, or FDA, we intend to initiate Phase 3 clinical trials and additional supporting trials in patients with acute exacerbated schizophrenia in the second half of 2014 and 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. In addition, in March 2014, we announced the initiation of 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. We believe that ITI-007 and follow-on compounds have utility to treat additional indications, which we may investigate, either on our own or with a partner. We hold exclusive, worldwide commercialization rights to ITI-007 and a family of related compounds from Bristol-Myers Squibb Company.

We have a second major program called ITI-002 that has yielded a portfolio of compounds that selectively inhibits the enzyme PDE1. We have licensed the lead compound in the ITI-002 portfolio, ITI-214, and other compounds in that portfolio, to Takeda. ITI-214 is the first compound in its class to successfully advance into Phase 1 clinical trials and is being developed for the treatment of cognitive impairment associated with schizophrenia and other disorders.

Our pipeline also includes preclinical 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.

Since inception, we have devoted all of our efforts and resources to our research and development activities. We have incurred significant net losses since inception. As of December 31, 2013, our accumulated deficit was $57.6 million. We expect to continue incurring substantial losses for the next several years as we continue to develop our clinical and pre-clinical drug candidates and programs. Our operating expenses are comprised of research and development expenses and general and administrative expenses.

We have not generated any revenue from product sales to date and we do not expect to generate revenues from product sales for at least the next several years. Our revenues for fiscal years ended December 31, 2013 and 2012 have been from the license and collaboration agreement with Takeda. In addition, we have received and may continue to receive grants from U.S. government agencies and foundations.

Our corporate headquarters and research facility are located in New York, New York.

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Reverse Merger and Private Placement in August 2013

On August 29, 2013, we consummated a merger with the privately held biopharmaceutical company formerly named Intra-Cellular Therapies, Inc., and changed our name from Oneida Resources Corp. to Intra-Cellular Therapies, Inc. The privately held company survived the merger as a wholly owned subsidiary of ours and changed its name to ITI, Inc., or ITI.

At the effective time of the merger, each share of ITI common stock and each share of ITI preferred stock that was issued and outstanding was automatically exchanged for 0.5 shares of our common stock. We issued an aggregate of 22,134,647 shares of our common stock upon such exchange of the outstanding shares of ITI common stock and preferred stock. In addition, at the effective time, we assumed all of ITI s outstanding stock options and its warrant to purchase common stock.

In accordance with Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, Topic 805, *Business Combinations*, ITI is considered the acquirer for accounting purposes, and we have accounted for the transaction as a capital transaction, because ITI s former stockholders received 100% of the voting rights in the combined entity and ITI s senior management represented all of the senior management of the combined entity. Consequently, the assets and liabilities and the historical operations that are reflected in our consolidated financial statements are those of ITI and are recorded at the historical cost basis of the Company.

Immediately prior to the Merger, ITI sold to accredited investors approximately $60.0 million of its shares of common stock, or 18,889,307 shares, at a price of $3.1764 per share, 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, or Notes, and which resulted in net proceeds, after expenses, of approximately $40.0 million. We refer to this transaction as the Private Placement.

Public Offering in February 2014

On February 5, 2014, we completed our initial public offering of 7,063,300 shares of our common stock at a price of $17.50 per share for aggregate gross proceeds of approximately $123.6 million, and net proceeds of approximately $115.4 million.

Results of Operations

Revenues

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

We have not generated any revenue from product sales to date and we do not expect to generate revenues from product sales for at least the next several years. Our revenues for fiscal years ended December 31, 2013 and 2012 have been from the license and collaboration agreement with Takeda. In addition, we have received and may continue to receive grants from U.S. government agencies and foundations.

The revenue from Takeda was comprised primarily of an upfront payment, a milestone payment and reimbursements for costs incurred in the development of and patent prosecutions for compounds subject to the collaboration. The upfront payment was evaluated and it was determined that there were separate units of accounting for the deliverables that are provided for in the license and collaboration agreement. A larger portion of the upfront payment was

considered a license fee, and the remaining portion was deemed to be related to the performance of agreed upon activities under the collaboration component of the license and collaboration agreement. We determined this amount in accordance with ASC Topic 605-25, *Revenue Recognition,* using best estimate of selling price, for the work that we would be required to perform. We considered multiple factors in estimating this amount, including, but not limited to, direct external expenses and internal costs for salary and

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related fringes, among others. The straight line method of amortization with a three-year schedule was used and revenue was recognized equally for the years 2011 through 2013. Revenue from the license payment was recognized as earned when received. Revenue from milestone payments is recognized when all of the following conditions are met: (1) the milestone payments are non-refundable, (2) the achievement of the milestone involves a degree of risk and was not reasonably assured at the inception of the arrangement, (3) substantive effort on our part is involved in achieving the milestone, (4) the amount of the milestone payment is reasonable in relation to the effort expended or the risk associated with achievement of the milestone, and (5) a reasonable amount of time passes between the up-front license payment and the first milestone payment. Reimbursement revenue is recognized when the costs are incurred and the services have been performed.

We expect our revenues for the next several years to consist of limited reimbursable costs incurred for patent prosecutions and reimbursements related to our collaboration with Takeda under the license and collaboration agreement. In addition, we expect to receive possible milestone payments under the license and collaboration agreement, but these are not assured at this time and would not be significant enough to fund operations for a meaningful period of time.

Expenses

The process of researching and developing drugs for human use is lengthy, unpredictable and subject to many risks. We are unable with any certainty to estimate either the costs or the timelines in which those costs will be incurred. We have one project, ITI-007 for the treatment of schizophrenia, which consumes a large proportion of our current, as well as projected, resources. In addition, in March 2014, we announced the initiation of 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. We intend to pursue other disease indications that ITI-007 may address, but there are large costs associated with pursuing FDA approval for those indications, which would include the cost of additional clinical trials. Our other projects, exclusive of the Takeda collaboration, are still in the preclinical stages, and will require extensive funding not only to complete preclinical testing, but to enter into and complete clinical trials. Expenditures that we incur on these projects will be subject to availability of funding in addition to the funding required for the advancement of ITI-007. Any failure or delay in the advancement of ITI-007 could require us to re-allocate resources from our other projects to the advancement of ITI-007, which could have a significant material adverse impact on the advancement of these other projects and on our operations.

Our operating expenses are comprised of (i) research and development expenses and (ii) general and administrative expenses. Our research and development costs are comprised of:

- internal recurring costs, such as labor and fringe benefits, materials and supplies, facilities and maintenance costs; and

- fees paid to external parties who provide us with contract services, such as preclinical testing, manufacturing and related testing, and clinical trial activities.

General and administrative expenses are incurred in three major categories:

salaries and related benefit costs;

patent, legal and professional costs; and

office and facilities overhead.

We expect that our general and administrative costs will increase substantially from prior periods due to the increased costs associated with being a public reporting entity.

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The following table sets forth our revenues and operating expenses for the fiscal years ended December 31, 2013 and 2012:

	For the Year Ended December 31,	
	2013	2012
	(in thousands)	
	(Audited)	
Revenues	$ 2,737	$ 3,118
Expenses		
Research and Development	23,028	15,486
General and Administrative	5,976	4,035
	29,004	19,521
Net Loss	$ (26,868)	$ (16,591)

Comparison of Years Ended December 31, 2013 and December 31, 2012

Revenues

Revenue decreased for the year ended December 31, 2013 as compared to the year ended December 31, 2012 by approximately $0.4 million, due primarily to lower reimbursable costs from Takeda in 2013 as compared to 2012.

Research and Development Expenses

Total research and development expenses were approximately $23.0 million for the fiscal year ended December 31, 2013, as compared to $15.5 million for the fiscal year ended December 31, 2012. This increase of $7.5 million in total research and development expenses is due primarily to an increase of $6.3 million in direct costs for clinical trials, which is primarily the result of an increase in the number of clinical trial subjects for our Phase 2 trial of ITI-007 in patients with acutely exacerbated schizophrenia and $1.25 million for a milestone payment we made related to our license agreement with BMS. Clinical trial costs for the fiscal year ended December 31, 2013 were $16.9 million as compared to $10.6 million for the fiscal year ended December 31, 2012 due to more patients screened and tested in 2013 versus 2012 and the costs associated with the non-patent related data, statistical and other testing needed to complete the study.

The research and development process necessary to develop a pharmaceutical product for commercialization is subject to extensive regulation by numerous governmental authorities in the United States and other countries. This process typically takes years to complete and requires the expenditure of substantial resources. The steps required before a drug may be marketed in the United States generally include the following:

- completion of extensive pre-clinical laboratory tests, animal studies, and formulation studies in accordance with the FDA s Good Laboratory Practice, or GLP, regulations;

submission to the FDA of an Investigational New Drug application, or IND, for human clinical testing, which must become effective before human clinical trials may begin;

performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the drug for each proposed indication;

submission to the FDA of a New Drug Application, or NDA, after completion of all clinical trials;

satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the active pharmaceutical ingredient, or API, and finished drug product are produced and tested to assess compliance with current Good Manufacturing Practices, or cGMPs;

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satisfactory completion of FDA inspections of clinical trial sites to assure that data supporting the safety and effectiveness of product candidates has been generated in compliance with Good Clinical Practices; and

FDA review and approval of the NDA prior to any commercial marketing or sale of the drug in the United States.

The successful development of our product candidates and the approval process requires substantial time, effort and financial resources, and is uncertain and subject to a number of risks. We cannot be certain that any of our product candidates will prove to be safe and effective, will meet all of the applicable regulatory requirements needed to receive and maintain marketing approval, or will be granted marketing approval on a timely basis, if at all. Data from preclinical studies and clinical trials are susceptible to varying interpretations that could delay, limit or prevent regulatory approval or could result in label warnings related to or recalls of approved products. We, the FDA, or other regulatory authorities may suspend clinical trials at any time if we or they believe that the subjects participating in such trials are being exposed to unacceptable risks or if such regulatory agencies find deficiencies in the conduct of the trials or other problems with our product candidates. Other risks associated with our product candidates are described in the Risk Factors section of this prospectus.

The research and development expenses incurred for amounts payable to external parties comprise a significant portion of our research and development spending during the fiscal years ended December 31, 2012 and 2013, due primarily to the preparation for and commencement of our Phase 2 clinical trial for ITI-007 in patients with acutely exacerbated schizophrenia. We incurred expenses of approximately $18.8 million and $12.6 million during the years ended December 31, 2013 and 2012, respectively, for amounts payable to external parties who manufactured, tested and performed clinical trial activities for all of our projects. During the same periods, our internal research and development expenses were approximately $3.0 million and $2.9 million during the years ended December 31, 2013 and 2012, respectively. As of December 31, 2013, we employed 13 full time personnel in our research and development group.

The clinical development work related to ITI-007 requires the largest portion of our resources and, consequently, comprises the majority of our spending. We spent approximately $21.0 million and $11.3 million on direct costs for the development of ITI-007 during the periods ended December 31, 2013 and 2012, respectively. As development of ITI-007 progresses, we anticipate costs for ITI-007 to increase considerably in the next several years as we conduct Phase 3 and other clinical trials. We are also required to complete non-clinical testing to obtain FDA approval and manufacture material needed for clinical trial use, which includes non-clinical testing of the drug product and the creation of an inventory of drug product in anticipation of possible FDA approval.

We currently have several projects in addition to ITI-007 that are in the research and development stages. These are in the areas of cognitive dysfunction and the treatment of neurodegenerative diseases, including Alzheimer s disease, among others. We have used internal resources and incurred expenses not only in relation to the development of ITI-007 but on these additional projects as well. We have not, however, reported these costs on a project by project basis, as they are broadly spread among these projects. The external costs for these projects have been minimal and are reflected in the amounts discussed in this section Research and Development Expenses. During the years ended December 31, 2013 and 2012, we also incurred costs that were both reimbursable and non-reimbursable under the license and collaboration agreement with Takeda. We incurred approximately $97,000 and $700,000 on direct costs that were billable to Takeda for the years ended December 31, 2013 and 2012, respectively. We anticipate that these costs will be reduced significantly as the research portion of the license and collaboration agreement concluded in February 2014.

General and Administrative Expenses

Salaries, bonuses and related benefit costs for our executive, finance and administrative functions for both 2013 and 2012 constituted slightly less than half of our total general and administrative costs. The next major

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categories of expenses are patent costs, some of which are reimbursed by Takeda, legal, accounting and other professional fees and, to a lesser extent, facilities and general office-related overhead. We expect all of these costs to increase significantly as we expand our operations and have become subject to the reporting requirements of a public company. General and administrative expenses were $6.0 million for the fiscal year ended December 31, 2013 compared to $4.0 million for the fiscal year ended December 31, 2012. The increase is the result of higher personnel costs, legal, accounting, patent and public company reporting-related costs, including costs related to the reverse merger and private placement in August 2013.

Liquidity and Capital Resources

Through December 31, 2013, we have funded our operations with approximately $149.8 million of cash that has been obtained from the following main sources: $40.0 million of net proceeds from the Private Placement which closed on August 29, 2013 (net of $0.2 million of unpaid costs); $25.4 million from other sales of equity; $0.4 million from the exercise of stock options; $15.3 million in sales of convertible promissory notes; $40.6 million from grants from government agencies and foundations; and $28.1 million in total payments received under the license and collaboration agreement with Takeda, including approximately $1.8 million for reimbursement of development costs incurred from 2011 through December 31, 2013, and $1.8 million for patent costs incurred during the same time period. During the fiscal year ended December 31, 2013, we did not receive any funding through grants. We do not believe that grant revenue will be a significant source of funding in the near future. We expect that reimbursements of our development costs by Takeda will decline going forward, and we do not expect such reimbursements to be a significant source of funding in the future. We also expect the reimbursements for patent filing costs will remain at the same level, but because reimbursements will be offset by the actual expenditures incurred, reimbursements do not represent a net source of funding for us.

In October and November 2012, we issued convertible promissory notes, or Notes, having an aggregate principal amount of approximately $15.2 million. We issued additional Notes having an aggregate principal amount of $0.1 million in March 2013. The Notes were unsecured and accrued interest at a rate of 6% per year, and were originally scheduled to mature on April 25, 2013, but maturity was extended until October 25, 2013. The principal amount of the Notes, together with the accrued interest thereon, converted into shares of ITI common stock at the closing of the Private Placement.

As of December 31, 2013, we had a total of $37.2 million in cash, cash equivalents and certificates of deposit, and approximately $6.8 million of short-term liabilities consisting of short-term liabilities from operations. Excluding the increase in net cash of approximately $40.0 million from the Private Placement which closed in August 2013 (net of $0.2 million of unpaid costs) and the conversion of $15.2 million of convertible notes outstanding at December 31, 2012, we used $25.3 million in working capital for the year ended December 31, 2013. This reduction in working capital is due primarily to the funding of the Phase 2 clinical trial for ITI-007 in patients with acutely exacerbated schizophrenia, and to a lesser extent to fund recurring operating expenses, the preparation for additional clinical trials and non-clinical testing. On February 5, 2014, we raised approximately $115.4 million in net proceeds from a public offering of our common stock. Excluding the effect of the offering, we expect to consume working capital of approximately $7.5 million to $8.0 million during the first quarter of 2014. This is expected to be due primarily to recurring expenses and for costs incurred for the completion of the Phase 2 clinical trial and the preparations for additional trials and non-clinical testing related to the development of ITI-007, including initiation of a Phase 3 clinical trial in patients with acutely exacerbated schizophrenia and a Phase 1/2 clinical trial in healthy geriatric subjects and in patients with dementia, including Alzheimer s disease. In connection with the completion of our Phase 2 clinical trial of ITI-007 in patients with acutely exacerbated schizophrenia, we made a milestone payment of $1.25 million to BMS during the fourth quarter of 2013.

Our cash, cash equivalents and investment securities totaled $37.2 million at December 31, 2013. In addition, we received net proceeds of approximately $115.4 million from our public offering of common stock, which closed on February 5, 2014. While we believe that our existing cash, cash equivalents and investment

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securities, together with interest on cash balances, will be sufficient to fund our operating expenses and capital expenditure requirements through early 2016, we will require significant additional financing in the future to continue to fund our operations. 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 acute exacerbated schizophrenia, our Phase 1/2 clinical trial of ITI-007 in healthy geriatric subjects and in patients with dementia, including Alzheimer s disease, for further development of ITI-007 in patients with bipolar disorder and other indications, and for development of our other product candidates.

We have incurred losses in every year since inception with the exception of, 2011, due to the up-front fee received from Takeda in connection with entry into our collaboration agreement. These losses have resulted in significant cash used in operations. During the fiscal years ended December 31, 2013 and 2012, our cash used in operations was approximately $22.6 million and $18.9 million respectively. This increase of cash used during the fiscal year ended December 31, 2013 is primarily due to the clinical development and clinical trial activities for ITI-007. While we have several research and development programs underway, the ITI-007 program has advanced the furthest and will continue to consume increasing amounts of cash for conducting clinical trials and the testing and manufacturing of product material. As we continue to conduct these activities necessary to pursue FDA approval of ITI-007 and our other product candidates, we expect the cash needed to fund operations to increase significantly over the next several years.

We seek to balance the level of cash, cash equivalents and marketable securities on hand with our projected needs and to allow us to withstand periods of uncertainty relative to the availability of funding on favorable terms. Until we can generate significant revenues from operations, we will need to satisfy our future cash needs through public or private sales of our equity securities, sales of debt securities, 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 cannot be sure that future funding will be available to us when we need it on terms that are acceptable to us, or at all. We sell securities and incur debt when the terms of such transactions are deemed favorable to us and as necessary to fund our current and projected cash needs. The amount of funding we raise through sales of our common stock or other securities depends on many factors, including, but not limited to, the status and progress of our product development programs, projected cash needs, availability of funding from other sources, our stock price and the status of the capital markets. Due to the recent volatile nature of the financial markets and, in particular, the adverse impact on market capitalization and valuation of biotechnology companies, equity and debt financing may be difficult to obtain. In addition, any unfavorable development or delay in the progress of our ITI-007 program could have a material adverse impact on our ability to raise additional capital.

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 adequate funds are not available to us on a timely basis, we may be required to: (1) delay, limit, reduce or terminate preclinical studies, clinical trials or other clinical development activities for one or more of our product candidates, including our lead candidate ITI-007 as well as our other preclinical stage product candidates; (2) delay, limit, reduce or terminate our discovery research or preclinical development activities; or (3) enter into licenses or other arrangements with third parties on terms that may be unfavorable to us or sell, license or relinquish rights to develop or commercialize our product candidates, technologies or intellectual property at an earlier stage of development and on less favorable terms than we would otherwise agree.

Our cash is maintained in money market accounts and, to a lesser extent, in certificates of deposit at major financial institutions. Due to the current low interest rates available for these instruments, we are earning limited

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interest income. Our investment portfolio has not been adversely impacted by the problems in the credit markets that have existed over the last several years, but there can be no assurance that our investment portfolio will not be adversely affected in the future.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP. The preparation of these financial statements requires management to make estimates and assumptions that affect reported amounts of assets and liabilities as of the date of the balance sheet and reported amounts of revenues and expenses for the periods presented. Judgments must also be made about the disclosure of contingent liabilities. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Management makes estimates and exercises judgment in revenue recognition and stock-based compensation. Actual results may differ from those estimates and under different assumptions or conditions.

We believe that the following critical accounting policies affect management s more significant judgments and estimates used in the preparation of our financial statements:

Revenue Recognition

Revenue is recognized when all terms and conditions of the agreements have been met, including persuasive evidence of an arrangement, delivery has occurred or services have been rendered, price is fixed or determinable and collectability is reasonably assured. We are reimbursed for certain costs incurred on specified research projects under the terms and conditions of grants, collaboration agreements, and awards. We record the amount of reimbursement as revenues on a gross basis in accordance with ASC Topic 605-45, *Revenue Recognition/Principal Agent Considerations*. We are the primary obligor with respect to purchasing goods and services from third-party suppliers, are obligated to compensate the service provider for the work performed, and have discretion in selecting the supplier. Provisions for estimated losses on research grant projects and any other contracts are made in the period such losses are determined.

Effective January 1, 2011, we adopted a new accounting standard that amends the guidance on the accounting for arrangements involving the delivery of more than one element. Pursuant to the new standard, each required deliverable is evaluated to determine whether it qualifies as a separate unit of accounting. For us, this determination is generally based on whether the deliverable has stand-alone value to the customer. We adopted this new accounting standard on a prospective basis for all Multiple-Deliverable Revenue Arrangements, or MDRAs, entered into on or after January 1, 2011, and for any MDRAs that were entered into prior to January 1, 2011, but materially modified on or after that date.

For MDRAs entered into prior to January 1, 2011 (pre-2011 arrangements) and not materially modified thereafter, we continue to apply our prior accounting policy with respect to such arrangements. Under this policy, in general, revenue from non-refundable, up-front fees related to intellectual property rights/licenses, where we have continuing involvement and where standalone value could not be determined under the previous guidance, is recognized ratably

over the estimated period of ongoing involvement. In general, the consideration with respect to the other deliverables is recognized when the goods or services are delivered.

The adoption of this accounting standard did not have a material impact on our results of operations for the years ended December 31, 2013, 2012 and 2011, or on our financial positions as of those dates.

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In January 2011, we adopted ASC Topic 605-28, *Milestone Method*. Under this guidance, we recognize revenue contingent upon the achievement of a substantive milestone in its entirety in the period the milestone is achieved. Substantive milestone payments are recognized upon achievement of the milestone only if all of the following conditions are met:

- the milestone payments are non-refundable;
- achievement of the milestone involves a degree of risk and was not reasonably assured at the inception of the arrangement;
- substantive effort on our part is involved in achieving the milestone;
- the amount of the milestone payment is reasonable in relation to the effort expended or the risk associated with achievement of the milestone; and
- a reasonable amount of time passes between the up-front license payment and the first milestone payment, as well as between each subsequent milestone payment.

Determination as to whether a payment meets the aforementioned conditions involves management s judgment. If any of these conditions are not met, the resulting payment would not be considered a substantive milestone, and therefore, the resulting payment would be considered part of the consideration for the single unit of accounting and be recognized as revenue as such performance obligations are performed under either the proportional performance or straight-line methods, as applicable. In addition, the determination that one such payment was not a substantive milestone could prevent us from concluding that subsequent milestone payments were substantive milestones and, as a result, any additional milestone payments could also be considered part of the consideration for the single unit of accounting and would be recognized as revenue as such performance obligations are performed under either the proportional performance or straight-line methods, as applicable.

Stock-Based Compensation

Stock-based payments are accounted for in accordance with the provisions of ASC Topic 718, *Compensation Stock Compensation*. The fair value of share-based payments is estimated, on the date of grant, using the Black-Scholes-Merton option-pricing model, or the Black-Scholes model. The resulting fair value is recognized ratably over the requisite service period, which is generally the vesting period of the option.

For all time vesting awards granted, expense is amortized using the straight-line attribution method. For awards that contain a performance condition, expense is amortized using the accelerated attribution method. As stock-based compensation expense recognized in the statements of operations for the fiscal years ended December 31, 2013, 2012 and 2011 is based on share-based awards ultimately expected to vest, it has been reduced for estimated forfeitures. ASC Topic 718 requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Pre-vesting forfeitures are based on our historical experience for the fiscal years ended December 31, 2013, 2012 and 2011, and have not been material.

We utilize the Black-Scholes model for estimating fair value of our stock options granted. Option valuation models, including the Black-Scholes model, require the input of subjective assumptions, and changes in the assumptions used can materially affect the grant date fair value of an award. These assumptions include the risk-free rate of interest, expected dividend yield, expected volatility and the expected life of the award.

Expected volatility rates are based on historical volatility of the common stock of comparable publicly traded entities and other factors due to the lack of historic information of our common stock. The expected life of stock-based options is the period of time for which the stock-based options are expected to be outstanding. Given the lack of historic exercise data, the expected life is determined using the simplified method which is defined as the midpoint between the vesting date and the end of the contractual term.

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The risk-free interest rates are based on the U.S. Treasury yield for a period consistent with the expected term of the option in effect at the time of the grant. We have not paid dividends to our stockholders since our inception and do not plan to pay cash dividends in the foreseeable future. Therefore, we have assumed an expected dividend rate of zero.

Given the absence of an active market for our common stock during 2012 and 2013, the exercise price of the stock options on the date of grant was determined and approved by the board of directors using several factors, including progress and milestones achieved in our business development and performance, the price per share of our convertible preferred stock offerings and general industry and economic trends. In establishing the estimated fair value of our common stock, we considered the guidance set forth in American Institute of Certified Public Accountants Practice Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*.

Under ASC Topic 718, the cumulative amount of compensation cost recognized for instruments classified as equity that ordinarily would result in a future tax deduction under existing tax law shall be considered to be a deductible difference in applying ASC Topic 740, *Income Taxes*. The deductible temporary difference is based on the compensation cost recognized for financial reporting purposes; however, these provisions currently do not impact us, as all the deferred tax assets have a full valuation allowance.

Since we had net operating loss carryforwards as of December 31, 2013 and 2012, no excess tax benefits for the tax deductions related to share-based awards were recognized in the statements of operations.

Equity instruments issued to non-employees are accounted for under the provisions of ASC Topic 718 and ASC Topic 505-50, *Equity/Equity-Based Payments to Non-Employees*. Accordingly, the estimated fair value of the equity instrument is recorded on the earlier of the performance commitment date or the date the services required are completed and are marked to market during the service period.

Recently Issued Accounting Pronouncements

We review new accounting standards to determine the expected financial impact, if any, that the adoption of each such standard will have. For the recently issued accounting standards that we believe may have an impact on our financial statements, see Notes to Consolidated Financial Statements Note 2 Summary of Significant Accounting Policies included in this prospectus.

Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

Effective at the Effective Time of the Merger, Raich Ende Malter & Co. LLP, or REM, was dismissed as the independent registered public accounting firm that audits the financial statements of the Company. Effective as of the Effective Time, our board of directors engaged Ernst & Young LLP, or E&Y, as the independent registered public accounting firm to audit the Company s financial statements for the fiscal year ended December 31, 2013.

REM s audit report on the Company s financial statements for the period from August 29, 2012 (inception) through March 31, 2013, did not contain an adverse opinion or a disclaimer of opinion and were not qualified or modified as to uncertainty, audit scope or accounting principles.

During the Company s most recent fiscal year (since inception) and any subsequent interim period prior to the date of this prospectus, there were no disagreements with REM on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedure, which disagreements, if not resolved to the satisfaction of REM, would have caused it to make reference to the subject matter thereof in connection with its report.

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During the Company s most recent fiscal year (since inception) and any subsequent interim period prior to the date of this prospectus, neither the Company nor anyone acting on its behalf consulted E&Y regarding the application of accounting principles to a specified transaction, either completed or proposed or the type of audit opinion that might be rendered on the Company s financial statements.

The Company has provided REM with a copy of this prospectus prior to the filing of the registration statement of which this prospectus forms a part, and has requested that REM furnish to the Company a letter addressed to the Securities and Exchange Commission stating whether REM agrees with the statements made by the Company in this prospectus. REM has furnished such letter, which letter is filed as Exhibit 16.1 to the registration statement of which this prospectus forms a part, as required by Item 304(a)(3) of Regulation S-K.

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DIRECTORS AND EXECUTIVE OFFICERS

The following table sets forth certain information concerning our executive officers and directors as of March 15, 2014:

Name	Age	Position
Executive Officers		
Sharon Mates, Ph.D.	61	Chairman, President and Chief Executive Officer
Lawrence J. Hineline	57	Vice President of Finance, Chief Financial Officer and Secretary
Allen A. Fienberg, Ph.D.	53	Vice President of Business Development
Juan F. Sanchez, M.D.	43	Vice President, Corporate Communications and Investor Relations
Kimberly E. Vanover, Ph.D.	48	Vice President, Clinical Development
Lawrence P. Wennogle, Ph.D.	64	Vice President, Drug Discovery
Non-Employee Directors		
Christopher Alafi, Ph.D.	50	Director
Richard Lerner, M.D.	75	Director
Joel S. Marcus	66	Director
Sir Michael Rawlins, M.D., FRCP, FMedSci	72	Director
Rory B. Riggs	60	Director
Robert L. Van Nostrand	56	Director

Executive Officers

Sharon Mates, Ph.D. Dr. Mates has been Chairman, President and Chief Executive Officer of the Company since the Merger in August 2013 and has been the Chairman of the board of directors, President and Chief Executive Officer of ITI since June 2002. Dr. Mates co-founded ITI in May 2002. Prior to co-founding ITI, Dr. Mates was a co-founder of Functional Genetics, and served as its Chairman and Chief Executive Officer from December 2000 until August 2003. From 1989 to 1998 Dr. Mates was the President and a board member of North American Vaccine Inc. and its predecessor companies. She has served on several boards, and recently completed a board membership and a two-year chairmanship of the Board of the New York Biotechnology Association. Dr. Mates has also served on the Advisory Council of the Center for Society and Health at the Harvard School of Public Health, the Board of Visitors of the Biotechnology Institute of the University of Maryland and the board of directors of Gilda s Club of New York. Earlier in her career, Dr. Mates spent several years as a research analyst and investment banker, and as an advisor to the life sciences industry. Dr. Mates received her B.S. from the Ohio State University and her Ph.D. from the University of Washington, and completed her postdoctoral fellowships at The Massachusetts General Hospital and Harvard Medical School.

We believe that Dr. Mates possesses specific attributes that qualify her to serve as chairman of our board of directors, including the perspective and experience she brings as the co-founder, President and Chief Executive of ITI, which brings historic knowledge, operational expertise and continuity to our board of directors, and her industry expertise, including over 24 years of experience leading both private and public companies.

Lawrence J. Hineline, *CPA*. Mr. Hineline has served as Vice President of Finance, Chief Financial Officer and Secretary of the Company since the Merger in August 2013 and has served as Vice President of Finance, Chief Financial Officer and Secretary of ITI since June 2002. From December 2000 to November 2003, Mr. Hineline was the Vice President of Finance and Chief Financial Officer of Functional Genetics, Inc. Prior to that, Mr. Hineline served as the Vice President of Finance of North American Vaccine, Inc. and its predecessor companies from 1993 to 2000, and he served as Corporate Controller from 1989 to 1993. During this time,

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Mr. Hineline oversaw the growth of the accounting function and its systems for the company that emerged as a start-up and was later acquired by Baxter Health Care. Mr. Hineline is a licensed CPA in the State of Maryland and received his Bachelor s Degree from the University of Maryland Baltimore County.

Allen A. Fienberg, Ph.D. Dr. Fienberg has served as Vice President of Business Development of the Company since the Merger in August 2013 and has served as Vice President of Business Development of ITI since June 2002. He co-founded ITI in May 2002. Dr. Fienberg received his A.B. degree in Genetics from the University of California, Berkeley and his Ph.D. in Human Genetics from Yale University. He completed post-doctoral studies at The Rockefeller University under the direction of Dr. Paul Greengard from 1991-1999. From 1999-2001, Dr. Fienberg was a staff scientist at the Genomics Institute of the Novartis Research Foundation and was appointed a Research Assistant Professor at The Rockefeller University from 2001-2002.

Juan F. Sanchez, M.D. Dr. Sanchez has been our Vice President, Corporate Communications and Investor Relations since March 2014. Previously, he was a healthcare research analyst at investment banking firm Ladenburg Thalmann & Co. Inc., with a deep focus on companies specializing in central nervous system diseases from 2008 to 2014, most recently as a Managing Director. Prior to that time, he was a Vice President of healthcare and nanotechnology equity research at investment banking firm Punk, Ziegel, & Co. Dr. Sanchez received his Master in International Affairs from Columbia University and his Master of Business Administration from University of Los Andes in Bogota, Colombia. Dr Sanchez practiced medicine for five years in his native country, Colombia, having received a medical degree from Pontifical Xavierian University, in Bogota.

Kimberly E. Vanover, Ph.D. Dr. Vanover has been Vice President, Clinical Development of the Company since the Merger in August 2013. Dr. Vanover joined ITI in March 2007 and has been Vice President, Clinical Development of ITI since January 2011. Previously, she was Executive Director, Clinical Development of ITI from January 2008 to December 2010 and Senior Director, Clinical Development of ITI from March 2007 to December 2007. She has spent over 20 years on the discovery and development of small molecule drugs for the treatment of neuropsychiatric and neurodegenerative diseases. Dr. Vanover was Postdoctoral Research Scientist at Lederle Laboratories from 1992 to 1994, Postdoctoral Research Trainee in the Department of Psychiatry at the University of California San Diego from 1994 to 1995, Senior Scientist and Group Leader at CoCensys from 1995 to 2000 and held positions as Group Leader and Director at ACADIA Pharmaceuticals from 2000 to 2007. In these positions, Dr. Vanover participated in the discovery and development of a broad range of new CNS therapeutics, including drugs to treat psychosis, insomnia, cognitive impairment, movement disorders, acute and neuropathic pain, anxiety, epilepsy, and drug abuse. Dr. Vanover received her B.A. in Psychology from the University of Missouri and her Ph.D. in Biopsychology from the University of Chicago.

Lawrence P. Wennogle, Ph.D. Dr. Wennogle has served as Vice President, Drug Discovery of the Company since the Merger in August 2013 and has served as Vice President, Drug Discovery of ITI since January 2003. For the past 33 years, Dr. Wennogle has been involved in research and development in the pharmaceutical industry aimed at the discovery of novel pharmaceutical entities for human diseases. He was a Staff Scientist and Principal Research Fellow at Ciba-Geigy and Novartis Pharmaceutical Corporation for 19 years, where he led drug discovery programs for CNS disorders, cardiovascular diseases, diabetes and inflammation. Dr. Wennogle received his B.A. from Ithaca College and his Ph.D. in Biochemistry from the University of Colorado, Boulder. He then completed two post-doctoral positions, one at the University of Colorado and the second at the Pasteur Institute in Paris, France, working under Jean-Pierre Changeux on the structure-function of the nicotinic acetylcholine receptor.

Non-Employee Directors

Christopher Alafi, Ph.D. Dr. Alafi became a director of the Company following the Merger that occurred in August 2013 and has served on the board of directors of ITI since January 2013. Dr. Alafi has been a General Partner of Alafi Capital Company, LLC, a venture capital firm, since 1995. He was previously a Physiology and Anatomy teacher at Santa Monica College, a visiting scholar in the Department of Chemistry at Stanford

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University and a researcher at DNAX. Dr. Alafi currently serves as a director of ISTO Technologies, Inc. and has previously served as a director of Coley Pharmaceutical Group, Inc., CyberGold, Inc. and Stereotaxis, Inc. Dr. Alafi received a B.A. in Biology from Pomona College and a D.Phil. in Biochemistry from the University of Oxford.

We believe that Dr. Alafi possesses specific attributes that qualify him to serve as a member of our board of directors, including the perspective and experience he brings as a General Partner of Alafi Capital Company, LLC.

Richard Lerner, M.D. Dr. Lerner became a director of the Company following the Merger that occurred in August 2013 and has served on the board of directors of ITI since 2002. Dr. Lerner served as President of the Scripps Research Institute, a private, non-profit biomedical research organization from 1986 to January 2012, and since then has served and continues to serve as Institute Professor. Dr. Lerner received the Wolf Prize in Chemistry in 1994, the California Scientist of the Year Award in 1996, the Paul Ehrlich and Ludwig Darmstaedter Prize in 2003, and the Prince of Asturias Award in 2012 for his achievements in the development of catalytic antibodies and combinatorial antibody libraries. Dr. Lerner is a member of the National Academy of Sciences and the Royal Swedish Academy of Sciences. Dr. Lerner served as a director of Kraft Foods, Inc. from 2005 to March 2012 and currently serves as a director of Opko Health, Inc., Teva Pharmaceutical Industries Ltd., and Sequenom, Inc. Dr. Lerner received his M.D. from Stanford Medical School.

We believe that Dr. Lerner possesses specific attributes that qualify him to serve as a member of our board of directors, including his service as a director of other public companies, combined with his business acumen and judgment provide our board of directors with valuable scientific and operational expertise and leadership skills.

Joel S. Marcus, J.D., CPA. Mr. Marcus became a director of the Company following the Merger that occurred in August 2013 and has served on the board of directors of ITI since April 2006. Mr. Marcus co-founded Alexandria Real Estate Equities, Inc. in 1994, Alexandria Venture Investments in 1996, and the annual Alexandria Summit in 2011. He has served as Chairman of the Board of Directors of Alexandria Real Estate Equities, Inc. since May 2007, Chief Executive Officer since March 1997, President since February 2009, and a director since the company s inception in 1994. From 1986 to 1994, Mr. Marcus was a partner at the law firm of Brobeck, Phleger & Harrison LLP, specializing in corporate finance and capital markets, venture capital, and mergers and acquisitions. From 1984 to 1994, he also served as General Counsel and Secretary of Kirin-Amgen, Inc., a joint venture that financed the development of, and owned patents to, two multi-billion dollar genetically engineered biopharmaceutical products. Mr. Marcus was formerly a practicing certified public accountant and tax manager with Arthur Young & Co. specializing in the financing and taxation of REITs. He received his undergraduate and Juris Doctor degrees from the University of California, Los Angeles. In addition to our board of directors, Mr. Marcus serves on the boards of the Accelerator Corporation, of which he was one of the original architects and co-founders, Foundation for the National Institutes of Health (FNIH), Multiple Myeloma Research Foundation (MMRF), and the Partnership for New York City. Mr. Marcus also served on the Board of Trustees of PennyMac Mortgage Investment Trust, a publicly traded mortgage REIT, from August 2009 to August 2012. Mr. Marcus received the Ernst & Young 1999 Entrepreneur of the Year Award (Los Angeles Real Estate).

We believe that Mr. Marcus possesses specific attributes that qualify him to serve as a member of our board of directors, including his many years of experience in the life sciences industry and his extensive experience serving as a director and an executive officer of other public companies.

Sir Michael Rawlins, M.D., FRCP, FMedSci. Sir Michael became a director of the Company following the Merger that occurred in August 2013 and has served on the board of directors of ITI since May 2013. Sir Michael is known for his long standing leadership of the United Kingdom s National Institute for Clinical Excellence, or NICE, which he led from its inception in 1999 through March 2013. Recently in July 2012, Sir Michael was appointed as the President

of the United Kingdom s Royal Society of Medicine, a center for education and

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scholarship both in the UK and globally. Sir Michael was a professor of clinical pharmacology and a general physician at the University of Newcastle upon Tyne from 1973 to 2006. He received the Prince Mahidol Award for Medicine in 2012, the Galen Medal in 2010, and the Hutchinson Medal in 2003. Sir Michael was appointed Knight Bachelor in 1999.

We believe that Sir Michael possesses specific attributes that qualify him to serve as a member of our board of directors, including his extensive experience in areas of health policy and economics.

Rory B. Riggs. Mr. Riggs has served on our board of directors since January 2014. Mr. Riggs co-founded Royalty Pharma, an investment company focused on drug royalties, in 1996 and has served as Chairman of its investment committee since July 2003. Since April 2010, Mr. Riggs has served as founder and Chief Executive Officer of Syntax Analytics, LLC, a development stage venture focused on creating a new information technology platform for large-scale portfolio management. Since June 2006, Mr. Riggs has also served as Managing Member of New Ventures, a venture fund focused on healthcare. Since January 2001, Mr. Riggs has served as Managing Member of Balfour LLC, an investment management company focused on healthcare, biotechnology and technology. From 1996 until 2000, Mr. Riggs served as President and as a director of Biomatrix, Inc., a publicly-traded biopharmaceutical company. From 1991 to 1995, Mr. Riggs served as President and Chief Executive Officer of RF&P Corporation, an investment company owned by the State of Virginia Retirement System. Prior to that, he served as a managing director in PaineWebber s mergers and acquisitions department from 1981 to 1990. In addition to Royalty Pharma, Mr. Riggs serves on the board of directors of FibroGen, Inc. (since September 1993), a private biotechnology company; Cibus, LLC (since November 2001), a private agricultural technology company; GeneNews (since January 1998), a publicly-traded molecular diagnostic company; and eReceivables (since September 2003), a private healthcare service technology company. Mr. Riggs graduated from Middlebury College and holds an MBA from Columbia University.

We believe that Mr. Riggs possesses specific attributes that qualify him to serve as a member of our board of directors, including his financial expertise, extensive knowledge of the life sciences industry, and many years of experience as a developer (founder), executive officer and director of successful companies (both public and private) in the life sciences and healthcare.

Robert L. Van Nostrand. Mr. Van Nostrand has served on our board of directors since January 2014. Mr. Van Nostrand was Executive Vice President and Chief Financial Officer of Aureon Biosciences, Inc., a private pathology life science company, from January 2010 to July 2010. Prior to joining Aureon Biosciences, Mr. Van Nostrand served as Executive Vice President and Chief Financial Officer of AGI Dermatics, Inc., a private biotechnology company, from July 2007 to September 2008 when the company was acquired. From May 2005 to July 2007, Mr. Van Nostrand served as the Senior Vice President and Chief Compliance Officer of OSI Pharmaceuticals, Inc., a publicly-traded biotechnology company, where he previously served as Vice President and Chief Financial Officer from December 1996 through May 2005 and as Vice President, Finance and Administration prior to that. He also served as OSI s Treasurer from March 1992 to May 2005 and Secretary from March 1995 to January 2004. Mr. Van Nostrand joined OSI as Controller and Chief Accounting Officer in September 1986. Prior to joining OSI, Mr. Van Nostrand served in a managerial position with the accounting firm, Touche Ross & Co., currently Deloitte. Mr. Van Nostrand serves as chairman of the board of directors of Metabolix, Inc., a publicly-traded biotechnology company, as well as chairman of its audit committee. Mr. Van Nostrand also serves on the board of directors of Achillion Pharmaceuticals, Inc., a publicly-traded biotechnology company, where he serves as chairman of the audit committee. He also serves on the board of directors of the Biomedical Research Alliance of New York, a private company providing clinical trial services. Mr. Van Nostrand was the former chairman of, and serves on, the board of the New York Biotechnology Association and serves on the Foundation Board of Farmingdale University. Previously, Mr. Van Nostrand served on the board of directors of Apex Bioventures, Inc., a special purpose acquisition company focused on life sciences.

Mr. Van Nostrand holds a B.S. in Accounting from Long Island University, New York. He is a Certified Public Accountant.

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We believe that Mr. Van Nostrand possesses specific attributes that qualify him to serve as a member of our board of directors, including his many years of experience in the life sciences industry, as well as his expertise in financial operations, transaction structuring and risk management.

Scientific Advisory Board

We have a Scientific Advisory Board which is chaired by Paul Greengard, Ph.D., one of our founders. Dr. Greengard received his Ph.D. in biophysics from Johns Hopkins University in 1953. After postgraduate work in England, he served for nine years as director of biochemical research at the Geigy Research Laboratories. In 1968, he was appointed Professor of Pharmacology at Yale University. In 1983, he was appointed the Vincent Astor Professor at The Rockefeller University, where he founded the Laboratory of Molecular and Cellular Neuroscience.

Dr. Greengard is a pioneer in the field of neuronal signal transduction and his seminal discoveries over the years have provided a framework by which to understand the complexity of how neurotransmitters function in the brain. Dr. Greengard s many awards and honors include the CIBA-Geigy Drew Award in Biomedical Research (1979), the New York Academy of Sciences Award in Biological and Medical Sciences (1980), the Andrew D. White Professorship-at-Large of Cornell University (1981-87), the Pfizer Biomedical Research Award (1987), the Ralph W. Gerard Prize in Neuroscience, Society for Neuroscience (1994), the Charles A. Dana Award for Pioneering Achievements in Health (1997), and the Nobel Prize in Physiology or Medicine (2000). Dr. Greengard has also been a consultant to major pharmaceutical companies and a Chairman and member of the scientific advisory boards of numerous biotechnology companies.

We have additional members of our Scientific Advisory Board who change from time to time, with whom we consult on an as-needed basis.

Medical Advisory Board

Carol A. Tamminga, M.D. is the Chair of our Medical Advisory Board. Dr. Tamminga is the Chair of the Psychiatry Department at the University of Texas Southwestern School of Medicine. She holds the McKenzie Foundation Chair in Psychiatry, the Communities Foundation of Texas, Inc. Chair in Brain Science and is the Chief of Translational Neuroscience Research in Schizophrenia.

Jeffrey Lieberman, M.D. is the Lawrence C. Kolb Professor and Chairman of Psychiatry, at the Columbia University College of Physicians and Surgeons; and Director, of the New York State Psychiatric Institute; Psychiatrist-in-Chief, New York Presbyterian Hospital-Columbia University Medical Center.

John M. Kane, M.D. is Professor and Chairman of Psychiatry at The Hofstra North Shore-LIJ School of Medicine and Vice President for Behavioral Health Services at The North Shore-LIJ Health System.

Christoph U. Correll, M.D. is Professor of Psychiatry and Molecular Medicine, Hofstra North Shore LIJ School of Medicine; Medical Director, Recognition and Prevention (RAP) Program, The Zucker Hillside Hospital, North Shore Long Island Jewish Health System.

Donald Goff, M.D. is Professor and Vice Chair for Research in the Department of Psychiatry at New York University Langone Medical Center (NYULMC) and Director of the Nathan S. Kline Institute for Psychiatric Research.

Board Composition and Election of Directors

Terms of Office

Our restated certificate of incorporation and our restated bylaws provide that, subject to any applicable rights of holders of any preferred stock then outstanding, the authorized number of directors may be changed

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only by resolution of our board of directors. We currently have authorized seven directors. In accordance with our restated certificate of incorporation and restated bylaws, our board of directors is divided into three classes with staggered three-year terms. At each annual meeting of stockholders commencing with the meeting in 2014, the successors to the directors whose terms then expire will be elected to serve until the third annual meeting following the election. Our directors are divided among the three classes as follows:

- the Class I directors are Richard Lerner, M.D. and Sir Michael Rawlins, M.D., FRCP, FMedSci, and their terms will expire at the annual meeting of stockholders to be held in 2014;
- the Class II directors are Christopher Alafi, Ph.D. and Joel S. Marcus, and their terms will expire at the annual meeting of stockholders to be held in 2015; and
- the Class III directors are Sharon Mates, Ph.D., Rory B. Riggs and Robert L. Van Nostrand, and their terms will expire at the annual meeting of stockholders to be held in 2016.

Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that each class will consist of approximately one-third of the directors.

Director Independence

Based upon information requested from and provided by each director concerning their background, employment and affiliations, including family relationships, our board of directors has determined that none of Dr. Alafi, Dr. Lerner, Mr. Marcus, Sir Michael, Mr. Riggs or Mr. Van Nostrand, representing six out of our seven directors, has a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is independent as that term is defined under Rule 5605(a)(2) of the NASDAQ Marketplace Rules. Dr. Mates is employed by the Company and is therefore not independent under NASDAQ Marketplace Rules.

Board of Directors Meetings

During the fiscal year ended December 31, 2013, there were ten meetings of the board of directors and one meeting of the compensation committee, which was the only standing committee of the board of directors. No director attended fewer than 75% of the total number of meetings of the board of directors and of the committee of the board on which he or she served during fiscal 2013, other than Richard Lerner, M.D., who attended five of the ten board meetings held during his tenure, and Sir Michael Rawlins, M.D., FRCP, FMedSci, who attended five of the eight board meetings held during his tenure. Both Rory B. Riggs and Robert L. Van Nostrand were not elected to our board of directors until 2014. Our board of directors has adopted a policy under which each member of our board of directors is strongly encouraged but not required to attend each annual meeting of our stockholders. We did not hold an annual meeting of stockholders in 2013.

Committees of the Board of Directors

Our board of directors has established an audit committee, a compensation committee and a nominating and governance committee. Each committee operates under a charter approved by our board of directors. Copies of each committee s charter are posted on the Investor Relations section of our website, which is located at

www.intracellulartherapies.com, under the caption Corporate Governance. The composition and function of each of these committees are described below.

Audit Committee. Our audit committee is comprised of Mr. Van Nostrand, Sir Michael and Mr. Riggs. Mr. Van Nostrand is the chairperson of the committee. Our board of directors has determined that Mr. Riggs is an audit committee financial expert, as defined by the rules of the Securities and Exchange Commission, and satisfies the financial sophistication requirements of applicable NASDAQ rules. Our board of directors has determined that each of Mr. Van Nostrand, Sir Michael and Mr. Riggs is an independent director under the NASDAQ Marketplace Rules and Rule 10A-3 of the Exchange Act.

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Our audit committee is authorized to:

- approve and retain the independent auditors to conduct the annual audit of our financial statements;
- review the proposed scope and results of the audit;
- review and pre-approve audit and non-audit fees and services;
- review accounting and financial controls with the independent auditors and our financial and accounting staff;
- review and approve transactions between us and our directors, officers and affiliates;
- recognize and prevent prohibited non-audit services;
- establish procedures for complaints received by us regarding accounting matters;
- oversee internal audit functions, if any; and
- prepare the report of the audit committee that the rules of the Securities and Exchange Commission require to be included in our annual meeting proxy statement.

Compensation Committee. Our compensation committee is comprised of Mr. Marcus, Dr. Alafi and Mr. Riggs. Mr. Marcus is the chairman of the committee. Our compensation committee is authorized to:

- review and recommend the compensation arrangements for management, including the compensation for our president and chief executive officer;
- establish and review general compensation policies with the objective to attract and retain superior talent, to reward individual performance and to achieve our financial goals;
- administer our stock incentive plans; and

prepare the report of the compensation committee that the rules of the Securities and Exchange Commission require to be included in our annual meeting proxy statement.

Nominating and Governance Committee. Our nominating and governance committee is comprised of Dr. Alafi, Mr. Lerner and Mr. Marcus. Dr. Alafi is the chairman of the committee. Our nominating and governance committee is authorized to:

identify and nominate members of the board of directors;

develop and recommend to the board of directors a set of corporate governance principles applicable to our company; and

oversee the evaluation of our board of directors.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our directors and executive officers, and persons who own more than ten percent of a registered class of our equity securities, to file with the SEC initial reports of ownership and reports of changes in ownership of our common stock and other equity securities. Officers, directors and greater than ten percent stockholders are required by SEC regulations to furnish us with copies of all Section 16(a) forms they file.

To our knowledge, based solely on a review of the copies of such reports furnished to us and written representations regarding the filing of required reports, we believe that all Section 16(a) filing requirements applicable to our directors, executive officers and greater-than-ten-percent beneficial owners with respect to fiscal 2013 were met.

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Code of Ethics

Prior to the Merger, when it was a public shell, the Company had adopted an initial code of conduct and ethics. We have adopted a new code of conduct and ethics to replace the existing code of conduct and ethics effective January 1, 2014, which applies to all of our employees, including our principal executive officer and our principal financial and accounting officer. We have posted a copy of such code of conduct and ethics on our website at www.intracellulartherapies.com. Disclosure regarding any amendments to, or waivers from, provisions of the code of conduct and ethics that apply to our directors, principal executive officer or principal financial officer will be included in a Current Report on Form 8-K within four business days following the date of the amendment or waiver, unless website posting or the issuance of a press release of such amendments or waivers is then permitted by The NASDAQ Stock Market LLC.

Board Leadership Structure and Role on Risk Oversight

Our board of directors does not have a policy regarding the separation of the roles of Chief Executive Officer and Chairman of the board of directors, as our board of directors believes it is in the best interest of the Company to make that determination based on the position and direction of the Company and the membership of the board of directors. Our board of directors has determined that having an employee director serve as Chairman is in the best interest of the Company s stockholders at this time because of the efficiencies achieved in having the role of Chief Executive Officer and Chairman combined, and because the detailed knowledge of our day-to-day operations and business that the Chief Executive Officer possesses greatly enhances the decision-making processes of our board of directors as a whole. We have a strong governance structure in place, including independent directors, to ensure the powers and duties of the dual role are handled responsibly. We do not have a lead independent director.

The Chairman of the board of directors and the other members of the board of directors work in concert to provide oversight of our management and affairs. Our board of directors encourages communication among its members and between management and the board of directors to facilitate productive working relationships. Working with the other members of the board of directors, Dr. Mates also strives to ensure that there is an appropriate balance and focus among key board responsibilities such as strategic development, review of operations and risk oversight.

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EXECUTIVE COMPENSATION

Unless we specifically indicate otherwise, all share and per share numbers included in this Executive Compensation section have been adjusted as necessary to reflect the exchange of shares in the Merger.

Summary Compensation Table

The following table shows the total compensation paid or accrued during the last two fiscal years ended December 31, 2013 and 2012 to (1) our President and Chief Executive Officer and (2) our two next most highly compensated executive officers who earned more than $100,000 during the fiscal year ended December 31, 2013 and were serving as executive officers as of such date. These executive officers are referred to as our named executive officers in this prospectus.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Option Awards ($)[1]	All Other Compensation ($)[2]	Total ($)
Sharon Mates, Ph.D.	2013	611,900	500,000[3]	115,000	8,442	1,235,342
Chairman, President and Chief Executive Officer	2012	588,400	117,700	100,000	7,750	813,850
Lawrence J. Hineline	2013	257,500	100,000[4]	23,000	8,166	388,666
Vice President of Finance, Chief Financial Officer and Secretary	2012	250,000	17,500	20,000	7,750	295,250
Allen A. Fienberg, Ph.D.	2013	257,900	25,800[5]	17,250	7,926	308,876
Vice President of Business Development	2012	250,400	8,800	20,000	7,750	286,950

(1) The options granted in 2013 were for the named executive officer s performance in 2012 and the options granted in 2012 were for the named executive officer s performance in 2011. These amounts represent the aggregate grant date fair value for option awards granted to our named executive officers, computed in accordance with FASB ASC Topic 718. See Note 4 to our audited consolidated financial statements for the fiscal years ended December 31, 2013 and 2012 included in this prospectus for details as to the assumptions used to calculate the fair value of the option awards. See also our discussion of stock-based compensation under Management s Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Policies and Estimates.

(2) For the fiscal year ended December 31, 2013, consists of $792 for Dr. Mates, $516 for Mr. Hineline and $276 for Dr. Fienberg in life insurance premiums we paid for a term life insurance policy to benefit the executive officer with a face value of $150,000, and the balance in matching contributions under our 401(k) plan. For the fiscal year ended December 31, 2012, consists of $250 in life insurance premiums we paid for a term life insurance policy to benefit the executive officer with a face value of $150,000, and the balance in matching contributions under our 401(k) plan.

(3) Dr. Mates received a bonus of $306,000 for her performance during the fiscal year ended December 31, 2013 plus an additional bonus of $194,000 for her performance in connection with the successful completion of the Private Placement, Merger and Phase 2 clinical trial of ITI-007.

(4) Mr. Hineline received a bonus of $51,500 for his performance during the fiscal year ended December 31, 2013 plus an additional bonus of $48,500 for his performance in connection with the successful completion of the

Private Placement, Merger and Phase 2 clinical trial of ITI-007.

(5) Dr. Fienberg received a bonus of $25,800 for his performance during the fiscal year ended December 31, 2013.

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2013 Fiscal Year Grants of Plan-Based Awards

The following table shows information regarding grants of equity awards that we made during the fiscal year ended December 31, 2013 to each of our named executive officers. We did not grant any non-equity incentive plan awards during the fiscal year ended December 31, 2013.

Name	Compensation Committee Approval[1]	Grant Date[1]	All Other Option Awards: Number of Securities Underlying Options (#)[2]	Exercise or Base Price of Option Awards ($/Sh)[3]	Grant Date Fair Value of Stock and Option Awards ($)[4]
Sharon Mates, Ph.D.	12/20/2012	5/31/2013	50,000	3.26	115,000
Lawrence J. Hineline	12/20/2012	5/31/2013	10,000	3.26	23,000
Allen A. Fienberg, Ph.D.	12/20/2012	5/31/2013	7,500	3.26	17,250

(1) On December 20, 2012, ITI s compensation committee approved grants of 50,000 options to Dr. Mates, 10,000 options to Mr. Hineline and 7,500 options to Dr. Fienberg to be granted following the completion of a valuation of ITI s common stock and an increase in the number of shares reserved under ITI s 2003 Equity Incentive Plan. Following the completion of the valuation of ITI s common stock and the increase in the number of shares reserved under ITI s 2003 Equity Incentive Plan, on May 31, 2013 the board of directors of ITI approved these option grants at an exercise price of $3.26 per share.

(2) These awards are subject to vesting, as described in detail under Outstanding Equity Awards at 2013 Fiscal Year-End below.

(3) The exercise price is equal to the fair market value of our common stock, determined in good faith by our board of directors in accordance with the 2003 Equity Incentive Plan, since ITI was a private company at the time of grant.

(4) These amounts represent the aggregate grant date fair value for option awards granted to our named executive officers, computed in accordance with FASB ASC Topic 718. See Note 4 to our audited consolidated financial statements for the fiscal years ended December 31, 2013 and 2012 included in this prospectus for details as to the assumptions used to calculate the fair value of the option awards. See also our discussion of stock-based compensation under Management s Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Policies and Estimates.

Narrative Disclosure to Summary Compensation Table

Sharon Mates, Ph.D. We entered into an employment agreement with Dr. Mates in February 2008, who has been our President and Chief Executive Officer since 2003. The agreement provides for a salary of $503,000 effective in February 2008, subject to our annual review and adjustment in the discretion of our board of directors, and that Dr. Mates is eligible for bonus payments and stock options as may be awarded by our board of directors. The most recent adjustment, effective on January 1, 2014, increased Dr. Mates salary to $636,000, which represented a 4% increase from her 2013 base salary of $611,900. In December 2013, she was awarded a bonus of $306,000, or 50% of her then base salary, for her performance during the fiscal year ended December 31, 2013, plus an additional bonus of $194,000 for her performance in connection with the successful completion of the Private Placement, Merger and Phase 2 clinical trial of ITI-007. In addition, her employment agreement provides that we will pay the premium on a life insurance policy in an amount equal to one and one half times her base salary; however, we paid a premium in the

amount of $792 on a life insurance policy with a face value of $150,000, to which she assented. For 2013, we also paid $7,650 in matching contributions under our 401(k) plan. The employment agreement also provides that Dr. Mates is entitled to participate in our benefit plans on the same basis as other executive level employees as well as long-term disability insurance and reimbursement for reasonable business expenses. The initial term of the agreement was three years and will be renewed for successive one year terms, unless we or Dr. Mates provides notice that we or she, as the case may be, does not wish to renew the agreement or wishes to renew the agreement on different terms than those contained in the agreement.

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If Dr. Mates employment is terminated for any reason, she will be entitled to compensation and benefits through the last day of her employment, including accrued but untaken vacation. If her employment is terminated due to her death or disability, we will also pay her or her estate the compensation which would otherwise have been payable to her through the end of the month in which such termination occurs as well as payment for any accrued but untaken vacation. If her employment is terminated without cause by us or she terminates her employment for good reason, she will receive the following severance benefits following her employment termination, on condition that she executes a general release in our favor: (a) payment of 12 months of her then current base salary and the pro rata portion of an amount equal to the bonus she was awarded for the previous year, if any, which severance payments will be paid in one lump sum on the date the general release she executes becomes effective; (b) payment for 12 months of the portion of the COBRA premiums that we paid prior to her termination; and (c) all of her unvested stock options will become fully vested and exercisable. Dr. Mates will also be entitled to such severance benefits if we elect not to renew her employment agreement for reasons other than death, disability or cause, but (i) such severance benefits are conditioned on Dr. Mates executing a general release in favor of us, returning all our property, and complying with her employment agreement, proprietary information, inventions, and non-competition agreement, and the general release and (ii) Dr. Mates will not be eligible for such severance benefits if she or we wish to renew the agreement on different terms than those contained in her employment agreement. In the event of a change of control, all of her unvested stock options and restricted stock will immediately vest. If her employment is terminated for reasons other than death or disability within three months before or 12 months following a change of control, she terminates her employment for good reason during such period, or she terminates her employment for any reason within one month following a change of control, she will be eligible for the following severance benefits following her employment termination: (a) payment of 18 months of her then current base salary and the pro rata portion of an amount equal to the bonus she was awarded for the previous year, which severance payments will be paid in one lump sum on the eighth day following the effective date of the general release, and (b) payment for 18 months of the portion of the COBRA premiums that we paid prior to her termination. Such severance benefits following a change of control are payable on condition that she executes a general release in favor of us, returns all our property and complies with her post-termination obligations under her employment agreement, her proprietary information, inventions, and non-competition agreement, and her general release.

Pursuant to her proprietary information, inventions, and non-competition agreement, Dr. Mates has agreed to not (i) solicit customers, consultants, contractors or employees of ours for a period of one year after the termination of her employment or (ii) compete with us for a period of one year after the later of the termination of her employment or the date a court of competent jurisdiction enters an order enforcing the non-competition provision.

Lawrence J. Hineline. We entered into an employment agreement with Mr. Hineline in February 2008, who has been our Vice President of Finance, Chief Financial Officer and Secretary since 2002. The agreement provides for a salary of $216,400 effective in February 2008, subject to our annual review and adjustment in the discretion of our board of directors, and that Mr. Hineline is eligible for bonus payments and stock options as may be awarded by our board of directors. The most recent adjustment, effective on January 1, 2014, increased Mr. Hineline s salary to $309,000, which represented a 20% increase from his 2013 base salary of $257,500. In December 2013, he was awarded a bonus of $51,500, or 20% of his then base salary, for his performance during the fiscal year ended December 31, 2013, plus an additional bonus of $49,500 for his performance in connection with the successful completion of the Private Placement, Merger and Phase 2 clinical trial of ITI-007. In addition, his employment agreement provides that we will pay the premium on a life insurance policy in an amount equal to one and one half times his base salary; however, we paid a premium in the amount of $516 on a life insurance policy with a face value of $150,000, to which he assented. For 2013, we also paid $7,650 in matching contributions under our 401(k) plan. The employment agreement also provides that Mr. Hineline is entitled to participate in our benefit plans on the same basis as other executive level employees as well as long-term disability insurance and reimbursement for reasonable business expenses. The initial term of the agreement was three years and will be renewed for successive one year terms, unless we or Mr. Hineline

provides notice that we or he, as the case may be, does not wish to renew the agreement or wishes to renew the agreement on different terms than those contained in the agreement.

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If Mr. Hineline s employment is terminated for any reason, he will be entitled to compensation and benefits through the last day of his employment, including accrued but untaken vacation. If his employment is terminated due to his death or disability, we will also pay him or his estate the compensation which would otherwise have been payable to him through the end of the month in which such termination occurs as well as payment for any accrued but untaken vacation. If his employment is terminated without cause by us or he terminates his employment for good reason, he will receive the following severance benefits following his employment termination, on condition that he executes a general release in our favor: (a) payment of 12 months of his then current base salary and the pro rata portion of an amount equal to the bonus he was awarded for the previous year, if any, which severance payments will be paid in one lump sum on the date the general release he executes becomes effective; (b) payment for 12 months of the portion of the COBRA premiums that we paid prior to his termination; and (c) all of his unvested stock options will become fully vested and exercisable. Mr. Hineline will also be entitled to such severance benefits if we elect not to renew his employment agreement for reasons other than death, disability or cause, but (i) such severance benefits are conditioned on Mr. Hineline executing a general release in our favor, returning all our property, and complying with his employment agreement, proprietary information, inventions, and non-competition agreement, and the general release and (ii) Mr. Hineline will not be eligible for such severance benefits if he or we wish to renew the agreement on different terms than those contained in his employment agreement. In the event of a change of control, all of his unvested stock options and restricted stock will immediately vest. If his employment is terminated for reasons other than death or disability within three months before or 12 months following a change of control, he terminates his employment for good reason during such period, or he terminates his employment for any reason within one month following a change of control, he will be eligible for the following severance benefits following his employment termination: (a) payment of 18 months of his then current base salary and the pro rata portion of an amount equal to the bonus he was awarded for the previous year, which severance payments will be paid in one lump sum on the eighth day following the effective date of the general release, and (b) payment for 18 months of the portion of the COBRA premiums that we paid prior to his termination. Such severance benefits following a change of control are payable on condition that he executes a general release in favor of us, returns all our property and complies with his post-termination obligations under his employment agreement, his proprietary information, inventions, and non-competition agreement, and his general release.

Pursuant to his proprietary information, inventions, and non-competition agreement, Mr. Hineline has agreed to not (i) solicit customers, consultants, contractors or employees of ours for a period of one year after the termination of his employment or (ii) compete with us for a period of one year after the later of the termination of his employment or the date a court of competent jurisdiction enters an order enforcing the non-competition provision.

Allen A. Fienberg, Ph.D. We entered into an employment agreement with Dr. Fienberg in February 2008, who has been our Vice President of Business Development since 2002. The agreement provides for a salary of $221,400 effective in February 2008, subject to our annual review and adjustment in the discretion of our board of directors, and that Dr. Fienberg is eligible for bonus payments and stock options as may be awarded by our board of directors. The most recent adjustment, effective on January 1, 2014, increased Dr. Fienberg s salary to $268,200, which represented a 4% increase from his 2013 base salary of $257,900. In December 2013, he was awarded a bonus of $25,800, or 10% of his then base salary, for his performance during the fiscal year ended December 31, 2013. In addition, his employment agreement provides that we will pay the premium on a life insurance policy in an amount equal to one and one half times his base salary; however, we paid a premium in the amount of $276 on a life insurance policy with a face value of $150,000, to which he assented. For 2012, we also paid $7,650 in matching contributions under our 401(k) plan. The employment agreement also provides that Dr. Fienberg is entitled to participate in our benefit plans on the same basis as other executive level employees as well as long-term disability insurance and reimbursement for reasonable business expenses. The initial term of the agreement was three years and will be renewed for successive one year terms, unless we or Dr. Fienberg provides notice that we or he, as the case may be, does not wish to renew the agreement or wishes to renew the agreement on different terms than those contained in the agreement.

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If Dr. Fienberg s employment is terminated for any reason, he will be entitled to compensation and benefits through the last day of his employment, including accrued but untaken vacation. If his employment is terminated due to his death or disability, we will also pay him or his estate the compensation which would otherwise have been payable to him through the end of the month in which such termination occurs as well as payment for any accrued but untaken vacation. If his employment is terminated without cause by us or he terminates his employment for good reason, he will receive the following severance benefits following his employment termination, on condition that he executes a general release in our favor: (a) payment of 12 months of his then current base salary and the pro rata portion of an amount equal to the bonus he was awarded for the previous year, if any, which severance payments will be paid in one lump sum on the date the general release he executes becomes effective; (b) payment for 12 months of the portion of the COBRA premiums that we paid prior to his termination; and (c) all of his unvested stock options will become fully vested and exercisable. Dr. Fienberg will also be entitled to such severance benefits if we elect not to renew his employment agreement for reasons other than death, disability or cause, but (i) such severance benefits are conditioned on Dr. Fienberg executing a general release in our favor, returning all our property, and complying with his employment agreement, proprietary information, inventions, and non-competition agreement, and the general release and (ii) Dr. Fienberg will not be eligible for such severance benefits if he or we wish to renew the agreement on different terms than those contained in his employment agreement. In the event of a change of control, 75% of his unvested stock options and restricted stock will immediately vest.

Pursuant to his proprietary information, inventions, and non-competition agreement, Dr. Fienberg has agreed to not (i) solicit customers, consultants, contractors or employees of ours for a period of one year after the termination of his employment or (ii) compete with us for a period of one year after the later of the termination of his employment or the date a court of competent jurisdiction enters an order enforcing the non-competition provision.

The meanings of the terms cause, good reason, disability and change of control for purposes of these employment agreements are described below under Potential Payments upon Termination or Change in Control.

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Outstanding Equity Awards at 2013 Fiscal Year-End

The following table shows grants of stock options outstanding on the last day of the fiscal year ended December 31, 2013, to each of the named executive officers.

Name	Number of Securities Underlying Unexercised Options (#)[1] Exercisable	Number of Securities Underlying Unexercised Options (#)[1] Unexercisable	Option Exercise Price ($)	Option Expiration Date
Sharon Mates, Ph.D.	50,000	0	$ 0.50	12/19/2014
	25,000	0	$ 0.60	12/14/2015
	25,000	0	$ 1.36	12/5/2016
	37,500	0	$ 1.50	12/12/2017
	50,000	0	$ 1.50	12/18/2018
	50,000	0	$ 2.74	6/10/2020
	50,000	0	$ 2.74	12/21/2020
	33,333	16,667	$ 2.84	4/30/2022
	16,666	33,334	$ 3.26	5/31/2023
Lawrence J. Hineline	37,500	0	$ 0.50	12/19/2014
	12,500	0	$ 0.60	12/14/2015
	12,500	0	$ 1.36	12/5/2016
	12,500	0	$ 1.50	12/12/2017
	10,000	0	$ 1.50	12/18/2018
	10,000	0	$ 2.74	6/10/2020
	10,000	0	$ 2.74	12/21/2020
	6,666	3,334	$ 2.84	4/30/2022
	3,333	6,667	$ 3.26	5/31/2023
Allen A. Fienberg, Ph.D.	37,500	0	$ 0.50	12/19/2014
	12,500	0	$ 0.60	12/14/2015
	12,500	0	$ 1.36	12/5/2016
	12,500	0	$ 1.50	12/12/2017
	10,000	0	$ 1.50	12/18/2018
	10,000	0	$ 2.74	6/10/2020
	10,000	0	$ 2.74	12/21/2020
	6,666	3,334	$ 2.84	4/30/2022
	2,500	5,000	$ 3.26	5/31/2023

(1) The remaining options to purchase shares of our common stock that expire on April 30, 2022 will vest on December 20, 2014. Each option to purchase our common stock that expires on May 31, 2023 vested as to 1/3 of the shares on December 20, 2013, and will vest as to 1/3 of the shares on December 20, 2014 and 1/3 of the shares on December 20, 2015. All options have a ten year term from the date of grant.

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Option Exercises and Stock Vested in 2013

The following table shows information regarding exercises of options to purchase our common stock by each of our named executive officers during the fiscal year ended December 31, 2013.

	Option Awards	
Name	Number of Shares Acquired on Exercise (#)	Value Realized on Exercise ($)[1]
Sharon Mates, Ph.D.	50,000	302,640
Lawrence J. Hineline	50,000	302,640
Allen A. Fienberg, Ph.D.	37,500	226,980

(1) Amounts shown in this column do not represent actual value realized from the sale of the shares acquired upon exercise of options because the shares were not sold on exercise but continue to be held by the executive officer exercising the option. As these options were exercised prior to the Merger, the amounts shown represent the difference between the option exercise price and $3.1764, the price at which ITI common stock was sold in the Private Placement (as adjusted to $6.3528 after giving effect to the Merger).

Pension Benefits

We do not have any qualified or non-qualified defined benefit plans.

Nonqualified Deferred Compensation

We do not have any nonqualified defined contribution plans or other deferred compensation plans.

Potential Payments upon Termination or Change in Control

Upon termination of employment without cause or a resignation for good reason, each as defined below, our named executive officers are entitled to receive severance payments. Severance for termination without cause or termination for good reason, each as defined below, for named executive officers is 12 months of base salary plus the pro rata portion of an amount equal to the bonus awarded to such named executive officer for the previous year, if any. In addition, each named executive officer is entitled to payment of 12 months of the portion of the premiums for medical insurance coverage under COBRA that we paid prior to such named executive officer s termination. Payment of these severance benefits is conditioned on the named executive officer signing a general release in our favor.

The table below summarizes the potential payments and benefits to each of our named executive officers assuming a termination without cause or resignation for good reason had occurred as of December 31, 2013.

Name	Severance Payments[1]	Bonus Payments[2]	Post-Termination Benefits[3]	Total Benefits

Sharon Mates, Ph.D.	$ 611,900	$ 117,700	$ 16,638	$ 746,238
Lawrence J. Hineline	$ 257,500	$ 17,500	$ 16,638	$ 291,638
Allen A. Fienberg, Ph.D.	$ 257,900	$ 8,800	$ 16,638	$ 283,338

(1) The severance agreements for our named executive officers are set forth in their respective employment agreements.

(2) Reflects a pro rata portion of the named executive officer s 2012 bonus based on the period from January 1, 2013 through December 31, 2013, which equals the full amount of the named executive officer s 2012 bonus. However, the 2013 bonus had already been paid to such named executive officers prior to

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December 31, 2013 in the amounts set forth in the Summary Compensation Table above, so we would not have paid the amounts set forth in this column at December 31, 2013 in addition to the 2013 bonus payments already made.

(3) Represents premiums that would be payable by us for continuation of the executive s medical and dental insurance coverage, assuming a termination without cause or resignation for good reason had occurred as of December 31, 2013.

The table below summarizes the potential payments and benefits to each of our named executive officers assuming a termination following a change in control had occurred at December 31, 2013. Each of our named executive officers has agreed in writing that the Merger did not constitute a change in control under their respective employment agreements.

Name	Severance Payments[1]	Bonus Payments[1][2]	Value of Additional Vested Option Awards[1][3]	Post-Termination Benefits[1][4]	Total Benefits
Sharon Mates, Ph.D.	$ 917,850	$ 117,700	$ 844,034	$ 24,957	$ 1,904,541
Lawrence J. Hineline	$ 386,250	$ 17,500	$ 168,817	$ 24,957	$ 597,524
Allen A. Fienberg, Ph.D.	$ 257,900	$ 8,800	$ 105,697	$ 16,638	$ 389,035

(1) Each of our named executive officers, except for Dr. Fienberg, shall, if the executive s employment is terminated for reasons other than death or disability within three months before or 12 months following a change of control, the executive terminates his or her employment for good reason during such period, or the executive terminates his or her employment for any reason within one month following a change of control, be entitled to (a) payment of 18 months of the executive s then current base salary and the pro rata portion of an amount equal to the bonus the executive was awarded for the previous year, if any, and (b) payment by us of 18 months of the portion of the premiums for medical insurance coverage under COBRA that we paid prior to such executive s termination. Such severance benefits following a change of control are payable on condition that the executive executes a general release in favor of us, returns all our property and complies with his or her post-termination obligations under his or her employment agreement, proprietary information, inventions, and non-competition agreement, and general release. Upon any such termination, Dr. Fienberg would be entitled to the same severance benefits that he otherwise would be entitled to receive without regard to a change of control as described above. In addition, in the event of a change of control, any unvested stock options or restricted stock awarded to Dr. Mates or Mr. Hineline will immediately vest and become exercisable and 75% of any unvested stock options or restricted stock awarded to Dr. Fienberg will immediately vest and become exercisable.

(2) Reflects a pro rata portion of the named executive officer s 2012 bonus based on the period from January 1, 2013 through December 31, 2013, which equals the full amount of the named executive officer s 2012 bonus. However, the 2013 bonus had already been paid to such named executive officers prior to December 31, 2013 in the amounts set forth in the Summary Compensation Table above, so we would not have paid the amounts set forth in this column at December 31, 2013 in addition to the 2013 bonus payments already made.

(3) This represents the intrinsic value of the number of option shares that would vest, assuming a change of control termination had occurred at December 31, 2013.

(4) Represents premiums that would be payable by us for continuation of the executive s medical and dental insurance coverage, assuming a change of control termination had occurred at December 31, 2013.

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The table below summarizes the potential payments and benefits to each of our named executive officers assuming a change in control without termination had occurred at December 31, 2013.

Name	Severance Payments	Bonus Payments	Value of Additional Vested Option Awards[1][2]	Post-Termination Benefits	Total Benefits
Sharon Mates, Ph.D.	N/A	N/A	$ 844,034	N/A	$ 844,034
Lawrence J. Hineline	N/A	N/A	$ 168,817	N/A	$ 168,817
Allen A. Fienberg, Ph.D.	N/A	N/A	$ 105,697	N/A	$ 105,697

(1) In the event of a change of control, any unvested stock options or restricted stock awarded to Dr. Mates or Mr. Hineline will immediately vest and become exercisable and 75% of any unvested stock options or restricted stock awarded to Dr. Fienberg will immediately vest and become exercisable.

(2) This represents the intrinsic value of the number of option shares that would vest, assuming a change of control without termination had occurred at December 31, 2013.

For purposes of severance payments, good reason is defined as an executive resigning after the occurrence of one of the following events without the executive s written consent:

The assignment to the executive of any duties or responsibilities which result in the material diminution of the executive s position;

a reduction by the Company in the executive s annual base salary of 5% or greater with respect to Dr. Mates and Mr. Hineline, and of greater than 5% with respect to Dr. Fienberg;

a material change in the geographic location at which the executive is required to perform services; or

material breach by the Company of any material provision of the executive s employment agreement.

The executive must provide us with written notice within 60 days after the occurrence of a good reason event, and we have 30 days to correct the event after receipt of the notice.

For purposes of severance payments, cause is defined as a termination by us after the occurrence of one of the following events:

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

the executive s conviction of a felony or crime involving fraud or embezzlement of Company property;

the executive s material breach of the executive s employment agreement which, if curable, has not been cured by the executive within 60 days after he or she receives written notice from the Company stating with reasonable specificity the nature of the breach;

material breach of fiduciary duty; or

refusal to follow or implement a clear and reasonable directive of our board of directors as a whole (or an officer of the Company, in the case of Mr. Hineline and Dr. Fienberg), provided that such directive is ethical and legal and which, if curable, has not been cured by the executive within 60 days after he or she receives written notice from the Company stating with reasonable specificity the nature of such refusal.

For purposes of severance payments, the determination of disability will occur when the executive is unable due to a physical or mental condition to perform the essential functions of his or her position with or without reasonable accommodation for 90 consecutive days, or 180 days in the aggregate whether or not consecutive, during any 360-day period, or based on the written certification by a licensed physician of the likely continuation of such condition for such period.

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For purposes of severance payments, a change in control means:

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

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

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

Notwithstanding the foregoing, a change in control will not be deemed to occur on account of the sale or acquisition of the Company s capital stock by institutional investors or venture capital firms for the primary purpose of obtaining financing for the Company.

Additional Narrative Disclosure

We sponsor a defined contribution 401(k) plan covering all full-time employees. Participants may elect to contribute their annual pre-tax earnings up to the federally allowed maximum limits. We make a matching contribution of 50% on the first 6% of contributions made by participants. For the fiscal year ended December 31, 2013, we made matching contributions in the amount of $7,650 to the 401(k) plan for each of our named executive officers.

Director Compensation

The following table shows the total compensation paid or accrued during the fiscal year ended December 31, 2013 to each of our directors, other than Dr. Mates who does not receive compensation for her service as a director.

Name[1]	Fees Earned or Paid in Cash ($)	Stock Awards ($)	Option Awards[2] ($)	Non-Equity Incentive Plan Compensation ($)	Change in Pension Value and Nonqualified Deferred Compensation Earnings	All Other Compensation ($)	Total ($)
Christopher Alafi, Ph.D.[3]	N/A	N/A	65,800	N/A	N/A	N/A	65,800
Richard Lerner, M.D.[4]	N/A	N/A	72,800	N/A	N/A	N/A	72,800
Joel S. Marcus[5]	N/A	N/A	72,800	N/A	N/A	N/A	72,800
Sir Michael Rawlins, M.D., FRCP, FMedSci[6]	N/A	N/A	60,480	N/A	N/A	N/A	60,480

(1) Mr. Riggs and Mr. Van Nostrand were appointed to our board of directors in January 2014 and therefore did not receive any compensation for service on our board of directors during the fiscal year ended December 31, 2013.

As of December 31, 2013, Mr. Riggs and Mr. Van Nostrand held no options to purchase shares of our common stock.

(2) These amounts represent the aggregate grant date fair value for option awards granted to our named executive officers, computed in accordance with FASB ASC Topic 718. See Note 4 to our audited consolidated financial statements for the fiscal years ended December 31, 2013 and 2012 included in this prospectus for details as to the assumptions used to calculate the fair value of the option awards. See also our discussion of stock-based compensation under Management s Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Policies and Estimates.

(3) As of December 31, 2013, Dr. Alafi held 29,375 options to purchase shares of our common stock, none of which were vested.

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(4) As of December 31, 2013, Dr. Lerner held 105,000 options to purchase shares of our common stock, of which 78,750 options were vested.
(5) As of December 31, 2013, Mr. Marcus held 110,000 options to purchase shares of our common stock, of which 83,750 options were vested.
(6) As of December 31, 2013, Sir Michael held 27,000 options to purchase shares of our common stock, none of which were vested.

Director Compensation Policy

As compensation to our non-employee directors for the year ended December 31, 2013 and 2012, we granted options to purchase 20,000 shares, and 12,500 shares of our common stock, respectively, to each of our non-employee directors serving during such years. We granted any non-employee director who resigned from or joined the ITI board of directors during such years the pro rata portion of the annual option grant representing the portion of such year during which such non-employee director served. We intend to adopt a non-employee director compensation policy designed to ensure that the compensation aligns the directors interests with the long-term interests of the stockholders, that the structure of the compensation is simple, transparent and easy for stockholders to understand and that our directors are fairly compensated.

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EQUITY COMPENSATION PLAN INFORMATION

The following table provides certain aggregate information with respect to all of our equity compensation plans in effect as of December 31, 2013.