Intra-Cellular Therapies, Inc.
Form 10-Q
August 12, 2014
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

x **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended June 30, 2014

or

¨ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File Number: 001-36274

INTRA-CELLULAR THERAPIES, INC.

(Exact name of registrant as specified in its charter)

Delaware	**36-4742850**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
3960 Broadway	
New York, New York	**10032**
(Address of principal executive offices)	**(Zip Code)**

(212) 923-3344

(Registrant s telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No x

As of August 8, 2014, the registrant had 29,386,722 shares of common stock outstanding.

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In this Quarterly Report on Form 10-Q, the terms we, us, our, and the Company mean Intra-Cellular Therapies, Inc. and our subsidiaries. ITI refers to our wholly-owned operating subsidiary, ITI, Inc., and its subsidiary.

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PART I: FINANCIAL INFORMATION

Item 1. FINANCIAL STATEMENTS

Intra-Cellular Therapies, Inc. and Subsidiaries

Condensed Consolidated Balance Sheets

	June 30, 2014 *(Unaudited)*	December 31, 2013 *(Audited)*
Assets		
Current assets:		
Cash and cash equivalents	**$ 91,140,138**	$ 35,150,924
Investment securities, available-for-sale	**49,355,284**	2,000,000
Accounts receivable	**219,238**	336,318
Prepaid expenses and other current assets	**493,356**	762,243
Total current assets	**141,208,016**	38,249,485
Property and equipment, net	**63,850**	68,272
Other assets	**70,944**	131,555
Total assets	**$ 141,342,810**	$ 38,449,312
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	**$ 415,791**	$ 3,395,067
Accrued and other current liabilities	**1,434,875**	2,611,091
Accrued employee benefits	**888,588**	827,879
Total current liabilities	**2,739,254**	6,834,037
Stockholders equity:		
Common stock, $.0001 par value: 100,000,000 shares authorized; 29,344,020 and 22,159,446 shares issued and outstanding at June 30, 2014 and December 31, 2013, respectively	**2,934**	2,216
Additional paid-in capital	**205,289,691**	89,177,556
Accumulated deficit	**(66,641,320)**	(57,564,497)
Accumulated other comprehensive loss	**(47,749)**	
Total stockholders equity	**138,603,556**	31,615,275
Total liabilities and stockholders equity	**$ 141,342,810**	$ 38,449,312

See accompanying notes to these condensed consolidated financial statements.

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Intra-Cellular Therapies, Inc. and Subsidiaries

Condensed Consolidated Statements of Operations

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	**2013**	**2014**	**2013**
	(Unaudited)	*(Unaudited)*	*(Unaudited)*	*(Unaudited)*
Revenues	**$ 219,238**	$ 643,264	**$ 387,025**	$ 1,241,516
Costs and expenses:				
Research and development	**2,709,702**	7,787,901	**5,539,001**	12,740,161
General and administrative	**2,121,120**	903,406	**4,034,071**	1,950,014
Total costs and expenses	**4,830,822**	8,691,307	**9,573,072**	14,690,175
Loss from operations	**(4,611,584)**	(8,048,043)	**(9,186,047)**	(13,448,659)
Interest expense	**(2,032)**	(231,756)	**(7,073)**	(473,072)
Interest income	**80,077**	2,408	**116,297**	5,963
Net loss	**$ (4,533,539)**	$ (8,277,391)	**$ (9,076,823)**	$ (13,915,768)
Net loss per common share:				
Basic & Diluted	**$ (0.15)**	$ (0.56)	**$ (0.33)**	$ (0.95)
Weighted average number of common shares:				
Basic & Diluted	**29,273,357**	14,690,942	**27,882,360**	14,645,529

See accompanying notes to these condensed consolidated financial statements.

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Intra-Cellular Therapies, Inc. and Subsidiaries

Condensed Consolidated Statements of Comprehensive Loss

	Three-Months Ended June 30,		Six-Months Ended June 30,	
	2014	**2013**	**2014**	**2013**
	(Unaudited)	*(Unaudited)*	*(Unaudited)*	*(Unaudited)*
Net loss	**$ (4,533,539)**	$ (8,277,391)	**$ (9,076,823)**	$ (13,915,768)
Other comprehensive loss:				
Unrealized loss on investment securities	**(47,749)**		**(47,749)**	
Comprehensive loss	**$ (4,581,288)**	$ (8,277,391)	**$ (9,124,572)**	$ (13,915,768)

See accompanying notes to these condensed consolidated financial statements.

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Intra-Cellular Therapies, Inc. and Subsidiaries

Condensed Consolidated Statements of Cash Flows

	(Unaudited)	
	Six-Months Ended June 30,	
	2014	2013
Cash flows provided by (used in) operating activities		
Net loss	**$ (9,076,823)**	$ (13,915,768)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	**12,747**	11,092
Share-based compensation expense	**490,215**	163,233
Amortization of premiums on investment activities	**41,753**	
Changes in operating assets and liabilities:		
Accounts receivable	**117,080**	24,504
Prepaid expenses and other assets	**329,498**	85,962
Accounts payable	**(2,979,276)**	2,737,604
Accrued liabilities	**(1,115,507)**	2,526,306
Deferred revenue		(833,328)
Net cash used in operating activities	**(12,180,313)**	(9,200,395)
Cash flows provided by (used in) investing activities		
Purchases of investments	**(72,444,786)**	
Maturities of investments	**25,000,000**	1,500,000
Purchase of property and equipment	**(8,325)**	(8,843)
Net cash (used in) provided by investing activities	**(47,453,111)**	1,491,157
Cash flows provided by (used in) financing activities		
Proceeds from issuance of convertible promissory notes, net		100,000
Proceeds from stock option exercises	**70,058**	194,223
Proceeds from stock subscriptions	**109,833**	109,834
Gross proceeds of public offering	**116,191,285**	
Payment of costs of public offering	**(748,538)**	
Net cash provided by financing activities	**115,622,638**	404,057
Net increase (decrease) in cash and cash equivalents	**55,989,214**	(7,305,181)
Cash and cash equivalents at beginning of period	**35,150,924**	15,645,528
Cash and cash equivalents at end of period	**$ 91,140,138**	$ 8,340,347
Cash paid for interest	**$ 7,073**	$

Cash paid for taxes	**$**	**27,866**	$	7,260

See accompanying notes to these condensed consolidated financial statements.

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Intra-Cellular Therapies, Inc.

Notes to Condensed Consolidated Financial Statements (Unaudited)

June 30, 2014

1. Organization

Intra-Cellular Therapies, Inc. (the Company), through its wholly-owned operating subsidiary, ITI, Inc. (ITI), is 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 (CNS). The Company s lead product candidate, ITI-007, is in late phase clinical development as a first-in-class treatment for schizophrenia.

ITI was incorporated in the State of Delaware on May 22, 2001 under the name Intra-Cellular Therapies, Inc. and commenced operations in June 2002. ITI was founded to discover and develop drugs for the treatment of neurological and psychiatric disorders.

On August 29, 2013, ITI completed a reverse merger (the Merger) with a public shell company named Oneida Resources Corp. (Oneida). Oneida was formed in August 2012 as a vehicle to investigate and, if such investigation warranted, acquire a target company or business seeking the perceived advantages of being a publicly held corporation. In the Merger, each outstanding share of capital stock of ITI was exchanged for 0.5 shares of common stock of Oneida, and each outstanding option to purchase one share of ITI common stock and each outstanding warrant to purchase one share of ITI common stock was assumed by Oneida and became exercisable for 0.5 shares of Oneida common stock. As a result of the Merger and related transactions, ITI survived as a wholly-owned subsidiary of Oneida, Oneida changed its fiscal year end from March 31 to December 31, and Oneida changed its name to Intra-Cellular Therapies, Inc. (the Company). In addition, the Company began operating ITI and its business, and therefore ceased being a shell company. Following the Merger and the redemption of all then outstanding shares of Oneida at the closing of the Merger, the former shareholders of ITI owned 100% of the shares of the Company s outstanding capital stock.

In accordance with Financial Accounting Standards Board (FASB), Accounting Standards Codification (ASC) Topic 805, *Business Combinations*, ITI is considered the acquirer for accounting purposes, and has 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 the Company s consolidated financial statements are those of ITI and have been recorded at the historical cost basis of the Company. All share and per share amounts in the condensed consolidated financial statements and related notes have been retrospectively adjusted to reflect the one for 0.5 shares common stock exchange as well as the conversion of the Notes (defined below) and Series A, B, and C redeemable convertible preferred stock of ITI.

Immediately prior to the Merger, on August 29, 2013, 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 (the Private Placement), 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 (the Notes).

On February 5, 2014, the Company completed a public offering of common stock in which the Company sold 7,063,300 shares of common stock, which included the exercise of the underwriters option to purchase 921,300

shares, at an offering price of $17.50 per share. After deducting underwriting discounts, commissions and offering expenses, the net proceeds to the Company were approximately $115.4 million.

The Company earns license and collaboration revenue from its significant partnership with Takeda Pharmaceutical Company Limited (Takeda). In order to further its research projects and support its collaborations, the Company will require additional financing until such time, if ever, that revenue streams are sufficient to generate consistent positive cash flow from operations. Possible sources of funds include 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.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Although actual results could differ from those estimates, management does not believe that such differences would be material.

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2. Summary of Significant Accounting Policies (continued)

Cash and Cash Equivalents

The Company considers all highly liquid investments with a maturity of three months or less from the date of purchase to be cash equivalents. Cash and cash equivalents consist of checking accounts, money market accounts, money market funds, and certificates of deposit with a maturity date of three months or less. Certificates of deposit, commercial paper, corporate notes and corporate bonds with a maturity date of more than three months are classified separately on the balance sheet. Their carrying values approximate the fair market value.

Investment Securities

Investment securities consisted of the following (in thousands):

	June 30, 2014			
	Amortized Cost	Unrealized Gains	Unrealized (Losses)	Estimated Fair Value
		(unaudited)		
Certificates of Deposit	$ 10,346	$	$	$ 10,346
Commercial Paper	18,467	5	(6)	18,466
Corporate Notes/Bonds	20,571		(28)	20,543
	$ 49,384	$ 5	$ (34)	$ 49,355

	December 31, 2013			
	Amortized Cost	Unrealized Gains	Unrealized (Losses)	Estimated Fair Value
FDIC Guaranteed Certificates of Deposit	$	$	$	$
Certificates of Deposit	2,000			2,000
Commercial Paper				
Corporate Notes/Bonds				
	$ 2,000	$	$	$ 2,000

The Company has classified all of its investment securities available-for-sale, including those with maturities beyond one year, as current assets on the consolidated balance sheets based on the highly liquid nature of the investment securities and because these investment securities are considered available for use in current operations. As of June 30, 2014 and December 31, 2013, the Company held $21.5 million and $2.0 million, respectively, of available-for-sale investment securities with contractual maturity dates more than one year and less than two years.

Fair Value Measurements

The Company applies the fair value method under ASC Topic 820, *Fair Value Measurements and Disclosures*. ASC Topic 820 defines fair value, establishes a fair value hierarchy for assets and liabilities measured at fair value and requires expanded disclosures about fair value measurements. The ASC Topic 820 hierarchy ranks the quality and reliability of inputs, or assumptions, used in the determination of fair value and requires assets and liabilities carried at fair value to be classified and disclosed in one of the following categories based on the lowest level input used that is significant to a particular fair value measurement:

Level 1 Fair value is determined by using unadjusted quoted prices that are available in active markets for identical assets and liabilities.

Level 2 Fair value is determined by using inputs other than Level 1 quoted prices that are directly or indirectly observable. Inputs can include quoted prices for similar assets and liabilities in active markets or quoted prices for identical assets and liabilities in inactive markets. Related inputs can also include those used in valuation or other pricing models, such as interest rates and yield curves that can be corroborated by observable market data.

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2. Summary of Significant Accounting Policies (continued)

Level 3 Fair value is determined by inputs that are unobservable and not corroborated by market data. Use of these inputs involves significant and subjective judgments to be made by a reporting entity e.g., determining an appropriate adjustment to a discount factor for illiquidity associated with a given security.

The Company evaluates financial assets and liabilities subject to fair value measurements on a recurring basis to determine the appropriate level at which to classify them each reporting period. This determination requires the Company to make subjective judgments as to the significance of inputs used in determining fair value and where such inputs lie within the ASC Topic 820 hierarchy.

The Company has no assets or liabilities that were measured using quoted prices for significant unobservable inputs (Level 3 assets and liabilities) as of June 30, 2014 and December 31, 2013. The carrying value of cash held in money market funds of approximately $2.4 million as of June 30, 2014 and $0.0 million as of December 31, 2013, is included in cash and cash equivalents and approximates market value based on quoted market price or Level 1 inputs.

The fair value measurements of the Company s cash equivalents and available-for-sale investment securities are identified in the following tables (in thousands):

		Fair Value Measurements at Reporting Date Using		
	June 30, 2014	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money market funds	$ 2,387	$ 2,387	$	$
FDIC certificates of deposit	8,586		8,586	
Certificates of deposit	41,000		41,000	
Commercial paper	18,466		18,466	
Corporate Bonds/Notes	20,543		20,543	
	$ 90,982	$ 2,387	$ 88,595	$

		Fair Value Measurements at Reporting Date Using		
	December 31, 2013	Quoted Prices in	Significant Other	Significant Unobservable

		Active Markets for Identical Assets (Level 1)	Observable Inputs (Level 2)	Inputs (Level 3)
Money market fund	$	$	$	$
Certificates of deposit	6,000		6,000	
	$ 6,000	$	$ 6,000	$

Financial Instruments

The Company considers the recorded costs of its financial assets and liabilities, which consist of cash equivalents, investment securities available-for-sale, accounts receivable, accounts payable and accrued liabilities, to approximate their fair value because of their relatively short maturities at June 30, 2014 and December 31, 2013. Management believes that the risks associated with its financial instruments are minimal as the counterparties are various corporations, financial institutions and government agencies of high credit standing.

Concentration of Credit Risk

Cash equivalents are held with major financial institutions in the United States. Certificates of deposit held with banks may exceed the amount of insurance provided on such deposits. Generally, these deposits may be redeemed upon demand and, therefore, bear minimal risk.

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2. Summary of Significant Accounting Policies (continued)

Accounts Receivable

Accounts receivable that management has the intent and ability to collect are reported in the balance sheets at outstanding amounts, less an allowance for doubtful accounts. The Company writes off uncollectible receivables when the likelihood of collection is remote.

The Company evaluates the collectability of accounts receivable on a regular basis. The allowance, if any, is based upon various factors including the financial condition and payment history of customers, an overall review of collections experience on other accounts and economic factors or events expected to affect future collections experience. No allowance was recorded as of June 30, 2014 and December 31, 2013, as the Company has a history of collecting on substantially all of its accounts, including government agencies and collaborations funding its research.

Property and Equipment

Property and equipment is stated at cost and depreciated on a straight-line basis over estimated useful lives ranging from three to five years. Leasehold improvements are amortized using the straight-line method over the shorter of the estimated useful life of the assets or the term of the related lease. Expenditures for maintenance and repairs are charged to operations as incurred.

When indicators of possible impairment are identified, the Company evaluates the recoverability of the carrying value of its long-lived assets based on the criteria established in ASC Topic 360, *Property, Plant and Equipment*. The Company considers historical performance and anticipated future results in its evaluation of potential impairment. The Company evaluates the carrying value of those assets in relation to the operating performance of the business and undiscounted cash flows expected to result from the use of those assets. Impairment losses are recognized when carrying value exceeds the undiscounted cash flows, in which case management must determine the fair value of the underlying asset. No such impairment losses have been recognized to date.

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. The Company is reimbursed for certain costs incurred on specified research projects under the terms and conditions of grants, collaboration agreements, and awards. The Company records the amount of reimbursement as revenues on a gross basis in accordance with ASC Topic 605-45, *Revenue Recognition/Principal Agent Considerations*. The Company is the primary obligor with respect to purchasing goods and services from third-party suppliers, is obligated to compensate the service provider for the work performed, and has 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.

The Company has entered into arrangements involving the delivery of more than one element. Each required deliverable is evaluated to determine whether it qualifies as a separate unit of accounting. For ITI, this determination is generally based on whether the deliverable has stand-alone value to the customer. The Company adopted this accounting standard on a prospective basis for all Multiple-Deliverable Revenue Arrangements (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.

The adoption of this accounting standard did not have a material impact on the Company s results of operations for the periods ended June 30, 2014 and 2013, or on the Company s financial positions as of June 30, 2014 and December 31, 2013.

The Company adopted ASC Topic 605-28, *Milestone Method*. Under this guidance, the Company recognizes 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 the Company s 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.

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2. Summary of Significant Accounting Policies (continued)

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 in accordance with the revenue models described above. In addition, the determination that one such payment was not a substantive milestone could prevent the Company 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.

Deferred Revenue

Cash received as prepayment on future services is deferred and recognized as revenue as the services are performed. The Company must remit interest on any deferred revenue related to a governmental agency. As of June 30, 2014 and December 31, 2013, no interest was due as the Company did not have any deferred revenue.

Research and Development

Except for payments made in advance of services, the Company expenses its research and development costs as incurred. For payments made in advance, the Company recognizes research and development expense as the services are rendered. Research and development costs consist primarily of salaries and related expenses for personnel and resources and the costs of clinical trials. Other research and development expenses include pre-clinical analytical testing, outside services providers, materials and consulting fees.

Income Taxes

Income taxes are accounted for using the liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and its respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the year in which those temporary differences are expected to be recovered or settled.

The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Valuation allowances are established when necessary to reduce net deferred tax assets to the amount expected to be realized. Income tax expense is the tax payable for the period and the change during the period in deferred tax assets and liabilities.

The Company accounts for uncertain tax positions pursuant to ASC Topic 740 (previously included in FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes an Interpretation of FASB Statement No. 109).* Financial statement recognition of a tax position taken or expected to be taken in a tax return is determined based on a more-likely-than-not threshold of that position being sustained. If the tax position meets this threshold, the benefit to be recognized is measured as the tax benefit having the highest likelihood of being realized upon ultimate settlement with the taxing authority. The Company recognizes interest accrued related to unrecognized tax benefits and penalties in the provision for income taxes.

Comprehensive Income (Loss)

All components of comprehensive income (loss), including net income (loss), are reported in the financial statements in the period in which they are incurred. Comprehensive income (loss) is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. In accordance with accounting guidance, the Company presents the impact of any unrealized gains or (losses) on its investment securities in a separate statement of comprehensive income (loss) for each period.

Share-Based Compensation

Share-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 (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 awards granted with time-based vesting conditions, 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 share-based compensation expense recognized in the statements of operations for the three and six months ended June 30, 2014 and 2013 is based on share-based awards ultimately expected to vest, it has been reduced for estimated forfeitures.

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2. Summary of Significant Accounting Policies (continued)

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 the Company s historical experience for the three and six months ended June 30, 2014 and 2013, and have not been material.

The Company utilizes the Black-Scholes model for estimating fair value of its 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 the Company s common stock. The expected life of stock options is the period of time for which the stock 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.

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. The Company has not paid dividends to its stockholders since its inception and does not plan to pay cash dividends in the foreseeable future. Therefore, the Company has assumed an expected dividend rate of zero.

For the three and six months ended June 30, 2013, given that there was no active market for the Company s common stock, the exercise prices of the stock options on the dates of grant were determined and approved by the board of directors using several factors, including progress and milestones achieved in the Company s business development and performance, the price per share of its convertible preferred stock offerings and general industry and economic trends. In establishing the estimated fair value of the common stock, the Company considered the guidance set forth in American Institute of Certified Public Accountants Practice Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. For the three and six months ended June 30, 2014, the exercise price was determined by using the closing market price of the Company s common stock on the date of grant.

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 the Company, as all the deferred tax assets have a full valuation allowance.

Since the Company had net operating loss carryforwards as of June 30, 2014 and 2013, no excess tax benefits for the tax deductions related to share-based awards were recognized in the statements of operations.

Equity instruments issued to consultants 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.

Loss Per Share

Basic net loss per common share is determined by dividing the net loss allocable to common stockholders by the weighted-average number of common shares outstanding during the period, without consideration of common stock equivalents. Diluted net loss per share is computed by dividing the net loss allocable to common stockholders by the weighted-average number of common stock equivalents outstanding for the period. The treasury stock method is used to determine the dilutive effect of the Company s stock option grants.

The following common stock equivalents were excluded in the calculation of diluted loss per share because their effect would be anti-dilutive as applied to the loss from operations for the three and six months ended June 30, 2014 and 2013:

	2014	2013
Stock options	**1,102,945**	823,899

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3. Property and Equipment

Property and equipment consist of the following:

	June 30, 2014	December 31, 2013
Computer equipment	**$ 85,846**	$ 82,252
Furniture and fixtures	**46,523**	46,523
Scientific equipment	**2,851,947**	2,851,947
Leasehold improvements	**319,553**	319,553
	3,303,869	3,300,275
Less accumulated depreciation	**(3,240,019)**	(3,232,003)
	$ 63,850	$ 68,272

Depreciation expense for the three and six months ended June 30, 2014 was $6,430 and $12,747, respectively.

4. Share-Based Compensation

The Company sponsors the Intra-Cellular Therapies, Inc. 2013 Equity Incentive Plan (the 2013 Plan) to provide for the granting of stock-based awards, such as stock options, restricted common stock and restricted stock units to employees, directors and consultants as determined by the Board of Directors. In August 2013, the Company assumed in the Merger the ITI 2003 Equity Incentive Plan , as amended (the 2003 Plan), which expired by its terms in July 2013. As of June 30, 2014, the outstanding awards under the 2003 Plan were options to purchase 1,289,576 shares of common stock. Effective in November 2013, the Company adopted the 2013 Plan. The Company reserved 2,850,000 shares of common stock for issuance under the 2013 Plan. In January 2014, the number of shares of common stock reserved for issuance under the 2013 Plan automatically increased by 800,000 pursuant to the evergreen provisions of the 2013 Plan.

Stock options granted under the 2013 Plan may be either incentive stock options (ISOs) as defined by the Internal Revenue Code, or non-qualified stock options. The Board of Directors determines who will receive options, the vesting periods (which are generally one to three years) and the exercise prices of such options. Options have a maximum term of 10 years. The exercise price of ISOs granted under the 2013 Plan must be at least equal to the fair market value of the common stock on the date of grant.

Total stock-based compensation expense related to all of the Company s share-based awards to employees, directors and consultants recognized during the three and six months ended June 30, 2014 and 2013, was comprised of the following:

	Three Months Ended	Six Months Ended
		June 30,

	June 30,			
	2014	**2013**	**2014**	**2013**
Research and development	**$ 134,833**	$ 31,466	**$ 232,250**	$ 58,087
General and administrative	**155,628**	57,697	**257,965**	105,146
Total share-based compensation expense	**$ 290,461**	$ 89,163	**$ 490,215**	$ 163,233

The following table describes the weighted-average assumptions used for calculating the value of options granted during the three months ended June 30, 2014:

	2014
Dividend yield	**0%**
Expected volatility	**80%**
Weighted-average risk-free interest rate	**2.0%**
Expected term	**6.2 years**

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4. Share-Based Compensation (continued)

Information regarding the stock options activity including with respect to grants to employees, directors and consultants as of June 30, 2014, and changes during the three month period then ended, are summarized as follows:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Contractual Life
Outstanding at December 31, 2013 (audited)	1,400,125	$ 1.98	5.3 years
Options granted (unaudited)	888,000	$ 16.95	9.9 years
Options exercised (unaudited)	(103,049)	$ 0.68	1.0 year
Options canceled or expired (unaudited)	(7,500)	$ 0.30	
Outstanding at June 30, 2014 (unaudited)	2,177,576	$ 8.15	7.1 years
Vested or expected to vest at June 30, 2014 (unaudited)	2,177,576	$ 8.15	
Exercisable at June 30, 2014 (unaudited)	1,079,779	$ 1.88	4.5 years

5. Collaborations and License Agreements

The Bristol-Myers Squibb License Agreement

On May 31, 2005, the Company (through its wholly owned operating subsidiary, ITI) entered into a worldwide, exclusive License Agreement with Bristol-Myers Squibb Company (BMS), pursuant to which the Company holds 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. The Company has the right to grant sublicenses of the rights conveyed by BMS. The Company is obliged under the license to use commercially reasonable efforts to develop and commercialize the licensed technology. The Company is also prohibited from engaging in the clinical development or commercialization of specified competitive compounds.

Under the agreement, the Company made an upfront payment of $1.0 million to BMS and a milestone payment of $1.25 million in December 2013. When the Company initiates the Phase 3 clinical trials for ITI-007 for patients with exacerbated schizophrenia, it will be obligated to pay a $1.5 million milestone payment. Possible milestone payments remaining total $11.0 million. The Company may be obliged to make other milestone payments for each licensed product of up to an aggregate of $14.75 million. The Company is also obliged to make tiered single digit percentage royalty payments on sales of licensed products. The Company is 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 agreement on the occurrence of certain events. On termination of the agreement, the Company 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.

The Takeda License and Collaboration Agreement

On February 25, 2011, the Company (through its wholly owned operating subsidiary, ITI) entered into a license and collaboration agreement with Takeda Pharmaceutical Company Limited (Takeda) under which the Company agreed to collaborate to research, develop and commercialize its proprietary compound ITI-214 and other selected compounds that selectively inhibit phosphodiesterase type 1 (PDE1) for use in the prevention and treatment of human diseases. As part of the agreement, the Company assigned to Takeda certain patents owned by the Company 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, the Company has retained rights to all compounds that do not meet the specified criteria and the Company continues to develop PDE1 inhibitors outside the scope of the agreement.

Under the terms of the agreement, the Company has 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. The Company was responsible for the Company s expenses incurred in the conduct of certain research activities specified in the research plan. Takeda agreed to reimburse the Company for expenses the Company incurred in conducting additional research activities.

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5. Collaborations and License Agreements (continued)

Takeda is obliged to use commercially reasonable efforts to develop and commercialize licensed compounds at its expense, and has agreed to reimburse the Company for the costs and expenses of development activities the Company may perform. The Company formed a joint steering committee with Takeda to coordinate and oversee activities on which the Company and Takeda collaborate under the agreement. The Company has 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.

The Company fulfilled its responsibility under the agreement to supply Takeda with ITI-214 for nonclinical activities and Phase 1 clinical trials at the Company s 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 the Company. The Company is 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 10 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 the Company the patents covering ITI-214 assigned to Takeda upon the execution of the agreement, to grant the Company a license to develop and commercialize licensed compounds developed by Takeda and to transfer to the Company certain materials, information and regulatory materials reasonably necessary for the Company to continue the development and commercialization of those compounds.

The Company evaluates all deliverables within an arrangement to determine whether or not they provide value on a stand-alone basis. The Company identified two deliverables in the arrangement, (1) a license to the Company s intellectual property, and (2) research and development services (R&D services). Based on this evaluation, the deliverables were separated into units of accounting. The arrangement consideration that is fixed or determinable at the inception of the arrangement was allocated to the separate units of accounting based on their relative selling prices. The Company may exercise significant judgment in determining whether a deliverable is a separate unit of accounting, as well as in estimating the selling prices of such unit of accounting.

During the three and six months ended June 30, 2014, the Company recognized revenue of approximately $219,000 and $387,000 under this agreement, respectively, as compared to $643,000 and $1.2 million for the three and six months ended June 30, 2013 also under this agreement. At June 30, 2014 and 2013, $0 and $833,000, respectively, of revenue was deferred under this agreement.

Other License Agreement

In May 2002, ITI entered into a license agreement (the License) and research agreement with a university. Under the provisions of the License, ITI is entitled to use this organization s patented technology and other intellectual property

relating to diagnosis and treatment of central nervous system disorders.

The License expires upon expiration of the patent rights or 15 years subsequent to the first sale of products developed through this License. ITI is required to make future milestone payments for initiation of clinical trials and approval of a New Drug Application (NDA). Should ITI commercialize the technology related to this License, ITI would be required to make royalty payments, and would also be required to pay fees under any sublicense agreements with third parties.

In connection with the License, ITI issued 400,000 shares of common stock to the organization. Upon issuance of the shares, ITI recorded the estimated fair value of the shares issued, approximately $120,000, as research and development expense.

In addition, ITI is required to use at least $1.0 million annually of its resources for the development and commercialization of the technology until ITI submits an NDA. ITI met its spending requirements in 2013. There were no other payments made or required for the three and six months ended June 30, 2014 and 2013.

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Item 2. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following in conjunction with our unaudited condensed consolidated financial statements and the related notes thereto that appear elsewhere in this Quarterly Report on Form 10-Q and the audited consolidated financial statements and notes thereto and under the heading Management s Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report on Form 10-K filed on March 25, 2014. In addition to historical information, the following discussion and analysis includes forward-looking information that involves risks, uncertainties and assumptions. Our actual results and the timing of events could differ materially from those anticipated by these forward-looking statements as a result of many factors, including those discussed under Risk Factors in our Annual Report on Form 10-K filed on March 25, 2014.

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 late phase clinical development as a first-in-class treatment for schizophrenia. Results from our Phase 2 trial are included in Business Our Clinical Programs ITI-007 Program under Item 1 of our Annual Report on Form 10-K filed on March 25, 2014. In June 2014, we had discussions with the U.S. Food and Drug Administration, or FDA, regarding our plans to initiate our Phase 3 clinical program of ITI-007 in schizophrenia. Following this meeting with the FDA, we are proceeding with Phase 3 development of ITI-007 for the treatment of schizophrenia. We plan to conduct two randomized, double-blind, placebo-controlled Phase 3 clinical trials of ITI-007 in patients with acutely exacerbated schizophrenia, with over 400 patients in each trial. Subject to finalizing the trial protocols and arrangements with clinical trial sites, we intend to initiate the first Phase 3 clinical trial in schizophrenia in the second half of 2014 and a second Phase 3 clinical trial in early 2015. In the first Phase 3 trial, we plan to randomize patients to two doses of ITI-007 (60mg or 40mg) or placebo over a 4-week treatment duration. We currently expect that the second Phase 3 trial will be conducted for a 6-week treatment duration. Subject to initiation of these trials as planned and timely enrollment, we anticipate that the results of the first Phase 3 clinical trial of ITI-007 in patients with schizophrenia could be available as early as the fourth quarter of 2015. Subject to further discussions with the FDA, we also 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 to our Phase 3 clinical trials, we will need to complete other clinical and non-clinical trials and manufacturing and pre-commercialization activities necessary to support the submission of a planned New Drug Application, or NDA, for ITI-007 in schizophrenia, which we currently expect could occur at the end of 2016 or the beginning of 2017. In addition, in 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.

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.

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

We have a second major program called ITI-002 that has yielded a portfolio of compounds that selectively inhibits the enzyme phosphodiesterase 1, or PDE1. We have licensed the lead compound in the ITI-002 portfolio, ITI-214, and other compounds in that 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. 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 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.

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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 June 30, 2014, our accumulated deficit was $66.6 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 the six months ended June 30, 2014 and the 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.

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 the six months ended June 30, 2014 and 2013 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.

We expect our revenues for the next several years to consist of limited reimbursable costs incurred for patent prosecutions and to a lesser extent 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 pre-clinical stages, and will require extensive funding not only to complete pre-clinical 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 results of 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 pre-clinical 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 research and development expenses will increase substantially as we prepare for and enter into Phase 3 clinical trials for ITI-007 for patients with exacerbated schizophrenia. We also expect that our general and administrative costs will increase substantially from prior periods primarily due to the increased costs associated with being a public reporting entity, which would include adding additional personnel. We have granted options to purchase 888,000 shares of our common stock in the current year and will be recognizing expense associated with these options over the next two years in both the research and development and general and administrative expense

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categories. We expect this non-cash expense to be material and affect quarter to quarter and year to date comparisons in the upcoming year. We expect to continue to grant stock options in the future, which will increase our stock-based compensation expense in future periods.

The following table sets forth our revenues and operating expenses for the three and six month periods ended June 30, 2014 and 2013:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	**2013**	**2014**	**2013**
	(Unaudited)		*(Unaudited)*	
	(In Thousands)		*(In Thousands)*	
Revenues	**$ 219**	$ 643	**$ 387**	$ 1,242
Expenses				
Research and Development	**2,710**	7,788	**5,539**	12,740
General and Administrative	**2,121**	903	**4,034**	1,950
	4,831	8,691	**9,573**	14,690
Net Loss	**$ (4,534)**	$ (8,277)	**$ (9,077)**	$ (13,916)

Comparison of Three and Six Month Periods Ended June 30, 2014 and June 30, 2013

Revenues

Revenue decreased for the six months ended June 30, 2014 as compared to the six months ended June 30, 2013 by approximately $854,000, or 69%, due primarily to the recognition of previously deferred revenue relating to the collaboration agreement with Takeda and lower reimbursable costs under the research agreement with Takeda in 2014, both associated with the Takeda agreement. Revenue decreased for the three months ended June 30, 2014 as compared to the three months ended June 30, 2013 by approximately $424,000, or 66%, due primarily to the prior year recognition of revenue previously deferred relating to the collaboration agreement with Takeda and lower reimbursable patent costs, offset in part by higher reimbursable costs under the research agreement with Takeda in 2014 compared to 2013.

Research and Development Expenses

Research and development expenses decreased for the three and six month periods ended June 30, 2014 as compared to the three and six month periods ended June 30, 2013 by approximately $5.1 million, or 65%, and $7.2 million, or 57%, respectively. The decreases in the three and six month periods are due almost exclusively to costs associated with outside clinical testing for our ITI-007 Phase 2 clinical trial that was completed in late 2013, with no such costs incurred in 2014. Partially offsetting the decreases in the three and six month period ended June 30, 2014 were expenses of approximately $1.0 million and $1.8 million, respectively, relating to the manufacturing and other clinical and non-clinical testing of our ITI-007 product candidate and to the costs associated with our ITI-007-200 Phase 1/2 clinical trial in dementia patients totaling approximately $372,000 and $1.4 million in the three and six month period ended June 30, 2014, respectively.

The research and development expenses incurred for amounts payable to external parties comprise a significant portion of our research and development expenses during the three and six months ended June 30, 2014 and 2013. We incurred expenses of approximately $3.8 million and $11.3 million during the six months ended June 30, 2014 and 2013, 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 $1.7 million and $1.5 million, respectively. During the three month periods ended June 30, 2014 and 2013, we incurred expenses of approximately $1.7 million and $7.0 million, 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 $920,000 and $740,000, respectively. As of June 30, 2014, we employed 14 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 $4.0 million and $9.4 million on direct costs for the development of ITI-007 during six months ended June 30, 2014 and 2013, respectively, and $1.9 million and $5.2 million during the three months ended June 30, 2014 and 2013, 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.

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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. In previous years we also incurred costs that were both reimbursable and non-reimbursable under the license and collaboration agreement with Takeda. For the six months ended June 30, 2014 and 2013, we incurred approximately $15,000 and $53,000, respectively, on direct costs that were billable to Takeda and for the three months ended June 30, 2014 and 2013 we incurred approximately $15,000 and $10,000, respectively, on direct costs that were billable to Takeda. We anticipate that these costs will be minimal in the future as the research portion of the license and collaboration agreement concluded in February 2014.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;

- 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

pre-clinical 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 section entitled Risk Factors in our Annual Report on Form 10-K filed with the SEC on March 25, 2014, as updated from time to time in our other periodic and current reports filed with the SEC.

General and Administrative Expenses

General and administrative expenses increased for the six month period ended June 30, 2014 as compared to the six month period ended June 30, 2013 by approximately $2.1 million, or 107%. The increase is primarily the result of higher professional fees, directors and officers insurance costs, and board of director compensation fees, which are due to the activities associated with being a public company, with the remainder comprised primarily of higher salary and benefit expenses. Salaries and related benefit costs for our executive, finance and administrative functions for the six months ended June 30, 2014 and 2013 constituted approximately 33% and 47%, respectively, of our total general and administrative costs. General and administrative expenses also include 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. The increase for the three month period ended June 30, 2014 as compared to the three month period ended June 30, 2013 was approximately $1.2 million, or 135%, and is primarily the result of professional fees, directors and officers insurance costs and board of director compensation fees, which are due to the activities associated with being a public company, with the remainder comprised primarily of higher salary and fringe expenses. Salaries and related benefit costs for our executive, finance and administrative functions for the three months ended June 30, 2014 and 2013 constituted approximately 35% and 51%,

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respectively, of our total general and administrative costs. We expect all of these costs to increase significantly as we expand our operations, including hiring of additional personnel, and continue to be subject to the reporting requirements of being a public company.

Liquidity and Capital Resources

Through June 30, 2014, we have provided funds for our operations by obtaining approximately $265.9 million of cash primarily through the public and private offering of our common stock and other securities, grants from government agencies and foundations and payments received under the license and collaboration agreement with Takeda. 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.

As of June 30, 2014, we had a total of $140.5 million in cash and cash equivalents and available-for-sale investment securities, and approximately $2.7 million of short-term liabilities consisting entirely of short-term liabilities from operations. Excluding the increase in net cash of approximately $115.4 million from the public offering which closed on February 5, 2014, we spent approximately $12.2 million in cash and reduced working capital by approximately $8.4 million for the six months ended June 30, 2014. This use of working capital is due primarily to funding recurring operating expenses and the preparation for additional clinical trials and non-clinical testing, including manufacturing related activities. We expect to use cash of up to $30.0 million during the remainder of 2014. This is expected to be due primarily to recurring expenses and for costs to produce, develop and validate materials to be used in clinical and non-clinical studies related to ITI-007. We expect to begin to incur significant expenditures in the remainder of 2014 and beyond as we plan to initiate a Phase 3 clinical trial in patients with acutely exacerbated schizophrenia and other planned clinical and non-clinical trials.

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, 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 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, when we received an up-front fee and a milestone payment related to our agreement with Takeda. These losses have resulted in significant cash used in operations. During the six months ended June 30, 2014 and 2013, our net cash used in operating activities was approximately $12.1 million and $9.2 million, respectively. 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 amount of cash needed to fund operations to increase significantly over the next several years.

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 and three months. We expect that our facility related costs will increase moderately when the lease commences in 2015.

We seek to balance the level of cash, cash equivalents and investments 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.

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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 pre-clinical studies, clinical trials or other clinical development activities for one or more of our product candidates, including our lead product candidate ITI-007 as well as our other pre-clinical stage product candidates; (2) delay, limit, reduce or terminate our discovery research or pre-clinical 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 checking accounts, money market accounts, money market funds, certificates of deposit, commercial paper, corporate notes and corporate bonds at major financial institutions. Due to the current low interest rates available for these instruments, we are earning limited 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.

We have entered into arrangements involving the delivery of more than one element. 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 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.

The adoption of this accounting standard did not have a material impact on our results of operations for the three and six months ended June 30, 2014 and 2013, or on our financial positions as of those dates.

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;

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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 awards granted with time-based vesting conditions, 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 three and six months ended June 30, 2014 and 2013 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 and 2012 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 options is the period of time for which the stock 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.

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.

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Since we had net operating loss carryforwards as of June 30, 2014 and 2013, 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 Recently Issued Accounting Pronouncements in our Annual Report on Form 10-K for the year ended December 31, 2013 filed on March 25, 2014.

Certain Factors That May Affect Future Results of Operations

The Securities and Exchange Commission encourages companies to disclose forward-looking information so that investors can better understand a company s future prospects and make informed investment decisions. This Quarterly Report on Form 10-Q contains such forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements involve known and unknown risks, uncertainties and other important factors which may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. Forward-looking statements include, but are not limited to, statements about: the accuracy of our estimates regarding expenses, future revenues, capital requirements and the need for additional financing; the initiation, cost, timing, progress and results of our development activities, pre-clinical 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 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 obtain and maintain intellectual property protection for our product candidates; our ability to successfully commercialize our product candidates; 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; and our ability to attract and retain key scientific or management personnel.

Words such as may, anticipate, estimate, expect, may, project, intend, plan, believe, potential, p will, would, could, should, continue and words and terms of similar substance used in connection with any discu of future operating or financial performance, identify forward-looking statements. All forward-looking statements are management s present expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those described in the forward-looking statements. These risks include, but are not limited to, those set forth under the heading Risk Factors in our Annual Report on Form 10-K filed on March 25, 2014.

In light of these assumptions, risks and uncertainties, the results and events discussed in the forward-looking statements contained in this Quarterly Report on Form 10-Q or in any document incorporated by reference might not occur. Stockholders are cautioned not to place undue reliance on the forward-looking statements, which speak only as

of the date of this Quarterly Report on Form 10-Q. We are not under any obligation, and we expressly disclaim any obligation, to update or alter any forward-looking statements, whether as a result of new information, future events or otherwise. All subsequent forward-looking statements attributable to the Company or to any person acting on its behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section.

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As a smaller reporting company as defined by Item 10 of Regulation S-K, the Company is not required to provide information required by this Item.

Item 4. CONTROLS AND PROCEDURES

(a) *Evaluation of Disclosure Controls and Procedures*. Our principal executive officer and principal financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as

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of the end of the period covered by this Form 10-Q, have concluded that, based on such evaluation, our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC s rules and forms, and is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

(b) *Changes in Internal Controls*. There were no changes in our internal control over financial reporting, identified in connection with the evaluation of such internal control that occurred during the three months ended June 30, 2014 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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PART II: OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS

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

Item 1A. RISK FACTORS

The following are material changes to the risk factors described in our Annual Report on Form 10-K for the year ended December 31, 2013, filed with the Securities and Exchange Commission on March 25, 2014.

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

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

The historical rate of failures for product candidates in clinical development and late-stage clinical trials is high. While we plan to conduct further clinical studies in patients with schizophrenia and other indications, including two Phase 3 clinical trials of ITI-007 in schizophrenia, there is no guarantee that we will have the same level of success in these trials as we have had in our earlier clinical trials, or be successful at all.

In addition, although we believe that ITI-007 and follow-on compounds may also have clinical utility in indications other than schizophrenia, such as behavioral disturbances in dementia, bipolar disorder, IED, non-motor disorders associated with Parkinson s disease, obsessive compulsive disorder and anxiety disorders and post-traumatic stress disorder, we have never tested ITI-007 in Phase 2 clinical trials in the patient population for these other indications 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 schizophrenia, those results are not necessarily predictive of results of future pivotal trials that may be needed before we may submit an NDA to the FDA for the initial or other future indications. Of the vast number of drugs in development, only a small percentage result in the submission of an NDA to the FDA, and even less result in the NDA ultimately being approved by the FDA for commercialization.

We are advancing ITI-007 into Phase 3 clinical trials for the treatment of schizophrenia. Although we have discussed our clinical development plans with the FDA, the agency may ultimately determine that our Phase 3 clinical trials and non-clinical studies, even if successfully completed, are not sufficient for regulatory approval. If

we are required to conduct additional clinical trials and non-clinical studies, our development of ITI-007 for schizophrenia will be more time-consuming and costly than we presently anticipate, which would have a material adverse effect on our business, results of operations and financial condition.

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

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

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

which would have a material adverse effect on our business, financial condition and results of operations.

Item 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

(a) Unregistered Sales of Equity Securities

On June 3, 2014, we issued to a foundation 18,225 unregistered shares of our common stock in connection with a grant in the amount of $109,833 that we received pursuant to a biotechnology grant funding agreement we entered into with the foundation in 2013. These shares were issued in reliance upon an exemption from registration under the federal securities laws pursuant to Section 4(a)(2) of the Securities Act of 1933, as amended, or the Securities Act, for the issuance of securities in transactions by an issuer not involving a public offering. We do not have an obligation, nor do we anticipate, registering these shares for resale on a registration statement pursuant to the Securities Act.

(b) Use of Proceeds from Registered Securities

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. The offer and sale of all of the shares in the offering were registered under the Securities Act pursuant to a registration statement on Form S-1, which was declared effective on January 30, 2014 (File No. 333-193313), and a registration statement on Form S-1 filed pursuant to Rule 462(b) promulgated under the Securities Act (File No. 333-193676). Leerink Partners LLC and Cowen and Company, LLC acted as joint book-running managers for the offering and as representatives of the underwriters. Guggenheim Securities, LLC and JMP Securities LLC acted as co-managers for the offering. The offering commenced on January 24, 2014 and did not terminate until the sale of all of the shares offered.

We received aggregate net proceeds from the offering of approximately $115.4 million, after deducting approximately $7.4 million of underwriting discounts and commissions, and approximately $0.8 million of offering expenses payable by us. None of the underwriting discounts and commissions or other offering expenses were incurred or paid to our directors or officers or their associates or to persons owning 10 percent or more of our common stock or to any of our affiliates.

We have invested the net proceeds from the offering in a variety of capital preservation investments, including short-term, investment grade, interest bearing instruments such as commercial paper and corporate debt securities, U.S. government securities, certificates of deposit and institutional money market funds. As of June 30, 2014, $11.5 million of the net proceeds of the offering had been used. There has been no material change in our planned use of the net proceeds from the offering as described in our final prospectus dated January 30, 2014 filed with the Securities and Exchange Commission pursuant to Rule 424(b) under the Securities Act on January 31, 2014. We have broad discretion in the use of the net proceeds from our initial public offering and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our stock.

(c) Issuer Purchases of Equity Securities

We did not repurchase any of our equity securities during the three months ended June 30, 2014.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

Item 5. OTHER INFORMATION

Not applicable.

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Item 6. EXHIBITS

Exhibit Number	Exhibit Description	Filed Herewith	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/ Reg. Number
10.1	Non-Employee Director Compensation Policy.*	X			
31.1	Certification of the Registrant s Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X			
31.2	Certification of the Registrant s Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X			
32	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X			
101+	The following materials from the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2014, formatted in XBRL (eXtensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets as of June 30, 2014 (unaudited) and December 31, 2013 (audited), (ii) Condensed Consolidated Statements of Operations (unaudited) for the three and six months ended June 30, 2014 and 2013, (iii) Condensed Consolidated Statements of Comprehensive Loss (unaudited) for the three and six months ended June 30, 2014 and 2013, (iv) Condensed Consolidated Statements of Cash Flows (unaudited) for the six	X			

months ended June 30, 2014 and 2013, and (v) Notes to Condensed Consolidated Financial Statements (unaudited).

* Management contract or compensatory plan or arrangement.

\+ Pursuant to Rule 406T of Regulation S-T, the Interactive Data Files on Exhibit 101 hereto are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and otherwise are not subject to liability under those sections.

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SIGNATURES

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

INTRA-CELLULAR THERAPIES, INC.

Date: August 12, 2014

By: /s/ Sharon Mates, Ph.D.
Sharon Mates, Ph.D.
Chairman, President and Chief Executive Officer

Date: August 12, 2014

By: /s/ Lawrence J. Hineline
Lawrence J. Hineline
Vice President of Finance, Chief Financial Officer and Secretary