Intra-Cellular Therapies, Inc.
Form 10-Q
November 09, 2016
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2016

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.)**

430 East 29th Street

New York, New York	**10016**
(Address of principal executive offices)	**(Zip Code)**

(646) 440-9333

(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 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 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

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

As of November 9, 2016, the registrant had 43,268,243 shares of common stock outstanding.

Table of Contents

Intra-Cellular Therapies, Inc.

Index to Form 10-Q

PART I: FINANCIAL INFORMATION		2
Item 1.	FINANCIAL STATEMENTS	2
	Condensed Consolidated Balance Sheets as of September 30, 2016 (unaudited) and December 31, 2015 (audited)	2
	Condensed Consolidated Statements of Operations (unaudited) for the three and nine months ended September 30, 2016 and 2015	3
	Condensed Consolidated Statements of Comprehensive Loss (unaudited) for the three and nine months ended September 30, 2016 and 2015	4
	Condensed Consolidated Statements of Cash Flows (unaudited) for the nine months ended September 30, 2016 and 2015	5
	Notes to Condensed Consolidated Financial Statements (unaudited)	6
Item 2.	MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS	17
Item 3.	QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK	28
Item 4.	CONTROLS AND PROCEDURES	28
PART II: OTHER INFORMATION		28
Item 1.	LEGAL PROCEEDINGS	28
Item 1A.	RISK FACTORS	29
Item 2.	UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS	32
Item 4.	MINE SAFETY DISCLOSURES	32
Item 5.	OTHER INFORMATION	32
Item 6.	EXHIBITS	34
SIGNATURES		35

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 subsidiary ITI, Inc. and ITI Limited refers to our wholly-owned subsidiary ITI Limited.

Table of Contents

PART I: FINANCIAL INFORMATION

Item 1. FINANCIAL STATEMENTS

Intra-Cellular Therapies, Inc. and Subsidiaries

Condensed Consolidated Balance Sheets

	September 30, 2016 *(Unaudited)*	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	**$ 200,388,020**	$ 47,159,303
Investment securities, available-for-sale	**337,405,780**	428,041,021
Accounts receivable	**1,309**	30,660
Prepaid expenses and other current assets	**4,023,405**	8,025,147
Total current assets	**541,818,514**	483,256,131
Property and equipment, net	**677,703**	775,522
Other assets	**75,765**	71,875
Total assets	**$ 542,571,982**	$ 484,103,528
Liabilities and stockholders equity		
Current liabilities:		
Borrowing under secured line of credit	**$ 125,000,000**	$
Accounts payable	**5,417,451**	1,632,905
Accrued and other current liabilities	**7,520,073**	3,423,464
Accrued employee benefits	**2,752,381**	1,207,143
Total current liabilities	**140,689,905**	6,263,512
Long-term liabilities	**2,563,809**	1,597,105
Total liabilities	**143,253,714**	7,860,617
Stockholders equity:		
Common stock, $.0001 par value: 100,000,000 shares authorized; 43,268,243 and 43,155,875 shares issued and outstanding at September 30, 2016 and December 31, 2015, respectively	**4,327**	4,316
Additional paid-in capital	**681,475,390**	669,878,103
Accumulated deficit	**(281,990,327)**	(193,049,098)
Accumulated comprehensive loss	**(171,122)**	(590,410)
Total stockholders equity	**399,318,268**	476,242,911

Total liabilities and stockholders equity	**$ 542,571,982**	$ 484,103,528

See accompanying notes to these condensed consolidated financial statements.

Table of Contents

Intra-Cellular Therapies, Inc. and Subsidiaries

Condensed Consolidated Statements of Operations

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	**2015**	**2016**	**2015**
	(Unaudited)	*(Unaudited)*	*(Unaudited)*	*(Unaudited)*
Revenues	**$ 4,362**	$	**$ 232,807**	$ 60,705
Costs and expenses:				
Research and development	**23,918,232**	28,457,631	**72,652,520**	64,852,576
General and administrative	**6,270,528**	3,891,744	**17,806,565**	11,649,169
Total costs and expenses	**30,188,760**	32,349,375	**90,459,085**	76,501,745
Loss from operations	**(30,184,398)**	(32,349,375)	**(90,226,278)**	(76,441,040)
Interest expense	**(12,260)**		**(12,260)**	
Interest income	**763,949**	188,892	**2,129,927**	482,415
Net loss before income tax	**$ (29,432,709)**	$ (32,160,483)	**$ (88,108,611)**	$ (75,958,625)
Income tax expense	**(832,618)**		**(832,618)**	
Net loss	**$ (30,265,327)**	$ (32,160,483)	**$ (88,941,229)**	$ (75,958,625)
Net loss per common share:				
Basic & Diluted	**$ (0.70)**	$ (0.91)	**$ (2.06)**	$ (2.25)
Weighted average number of common shares:				
Basic & Diluted	**43,253,429**	35,320,046	**43,229,087**	33,716,032

See accompanying notes to these condensed consolidated financial statements.

Table of Contents

Intra-Cellular Therapies, Inc. and Subsidiaries

Condensed Consolidated Statements of Comprehensive Loss

	Three-Months Ended September 30,		Nine-Months Ended September 30,	
	2016	**2015**	**2016**	**2015**
	(Unaudited)	*(Unaudited)*	*(Unaudited)*	*(Unaudited)*
Net loss	**$ (30,265,327)**	$ (32,160,483)	**$ (88,941,229)**	$ (75,958,625)
Other comprehensive loss:				
Unrealized gain (loss) on investment securities	**(230,935)**	33,303	**419,288**	85,259
Comprehensive loss	**$ (30,496,262)**	$ (32,127,180)	**$ (88,521,941)**	$ (75,873,366)

See accompanying notes to these condensed consolidated financial statements.

Table of Contents

Intra-Cellular Therapies, Inc. and Subsidiaries

Condensed Consolidated Statements of Cash Flows

	(Unaudited)	
	Nine Months Ended September 30,	
	2016	2015
Cash flows provided by (used in) operating activities		
Net loss	**$ (88,941,229)**	$ (75,958,625)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	**146,784**	92,594
Share-based compensation expense	**10,975,931**	7,466,595
Issuance of common stock for services	**171,059**	136,984
Amortization of premiums on investment securities	**420,275**	520,328
Changes in operating assets and liabilities:		
Accounts receivable	**29,351**	51,603
Prepaid expenses and other assets	**3,997,852**	(244,886)
Accounts payable	**3,784,546**	(1,347,722)
Accrued liabilities	**5,641,847**	1,177,654
Deferred rent	**966,704**	881,143
Net cash used in operating activities	**(62,806,880)**	(67,224,332)
Cash flows provided by (used in) investing activities		
Purchases of investments	**(320,098,309)**	(231,146,274)
Maturities of investments	**410,732,563**	121,128,184
Purchases of property and equipment	**(48,965)**	(823,585)
Net cash provided by (used in) investing activities	**90,585,289**	(110,841,675)
Cash flows provided by (used in) financing activities		
Proceeds from secured line of credit	**125,000,000**	
Proceeds from stock option exercises	**450,308**	317,508
Gross proceeds of public offering		449,996,887
Payment of costs of public offering		(745,143)
Net cash provided by financing activities	**125,450,308**	449,569,252
Net increase in cash and cash equivalents	**153,228,717**	271,503,245
Cash and cash equivalents at beginning of period	**47,159,303**	61,325,044
Cash and cash equivalents at end of period	**$ 200,388,020**	$ 332,828,289

See accompanying notes to these condensed consolidated financial statements.

5

Table of Contents

Intra-Cellular Therapies, Inc.

Notes to Condensed Consolidated Financial Statements (Unaudited)

September 30, 2016

1. Organization

Intra-Cellular Therapies, Inc. (the Company), through its wholly-owned operating subsidiaries, ITI, Inc. (ITI) and ITI Limited, 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 Phase 3 clinical development as a novel treatment for schizophrenia, bipolar depression and agitation associated with dementia, including Alzheimer s disease.

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). 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.

On March 11, 2015, the Company completed a public offering of common stock in which the Company sold 5,411,481 shares of common stock, which included the exercise of the underwriters option to purchase an additional 661,481 shares, at an offering price of $24.00 per share for aggregate gross proceeds of approximately $129.9 million. After deducting underwriting discounts, commissions and offering expenses, the net proceeds to the Company were approximately $121.8 million.

On September 28, 2015, the Company completed a public offering of common stock in which the Company sold 7,935,000 shares of common stock, which included the exercise of the underwriters option to purchase an additional 1,035,000 shares, at an offering price of $43.50 per share for aggregate gross proceeds of approximately $345.2 million. After deducting underwriting discounts, commissions and offering expenses, the net proceeds to the Company were approximately $327.4 million.

In September 2016, we licensed certain intellectual property rights to our wholly-owned subsidiary, ITI Limited, which was formed in the third quarter of 2016. Although the license of intellectual property rights did not result in any gain or loss in the condensed consolidated statements of operations, the transaction generated a taxable gain in the U.S., and we are utilizing a portion of our available federal and state net operating loss carryforwards to offset the majority of this gain. Any taxes incurred related to intercompany transactions are treated as tax expense in our condensed consolidated statement of operations. In addition to the license, we also entered into a research and development agreement with ITI Limited pursuant to which the Company will conduct research and development services related to the license agreement and charge ITI Limited for these services.

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 the Company s equity securities, sales of debt securities, the

incurrence of debt from commercial lenders, strategic collaborations, licensing a portion or all of the Company s product candidates and technology and, to a lesser extent, grant funding. On September 2, 2016, the Company filed a universal shelf registration statement on Form S-3, which was declared effective by the Securities and Exchange Commission (the SEC) on September 14, 2016, to register $350 million of the Company s common stock, preferred stock, various series of debt securities, warrants, rights and purchase contracts to purchase any of such securities, either individually or in units, for issuance from time to time at prices and on terms to be determined at the time of any such offering (including the approximately $4.8 million of securities that remained available for issuance under the Company s previous shelf registration). This registration statement will remain in effect for up to three years from the initial effective date.

Table of Contents

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America (GAAP). Any reference in these notes to applicable guidance is meant to refer to the authoritative United States generally accepted accounting principles as found in the Accounting Standards Codification (ASC) and Accounting Standards Update (ASU) of the Financial Accounting Standards Board (FASB). All intercompany accounts and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with GAAP 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.

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 mutual funds, and certificates of deposit with a maturity date of three months or less. The carrying values of cash and cash equivalents approximate the fair market value. 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. In conjunction with the capitalization of ITI Limited, the Company entered into a short term line of credit with a lender collateralized by Company investments held by the lender. On September 30, 2016, the Company drew down $125.0 million under the line of credit and used those funds to capitalize ITI Limited. On September 30, 2016, ITI Limited made a $125.0 million payment to the Company in connection with the license of certain intellectual property from the Company to ITI Limited. On October 3, 2016, the Company repaid $125.0 million to the lender and the line of credit was terminated on October 6, 2016.

Investment Securities

Investment securities consisted of the following (in thousands):

	September 30, 2016			
	Amortized Cost	Unrealized Gains	Unrealized (Losses)	Estimated Fair Value
		(unaudited)		
U.S. Government Agency Securities	$ 66,026	$ 18	$ (25)	$ 66,019
FDIC Certificates of Deposit (1)	31,037	3		31,040
Certificates of Deposit	82,000			82,000
Commercial Paper	59,960	19	(66)	59,913
Corporate Notes/Bonds	98,554	7	(127)	98,434
	$ 337,577	$ 47	$ (218)	$ 337,406

	December 31, 2015			
	Amortized Cost	Unrealized Gains	Unrealized (Losses)	Estimated Fair Value
U.S. Government Agency Securities	$ 61,510	$	$ (271)	$ 61,239
FDIC Certificates of Deposit (1)	41,343	1	(11)	41,333
Certificates of Deposit	219,500			219,500
Commercial Paper	30,122		(48)	30,074
Corporate Notes/Bonds	76,157		(262)	75,895
	$ 428,632	$ 1	$ (592)	$ 428,041

(1) FDIC Certificates of Deposit consist of deposits that are less than $250,000.

Table of Contents

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 September 30, 2016 and December 31, 2015, the Company held $66.1 million and $142.4 million, respectively, of available-for-sale investment securities with contractual maturity dates more than one year and less than two years.

The Company monitors its investment portfolio for impairment quarterly or more frequently if circumstances warrant. In the event that the carrying value of an investment exceeds its fair value and the decline in value is determined to be other-than-temporary, the Company records an impairment charge within earnings attributable to the estimated credit loss. In determining whether a decline in the value of an investment is other-than-temporary, the Company evaluates currently available factors that may include, among others: (1) general market conditions; (2) the duration and extent to which fair value has been less than the carrying value; (3) the investment issuer s financial condition and business outlook; and (4) the Company s assessment as to whether it is more likely than not that the Company will be required to sell a security prior to recovery of its amortized cost basis.

As of December 31, 2015, the Company had approximately $9.2 million of investments that had been held for greater than one year which had a temporary impairment of approximately $19,000. As of September 30, 2016, the Company had no investments that had been held for greater than one year which had a temporary impairment.

The Company attributes the unrealized losses on the available-for-sale securities as of September 30, 2016 and December 31, 2015, to the variability in related market interest rates. The Company does not intend to sell these securities, nor is it more likely than not that the Company will be required to sell them prior to the end of their contractual terms. Furthermore, the Company does not believe that these securities expose the Company to undue market risk or counterparty credit risk. As such, the Company does not consider these securities to be other-than-temporarily impaired.

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.

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 September 30, 2016 and December 31, 2015. The carrying value of cash held in money market funds of approximately $16.0 million as of September 30, 2016 and $31.1 million as of December 31, 2015, is included in cash and cash equivalents and approximates market value based on quoted market price or Level 1 inputs. The Company s borrowings under its secured line of credit approximate the fair value because of their relatively short maturity at September 30, 2016.

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

Table of Contents

	September 30, 2016	Fair Value Measurements at Reporting Date Using Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money Market Funds	$ 15,986	$ 15,986	$	$
U.S. Government Agency Securities	66,019		66,019	
FDIC Certificates of Deposit	31,040		31,040	
Certificates of Deposit	82,000		82,000	
Commercial Paper	59,913		59,913	
Corporate Notes/Bonds	98,434		98,434	
	$ 353,392	$ 15,986	$ 337,406	$

	December 31, 2015	Fair Value Measurements at Reporting Date Using Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money Market Funds	$ 31,114	$ 31,114	$	$
U.S. Government Agency Securities	61,239		61,239	
FDIC Certificates of Deposit	41,333		41,333	
Certificates of Deposit	219,500		219,500	
Commercial Paper	30,074		30,074	
Corporate Notes/Bonds	75,895		75,895	
	$ 459,155	$ 31,114	$ 428,041	$

Financial Instruments

The Company considers the recorded costs of its financial assets and liabilities, which consist of cash equivalents, accounts receivable, borrowings under secured line of credit, accounts payable and accrued liabilities, to approximate their fair value because of their relatively short maturities at September 30, 2016 and December 31, 2015.

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.

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 September 30, 2016 and December 31, 2015, as the Company has a history of collecting on all of its accounts, including government agencies and collaborations funding its research.

Table of Contents

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 the Company, 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 Company has 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.

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. 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**.**

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 primarily consist 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.

Table of Contents

Costs for certain development activities, such as clinical trials, are recognized based on an evaluation of the progress to completion of specific tasks using data such as subject enrollment, clinical site activations or information provided to the Company by its vendors with respect to their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the financial statements as prepaid or accrued research and development expense, as the case may be.

As part of the process of preparing its financial statements, the Company is required to estimate its expenses resulting from its obligations under contracts with vendors, clinical research organizations and consultants and under clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided under such contracts. The Company s objective is to reflect the appropriate clinical trial expenses in its financial statements by matching those expenses with the period in which services are performed and efforts are expended. The Company accounts for these expenses according to the progress of the clinical trial as measured by subject progression and the timing of various aspects of the trial. The Company determines accrual estimates through financial models taking into account discussion with applicable personnel and outside service providers as to the progress or state of consummation of trials, or the services completed. During the course of a clinical trial, the Company adjusts its clinical expense recognition if actual results differ from its estimates. The Company makes estimates of its accrued expenses as of each balance sheet date based on the facts and circumstances known to it at that time. The Company s clinical trial accruals are dependent upon the timely and accurate reporting of contract research organizations and other third-party vendors. Although the Company does not expect its estimates to be materially different from amounts actually incurred, its understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in it reporting amounts that are too high or too low for any particular period. For the three and nine months ended September 30, 2016 and 2015, there were no material adjustments to the Company s prior period estimates of accrued expenses for clinical trials.

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 their 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.

Table of Contents

For all awards granted with time-based vesting conditions, expense is amortized using the straight-line attribution method. For awards that contain a performance vesting condition, expense is amortized using the accelerated attribution method. As share-based compensation expense recognized in the statements of operations for the three and nine months ended September 30, 2016 and 2015 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 the Company s historical experience for the three and nine months ended September 30, 2016 and 2015, 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 Company s common stock, historical volatility of the common stock of comparable publicly traded entities in the Company s industry and other factors. 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 dates 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.

Prior to January 1, 2014, given that there was no active market for the Company s common stock, 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 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 stock options granted in 2014, 2015 and 2016, the exercise price was determined by using the closing market price of the Company s common stock on the date of grant.

A restricted stock unit (RSU) is a stock award that entitles the holder to receive shares of the Company s common stock as the award vests. The fair value of each RSU is based on the closing price of the Company s stock on the date of grant. The Company has granted RSUs with service conditions that vest in three equal annual installments provided that the employee remains employed with the Company. As of September 30, 2016, there was $3,402,792 of unrecognized compensation costs related to unvested RSUs.

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 September 30, 2016 and 2015, 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.

Loss Per Share

Basic net loss per common share is determined by dividing the net loss 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 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 and RSUs.

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 nine months ended September 30, 2016 and 2015:

Table of Contents

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2016	2015	2016	2015
Stock options	1,528,266	1,746,502	1,528,266	1,742,555
RSUs	39,420		38,844	

Recently Issued Accounting Standards

In May 2014, the FASB issued Accounting Standards Update No. 2014-09, Revenue from Contracts with Customers (ASU 2014-09). ASU 2014-09 will eliminate transaction-specific and industry-specific revenue recognition guidance under current GAAP and replace it with a principles-based approach for determining revenue recognition. ASU 2014-09 will require that companies recognize revenue based on the value of transferred goods or services as they occur in the contract. ASU 2014-09 also will require additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. In July 2015, the FASB decided to defer the effective date of the standard from January 1, 2017 to January 1, 2018, with an option that permits companies to adopt the standard as early as the original effective date. Early application prior to the original effective date is not permitted. The standard permits the use of either the retrospective or cumulative effect transition method. Presently, the Company is assessing what effect the adoption of this standard will have on the Company s consolidated financial statements and accompanying notes.

In January 2016, the FASB issued Accounting Standards Update 2016-01, Recognition and Measurement of Financial Assets and Financial Liabilities (ASU 2016-01). ASU 2016-01 eliminates the requirement to disclose the methods and significant assumptions used to estimate the fair value that is required to be disclosed for financial instruments measured at amortized cost on the balance sheet. The standard also clarifies the need to evaluate a valuation allowance on a deferred tax asset related to available-for-sale securities in combination with the Company s other deferred tax assets. ASU 2016-01 is effective for annual reporting periods beginning after December 15, 2017. The adoption of this standard is not expected to have a material impact on the Company s financial statements.

In February 2016, the FASB issued Accounting Standards Update 2016-02, Leases (ASU 2016-02). ASU 2016-02 allows the recognition of lease assets and lease liabilities by lessees for those leases classified as operating leases under previous GAAP. The classification criteria for distinguishing between finance leases and operating leases are substantially similar to the classification criteria for distinguishing between capital leases and operating leases in the previous leases guidance. ASU 2016-02 is effective for annual reporting periods beginning after December 15, 2018 and early adoption is permitted. The adoption of this standard is not expected to have a material impact on the Company s financial statements.

In March 2016, the FASB issued Accounting Standards Update 2016-09, Compensation Stock Compensation (ASU 2016-09). ASU 2016-09 simplifies several areas of accounting for stock compensation, including simplification of the accounting for income taxes, classification of excess tax benefits on the Statement of Cash Flows and forfeitures. ASU 2016-09 is effective for annual reporting periods beginning after December 15, 2016. An entity that elects early adoption must adopt all of the amendments in the same period. The Company did not early adopt ASU 2016-09 as of and for the period ended September 30, 2016. The adoption of this standard is not expected to have a material impact on the Company s financial statements.

3. Property and Equipment

Property and equipment consist of the following:

	September 30, 2016	December 31, 2015
Computer equipment	**$ 39,095**	$ 42,064
Furniture and fixtures	**292,423**	266,695
Scientific equipment	**2,844,866**	2,823,601
	3,176,384	3,132,360
Less accumulated depreciation	**(2,498,681)**	(2,356,838)
	$ 677,703	$ 775,522

Depreciation expense for the nine months ended September 30, 2016 and 2015 was $146,784 and $92,594 respectively.

Table of Contents

4. Share-Based Compensation

The Company sponsors the Intra-Cellular Therapies, Inc. Amended and Restated 2013 Equity Incentive Plan (the 2013 Plan) to provide for the granting of stock-based awards, such as stock options, restricted common stock, RSUs and stock appreciation rights to employees, directors and consultants as determined by the Board of Directors. In August 2013, in connection with the Merger, the Company assumed the ITI 2003 Equity Incentive Plan, as amended (the 2003 Plan), which expired by its terms in July 2013. As of September 30, 2016, there were options to purchase 685,660 shares of common stock outstanding under the 2003 Plan and options to purchase 2,425,267 shares of common stock outstanding under the 2013 Plan. Effective in November 2013, the Company adopted the 2013 Plan. The Company initially reserved 2,850,000 shares of common stock for issuance under the 2013 Plan. In both January 2015 and 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. On June 16, 2015, the stockholders of the Company approved, at the Company s 2015 Annual Meeting of Stockholders, an amendment to the 2013 Plan to increase the number of shares of common stock available for issuance under the plan by 3,100,000 shares, to increase by 100,000 shares the maximum number of shares available for the issuance of options, stock appreciation rights and other similar awards to any one participant in any calendar year for purposes of meeting the requirements for qualified performance-based compensation under Section 162(m) of the Internal Revenue Code of 1986, as amended (the Code), and to eliminate the evergreen provisions of the 2013 Plan under which 800,000 shares were automatically added to the plan on each of January 1, 2014 and 2015. Stock options granted under the 2013 Plan may be either incentive stock options (ISOs) as defined by the Code, or non-qualified stock options. The Board of Directors determines who will receive options, the vesting periods (which are generally two 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 including stock options and RSUs to employees, directors and consultants recognized during three and nine months ended September 30, 2016 and 2015, was comprised of the following:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	**2015**	**2016**	**2015**
Research and development	**$ 1,045,547**	$ 1,220,602	**$ 3,400,324**	$ 2,892,258
General and administrative	**2,641,199**	1,645,388	**7,575,607**	4,574,337
Total share-based compensation expense	**$ 3,686,746**	$ 2,865,990	**$ 10,975,931**	$ 7,466,595

The following table describes the weighted-average assumptions used for calculating the value of options granted during the nine months ended September 30, 2016 and 2015:

	2016	**2015**
Dividend yield	**0%**	**0%**
Expected volatility	**80%**	**80%**
Weighted-average risk-free interest rate	**1.7%**	**1.8%**

Expected term	**5.9 years**	**6.3 years**

Information regarding the stock options activity, including with respect to grants to employees, directors and consultants as of September 30, 2016 and changes during the nine-month period then ended, is summarized as follows:

	Number of Shares	**Weighted-Average Exercise Price**	**Weighted-Average Contractual Life**
Outstanding at December 31, 2015	2,737,657	$ 13.72	7.6 years
Options granted	478,265	$ 49.47	5.9 years
Options exercised	(104,995)	$ 4.29	3.7 years
Options canceled or expired		$	
Outstanding at September 30, 2016	3,110,927	$ 19.53	7.4 years
Vested or expected to vest at September 30, 2016	3,110,927	$ 19.53	
Exercisable at September 30, 2016	1,836,573	$ 11.74	6.7 years

Table of Contents

The fair value of an RSU is based on the closing price of the Company s stock on the date of grant. Information regarding RSU activity, including with respect to grants to employees as of September 30, 2016 and changes during the nine-month period then ended, is summarized as follows:

	Number of Shares	Weighted-Average Grant Date Fair Value
Outstanding at December 31, 2015	5,272	$ 56.90
RSU s granted in 2016	78,806	$ 53.63
Outstanding at September 30, 2016	84,078	$ 53.84

The Company recognized non-cash stock-based compensation expense related to RSU s for the nine months ending September 30, 2016 and 2015 of approximately $1.1 million and $0, respectively.

5. Line of Credit

On September 30, 2016, the Company entered into a secured line of credit with a lender for an amount not to exceed $150.8 million. This line of credit was secured by approximately $150.8 million of collateral held by the lender. The interest on advances under this line of credit was fixed at LIBOR plus 2.991% on the date of advance. The Company borrowed $125.0 million on September 30, 2016 and repaid the entire amount on October 3, 2016. Interest expense under this secured line of credit was $12,260 for the quarter ended September 30, 2016. On October 6, 2016, the line of credit was terminated by the Company. The fair value of this line of credit was $125.0 million on September 30, 2016.

6. Collaborations and License Agreements

The Bristol-Myers Squibb License Agreement

On May 31, 2005, the Company 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 BMS Agreement). The BMS 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 BMS Agreement 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 BMS Agreement, the Company made an upfront payment of $1.0 million to BMS, a milestone payment of $1.25 million in December 2013, and a milestone payment of $1.5 million in December 2014 following the initiation of the Company s first Phase 3 clinical trial for ITI-007 for patients with schizophrenia. Possible milestone payments remaining total $12.0 million. Under the agreement, the Company may be obliged to make other milestone payments to BMS for each licensed product of up to an aggregate of approximately $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 BMS 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.

In September 2016, the Company transferred certain of its rights under the BMS Agreement to its wholly owned subsidiary, ITI Limited. In connection with the transfer, the Company guaranteed ITI Limited s performance of its obligations under the BMS Agreement.

Table of Contents

The Takeda Pharmaceutical License and Collaboration Agreement and Termination Agreement

On February 25, 2011, the Company entered into a license and collaboration agreement (the Takeda License 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 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.

On October 31, 2014, the Company entered into an agreement with Takeda terminating the Takeda License Agreement, pursuant to which all rights granted under the Takeda License Agreement were returned to the Company. On September 15, 2015, Takeda completed the transfer of the Investigational New Drug Application (IND) for ITI-214 to the Company. ITI-214 is the first compound in its class to successfully advance into Phase 1 clinical trials. The Company intends to explore the development of its PDE program, including ITI-214 for the treatment of several CNS and non-CNS conditions, which may include cognition in Parkinson s disease, cognition in Alzheimer s disease, cognition in schizophrenia and in other non-CNS indications. Other compounds in the PDE portfolio are also being advanced for the treatment of various indications.

Other License Agreement

In May 2002, the Company entered into a license agreement (the License) and research agreement with a university. Under the provisions of the License, the Company 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 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 2015 and 2016. There were no other payments made or required for the nine months ended September 30, 2016 and 2015.

Table of Contents

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 February 25, 2016. 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 February 25, 2016, as updated from time to time in our subsequent periodic and current reports filed with the SEC.

Overview

We are a biopharmaceutical company focused on the discovery and clinical development of innovative, small molecule drugs that address underserved medical needs in neuropsychiatric and neurological disorders by targeting intracellular signaling mechanisms within the central nervous system, or CNS. ITI-007 is our lead product candidate with mechanisms of action that, we believe, may represent an effective treatment across multiple therapeutic indications. In our pre-clinical and clinical trials to date, ITI-007 combines potent serotonin 5-HT2A receptor antagonism, dopamine receptor phosphoprotein modulation, or DPPM, glutamatergic modulation, and serotonin reuptake inhibition into a single drug candidate for the treatment of acute and residual schizophrenia and for the treatment of bipolar disorder, including bipolar depression. At dopamine D_2 receptors, ITI-007 has been demonstrated to have dual properties and to act as both a pre-synaptic partial agonist and a post-synaptic antagonist. ITI-007 has also been demonstrated to have affinity for dopamine D1 receptors and indirectly stimulate phosphorylation of glutamatergic NMDA GluN2B receptors in a mesolimbic specific manner. We believe that this regional selectivity in brain areas thought to mediate the efficacy of antipsychotic drugs, together with serotonergic, glutamatergic, and dopaminergic interactions, may result in efficacy for a broad array of symptoms associated with schizophrenia and bipolar disorder with improved psychosocial function. The serotonin reuptake inhibition potentially allows for antidepressant activity in the treatment of schizoaffective disorder, other disorders with co-morbid depression, and/or as a stand-alone treatment for major depressive disorder. We believe ITI-007 may also be useful for the treatment of other psychiatric and neurodegenerative disorders, particularly behavioral disturbances associated with dementia, autism, and other CNS diseases. ITI-007 is in Phase 3 clinical development as a novel treatment for schizophrenia, bipolar depression and agitation associated with dementia, including Alzheimer s disease, or AD.

ITI-007 for the Treatment of Schizophrenia

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

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

In September 2015, we also announced top-line data from an open-label positron emission tomography, or PET, study of ITI-007 examining brain occupancy of striatal D_2 receptors. This study was conducted in patients diagnosed with schizophrenia who were otherwise healthy and stable with respect to their psychosis. After washout from their previous antipsychotic medication for at least

Table of Contents

two weeks, PET was used to determine target occupancy in brain regions at baseline (drug-free) and again after two weeks of once daily ITI-007 oral administration. In this trial, the 60 mg dose of ITI-007 was associated with a mean of approximately 40% striatal dopamine D_2 receptor occupancy. As predicted by preclinical and earlier clinical data, ITI-007 demonstrated antipsychotic effect at relatively low striatal D_2 receptor occupancy, lower than the occupancy range required by most other antipsychotic drugs. Unlike any existing schizophrenia treatment, this dopamine receptor phosphoprotein modulator, or DPPM, acts as a pre-synaptic partial agonist and post-synaptic antagonist at D_2 receptors. We believe this mechanism likely contributes to the favorable safety profile of ITI-007, with reduced risk for hyperprolactinemia, akathisia, extrapyramidal symptoms, and other motoric side effects.

The top-line results from our first Phase 3 clinical trial of ITI-007 confirm the earlier Phase 2 results that we announced in December 2013, in which ITI-007 exhibited antipsychotic efficacy in a randomized, double-blind, placebo and active controlled clinical trial in patients with schizophrenia. In this Phase 2 trial (ITI-007-005), 335 patients were randomized to receive one of four treatments: 60 mg of ITI-007, 120 mg of ITI-007, 4 mg of risperidone (active control) or placebo in a 1:1:1:1 ratio, orally once daily for 28 days. The primary endpoint for this clinical trial was change from baseline to Day 28 on the PANSS total score. In this study, ITI-007 met the trial s pre-specified primary endpoint, improving symptoms associated with schizophrenia as measured by a statistically significant and clinically meaningful decrease in the PANSS total score. The trial also met key secondary outcome measures related to efficacy on PANSS subscales and safety.

In September 2016, we announced top-line results from the second Phase 3 clinical trial (ITI-007-302) of ITI-007 for the treatment of patients with schizophrenia. In this trial, neither dose of ITI-007 separated from placebo on the primary endpoint, change from baseline on the PANSS total score, in the pre-defined patient population. The active control, risperidone, did separate from placebo. In this trial, ITI-007 was statistically significantly better than risperidone on key safety and tolerability parameters and exhibited a safety profile similar to placebo. This replicates the safety and tolerability findings of our Phase 2 study (ITI-007-005) in which the efficacy of ITI-007 60 mg and risperidone, the active control, were similar. We believe ITI-007 did not separate from placebo on the pre-specified primary endpoint in the ITI-007-302 study in part due to an unusually high placebo response at certain sites which disproportionately affected the trial results and contributed to the efficacy outcome of this study compared to our two previous positive efficacy studies. We believe the ITI-007 late-stage clinical development program, including two large, well-controlled positive studies and supportive evidence from this second Phase 3 study, collectively provide evidence of the efficacy and safety of ITI-007 for the treatment of schizophrenia. Across all three of our efficacy trials, ITI-007 60 mg improved symptoms of schizophrenia with the same trajectory and magnitude of change from baseline in the primary endpoint, the PANSS total score. We have requested a meeting with the Division of Psychiatry Products of the U.S. Food and Drug Administration, or FDA, to discuss the submission of an NDA for ITI-007 in schizophrenia. We expect to provide an update on the status of our discussions with the FDA in the first quarter of 2017.

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

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

Our bipolar depression program consists of two Phase 3 multi-center, randomized, double-blind, placebo-controlled clinical trials: one to evaluate ITI-007 as a monotherapy and the other to evaluate ITI-007 as an adjunctive therapy with lithium or valproate. In each trial, approximately 550 patients with a clinical diagnosis of Bipolar I or Bipolar II disorder and who are experiencing a current major depressive episode will be randomized to receive one of three treatments: 60 mg ITI-007, 40 mg ITI-007, or placebo in a 1:1:1 ratio orally once daily for 6 weeks. In the

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

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

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

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

Table of Contents

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

Other Indications for ITI-007

We are also pursuing clinical development of ITI-007 for the treatment of additional CNS diseases and disorders. At the lowest doses, ITI-007 has been demonstrated to act primarily as a potent 5-HT2A serotonin receptor antagonist. As the dose is increased, additional benefits are derived from the engagement of additional drug targets, including modest dopamine receptor modulation and modest inhibition of serotonin transporters. We believe that combined interactions at these receptors may provide additional benefits above and beyond selective 5-HT2A antagonism for treating agitation, aggression and sleep disturbances in diseases that include dementia, AD, Huntington s disease and autism spectrum disorders, while avoiding many of the side effects associated with more robust dopamine receptor antagonism. As the dose of ITI-007 is further increased, leading to moderate dopamine receptor modulation, inhibition of serotonin transporters, and indirect glutamate modulation, these actions complement the complete blockade of 5-HT2A serotonin receptors. At a dose of 60 mg, ITI-007 has been shown effective in treating the symptoms associated with schizophrenia, and we believe this higher dose range will be useful for the treatment of bipolar disorder, depressive disorders and other neuropsychiatric diseases. Within the ITI-007 portfolio, we are also developing a long-acting injectable formulation to provide more treatment options to patients suffering from mental illness. Given the encouraging tolerability data to date with oral ITI-007, we believe that a long-acting injectable option, in particular, may lend itself to being an important formulation choice for patients.

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

Other Product Candidates

We have a second major program called ITI-002 that has yielded a portfolio of compounds that selectively inhibits the enzyme phosphodiesterase type 1, or PDE1. We believe PDE1 helps regulate brain activity related to cognition, memory processes and movement/coordination. On February 25, 2011, we (through our wholly owned operating subsidiary, ITI) and Takeda Pharmaceutical Company Limited, or Takeda, entered into a license and collaboration agreement, or the Takeda License Agreement, under which we agreed to collaborate to research, develop and commercialize our proprietary compound ITI-214 and other selected compounds that selectively inhibit PDE1 for use in the prevention and treatment of human diseases. On October 31, 2014, we entered into an agreement with Takeda

terminating the Takeda License Agreement, or the Termination Agreement, pursuant to which all rights granted under the Takeda License Agreement were returned to us. On September 15, 2015, Takeda completed the transfer of the Investigational New Drug application, or IND, for ITI-214 to us. ITI-214 is the first compound in its class to successfully advance into Phase 1 clinical trials. We intend to pursue the development of our PDE program, including ITI-214 for the treatment of several CNS and non-CNS conditions, which may include cognition in Parkinson s disease, cognition in AD, cognition in schizophrenia and in other non-CNS indications. We expect to advance ITI-214 into additional clinical development trials later this year or in early 2017 in both CNS and non-CNS indications. Other compounds in the PDE portfolio are also being advanced for the treatment of various indications.

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

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

Table of Contents

Since inception, we have devoted substantially all of our efforts and resources to our research and development activities. We have incurred significant net losses since inception. As of September 30, 2016, our accumulated deficit was $282.0 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. Our corporate headquarters and laboratory are located in New York, New York.

Results of Operations

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

Revenues

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 three and nine months ended September 30, 2016 and 2015 have been from a government grant. We have received and may continue to receive grants from U.S. government agencies and foundations.

We do not expect any revenues that we may generate in the next several years to be significant enough to fund our operations.

Expenses

The process of researching and developing drugs for human use is lengthy, unpredictable and subject to many risks. We are unable to predict with certainty either the costs or the timelines in which those costs will be incurred. The clinical development of ITI-007 for the treatment of schizophrenia, bipolar depression and agitation in patients with dementia, including AD, consumes and will continue to consume a large portion of our current, as well as projected, resources. We intend to pursue other disease indications that ITI-007 may address, but there are significant costs associated with pursuing FDA approval for those indications, which would include the cost of additional clinical trials.

Our ITI-002 program has a compound, ITI-214, in Phase 1 development. We intend to pursue the development of our PDE program, including ITI-214 for the treatment of several CNS and non-CNS conditions, which may include cognition in Parkinson s disease, cognition in AD, cognition in schizophrenia and in other non-CNS indications. Our other projects 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;

fees paid to external parties who provide us with contract services, such as pre-clinical testing, manufacturing and related testing, clinical trial activities and license milestone payments; and

stock-based compensation expense.

General and administrative expenses are incurred in these major categories:

salaries and related benefit costs;

patent, legal and professional costs;

office and facilities overhead; and

stock-based compensation expense.

We expect that research and development expenses will increase as we proceed with our development programs for ITI-007 in patients with schizophrenia, bipolar disorder and behavioral disturbances associated with dementia and related disorders, including AD. We also expect that our general and administrative costs will increase from prior periods primarily due to costs to expand our operations and conduct pre-commercialization activities. We granted options to purchase 884,703 shares of our common stock in 2015 and have granted options to purchase an additional 478,265 shares of our common stock in the nine months ended September 2016. We also granted restricted stock units, or RSUs, for 5,272 and 78,806 shares of our common stock in December 2015 and January 2016, respectively. We will recognize expense associated with these RSUs and options over three years in both research and

Table of Contents

development expenses and general and administrative expenses. 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 and other stock-based awards in the future, which will increase our stock-based compensation expense in future periods.

Table of Contents

The following table sets forth our revenues and operating expenses for the three and nine months ended September 30, 2016 and 2015 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
	(Unaudited)		*(Unaudited)*	
Revenues	**$ 4**	$	**$ 232**	$ 61
Expenses				
Research and Development	**23,918**	28,457	**72,653**	64,853
General and Administrative	**6,271**	3,892	**17,806**	11,649
	30,189	32,349	**90,459**	76,502
Interest Income, net	**752**	189	**2,118**	482
Net Loss before Income Tax	**$ (29,433)**	$ (32,160)	**$ (88,109)**	$ (75,959)
Income tax Expense	**(832)**		**(832)**	
Net Loss	**$ (30,265)**	$ (32,160)	**$ (88,941)**	$ (75,959)

Comparison of Three and Nine Month Periods Ended September 30, 2016 and September 30, 2015

Revenues

Revenues increased for the three and nine months ended September 30, 2016 as compared to the three and nine months ended September 30, 2015 by approximately $4,000 and $172,000, respectively, due to the timing of government grants.

Research and Development Expenses

Research and development expenses decreased to $23.9 million for the three month period ended September 30, 2016 as compared to $28.5 million for the three month period ended September 30, 2015, or 16%. This change is due primarily to a decrease of approximately $4.9 million of costs associated with outside clinical and non-clinical costs and an increase of approximately $424,000 of internal costs in the three month period ended September 30, 2016 over the three month period ended September 30, 2015. In the three months ended September 30, 2015, most of the $28.5 million of research and development costs were related to the second Phase 3 trial of ITI-007 in patients with schizophrenia. In the three months ended September 30, 2016, a much lesser percentage of the research and development costs were related to the second Phase 3 trial of ITI-007 in patients with schizophrenia. In 2016, we incurred costs for the first time for the Phase 3 trials of ITI-007 in patients with bipolar depression, the Phase 3 trial of ITI-007 for the treatment of agitation in patients with dementia, including AD, and supporting trials for ITI-007. We also had increased costs in 2016 for manufacturing-related activities for ITI-007. Amounts payable to external parties comprised a significant portion of our research and development costs. In the three months ended September 30, 2016, we incurred approximately $20.9 million of costs to external parties who manufactured, tested and performed clinical trial related activities as compared to $25.8 million in the three month period ended September 30, 2015. Of these external costs, approximately $20.8 million in the three months ended September 30, 2016 and approximately $25.5 million in the three month period ended September 30, 2015 were for ITI-007 related projects. The remaining external costs for each of these periods were spent on other projects. Internal costs are comprised primarily of labor, fringe

benefits, materials, stock-based compensation, supplies and facilities and maintenance costs and were approximately $3.0 million and $2.6 million in the three months ended September 30, 2016 and 2015, respectively.

Research and development expenses increased to $72.7 million for the nine month period ended September 30, 2016 as compared to $64.9 million for the nine month period ended September 30, 2015, or 12%. This change is due primarily to an increase of approximately $5.2 million of costs associated with outside clinical and non-clinical costs and an increase of approximately $2.6 million of internal costs in the nine month period ended September 30, 2016 over the nine month period ended September 30, 2015. In the nine months ended September 30, 2015, the majority of the $64.9 million of research and development costs were related to the first and second Phase 3 trial of ITI-007 in patients with schizophrenia (ITI-007-301 and ITI-007-302). In the first nine months of 2016, the majority of the $72.7 million in research and development costs were related to the second Phase 3 trial of ITI-007 in patients with schizophrenia and to a lesser extent the Phase 3 trials of ITI-007 in patients with bipolar depression and the Phase 3 trial

Table of Contents

of ITI-007 for the treatment of agitation in patients with dementia, including AD, other supporting trials for ITI-007 which commenced in the third quarter of 2016 and a significant amount of costs for manufacturing ITI-007. Amounts payable to external parties comprised most of our research and development costs. In the nine months ended September 30, 2016, we incurred approximately $63.3 million of costs to external parties who manufactured, tested and performed clinical trial related activities as compared to $58.1 million in the nine month period ended September 30, 2015. Of these external costs, approximately $62.8 million in the nine months ended September 30, 2016 and approximately $57.6 million in the nine month period ended September 30, 2015 were for ITI-007 related projects. The remaining external costs for each of these periods were spent on other projects. Internal costs are comprised primarily of labor, fringe benefits, materials, stock-based compensation, supplies and facilities and maintenance costs and were approximately $9.4 million and $6.7 million in the nine months ended September 30, 2016 and 2015, respectively.

As development of ITI-007 progresses, we anticipate costs for ITI-007 to increase considerably in the remainder of 2016 and in the next several years as we conduct Phase 3 and other clinical trials. We are also required to complete non-clinical testing to obtain FDA approval and manufacture material needed for clinical trial use, which includes non-clinical testing of the drug product and the creation of an inventory of drug product in anticipation of possible FDA approval. We have requested a meeting with the FDA to discuss the submission of an NDA for ITI-007 in schizophrenia. We expect to provide an update on the status of our discussions with the FDA in the first quarter of 2017. As of September 30, 2016, we employed 28 full time personnel in our research and development group as compared to 22 full time personnel at September 30, 2015. We expect to hire additional staff as we increase our development efforts and grow our business in the upcoming years.

We currently have several projects, in addition to ITI-007, that are in the research and development stages, including in the areas of cognitive dysfunction and the treatment of neurodegenerative diseases, including AD, among others. We have used internal resources and incurred expenses not only in relation to the development of ITI-007, but also in connection with these additional projects as well. We have not, however, reported these costs on a project by project basis, as these costs are broadly spread among these projects. The external costs for these projects have been modest and are reflected in the amounts discussed in this section Research and Development Expenses.

During previous years we also incurred costs that were both reimbursable and non-reimbursable under the Takeda License Agreement. For the three and nine month periods ended September 30, 2016 and 2015, we incurred no direct costs that were billable to Takeda and we do not expect to incur any such costs in future periods. We intend to continue clinical development of ITI-214, a molecule in our PDE1 inhibitor program that was returned to us from Takeda, and we expect a moderate increase in our operating expenses related to our PDE development programs in 2016 over 2015.

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

Table of Contents

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 February 25, 2016, 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 three month period ended September 30, 2016 as compared to the three month period ended September 30, 2015 by approximately $2.4 million, or 61%. The largest portion of the increase is the result of stock option expense followed by expenses relating to the license of certain intellectual property by us to our wholly-owned subsidiary ITI Limited. To a lesser extent, we incurred increased costs relating to pre-commercialization activities, in addition to increased labor and related costs. Salaries, bonuses and related benefit costs for our executive, finance and administrative functions for the three months ended September 30, 2016 and 2015 constituted approximately 55% and 60%, respectively, of our total general and administrative costs. The next major categories of expenses are patent costs, legal, accounting and other professional fees and, to a lesser extent, facilities and general office-related overhead. We expect all general and administrative costs to increase as we expand our operations and conduct pre-commercialization activities.

General and administrative expenses increased for the nine month period ended September 30, 2016 as compared to the nine month period ended September 30, 2015 by approximately $6.2 million, or 53%. The increase is primarily the result of stock option expense and, to a lesser extent, increases in costs associated with pre-commercialization activities, expenses relating to the license of certain intellectual property by us to our wholly-owned subsidiary ITI Limited, and increased labor and related costs. Salaries, bonuses and related benefit costs for our executive, finance and administrative functions for the nine months ended September 30, 2016 and 2015 constituted approximately 62% and 58%, respectively, of our total general and administrative costs. The next major categories of expenses are patent costs, legal, accounting and other professional fees and, to a lesser extent, facilities and general office-related overhead. We expect all general and administrative costs to increase significantly as we expand our operations and conduct pre-commercialization activities.

We expect general and administrative costs to increase significantly as we hire additional staff, expand our operations including our pre-commercialization program, and incur additional costs associated with being a public company and complying with exchange listing and SEC requirements, including the additional complexities and related costs of our transition at the end of 2015 from an emerging growth company to a large accelerated filer under the rules of the SEC. These increases could include higher legal fees, accounting fees and fees associated with investor relations activities, among others.

Liquidity and Capital Resources

Through September 30, 2016, we provided funds for our operations by obtaining approximately $716.9 million of cash primarily through public and private offerings of our common stock and other securities, grants from government agencies and foundations and payments received under the terminated Takeda License Agreement. We do not believe that grant revenue will be a significant source of funding in the near future, and Takeda does not have ongoing funding obligations following the termination of the Takeda License Agreement on October 31, 2014. On March 11, 2015, we completed a public offering of 5,411,481 shares of our common stock for aggregate gross proceeds of approximately $129.9 million and net proceeds of approximately $121.8 million. On September 28, 2015, we completed an additional public offering of 7,935,000 shares of our common stock for aggregate gross proceeds of approximately $345.2 million and net proceeds of approximately $327.4 million.

In conjunction with the license of certain intellectual property to our wholly owned subsidiary, ITI Limited, we borrowed $125.0 million under a secured line of credit, collateralized by existing investments, to capitalize ITI Limited. ITI Limited used these funds to pay $125.0 million to us on September 30, 2016 in connection with the license of the intellectual property. On October 3, 2016, we repaid the entire amount borrowed under the line of credit and terminated the line of credit on October 6, 2016. In addition to the licensing transactions discussed above, we entered into a research and development agreement, or the Intracompany R&D Agreement, with ITI Limited. We will perform research and development and related services for ITI Limited and will charge ITI Limited for such services. The payments in connection with the services provided under the Intracompany R&D Agreement could result in us being profitable for tax purposes in the U.S. because sufficient net operating losses may not be available to offset such profits.

As of September 30, 2016, we had a total of approximately $537.8 million in cash and cash equivalents and available-for-sale investment securities, and approximately $140.7 million of short-term liabilities which includes a short term line of credit of $125 million and liabilities from operations. We had reserved $125.0 million of our cash to repay the short term line of credit, which was fully repaid in October 2016. As of September 30, 2016, our net cash and investments available for operations was $412.8 million, excluding the $125.0 million that we repaid under the short term line of credit in October 2016. We spent approximately $62.9 million in cash for operations and equipment and we reduced working capital by approximately $75.9 million for the nine months ended September 30, 2016. This use of cash was primarily for conducting clinical trials and non-clinical testing, including manufacturing related activities and funding recurring operating expenses. On October 6, 2016, we repaid the $125.0 million secured line of credit, thereby reducing our cash and short term liabilities.

Table of Contents

We expect to spend approximately $45 million during the remainder of 2016. We expect these expenditures to be due primarily to the development of ITI-007 in patients with schizophrenia, bipolar disorder and depressive disorders, behavioral disturbances in dementia, our ITI-007 long acting injectable development program through pre-clinical and early clinical development, research and preclinical development of our other product candidates, the continuation of manufacturing activities in connection with the development of ITI-007, recurring expenses and costs to produce, develop and validate materials to be used in clinical and non-clinical studies related to ITI-007, and expenses associated with our other development programs and general operations. We expect that cash expenditures will continue to increase after 2016 as we further expand the ITI-007 clinical stage programs and the ITI-007 long acting injectable development program through pre-clinical and early clinical development; research, preclinical and clinical development of our other product candidates; the continuation of manufacturing, pre-commercial activities in connection with the development of ITI-007 and the early stage pre-commercial launch activities for ITI-007. We believe that our existing cash and cash equivalents and investments will be sufficient to fund our operating expenses and capital expenditure requirements through the end of 2018.

We will require significant additional financing in the future to continue to fund our operations. We believe that we have the funding in place to complete the additional clinical and non-clinical trials, manufacturing and pre-commercialization activities needed for potential regulatory approval and commercialization of ITI-007 in patients with schizophrenia. With the remaining proceeds from our public offerings in March 2015 and September 2015, we believe that we have the funds to complete our ongoing clinical trials of ITI-007 in bipolar disorder as a monotherapy and as an adjunctive therapy with lithium or valproate and our ongoing clinical trial of ITI-007 for the treatment of agitation in patients with dementia, including AD. We will also be funding additional clinical trials of ITI-007 for the treatment of behavioral disturbances in dementia; preclinical and clinical development of ITI-007 long acting injectable development program; additional clinical trials of ITI-007; continued clinical development of our PDE program, including ITI-214, which could include clinical trials; research and preclinical development of our other product candidates; and the continuation of manufacturing activities in connection with the development of ITI-007. We may require additional funds to obtain regulatory approval for ITI-007 for patients with bipolar disorder. We anticipate requiring additional funds to obtain regulatory approval for ITI-007 for patients with dementia, including AD, for further development of ITI-007 in other programs including in patients with depressive disorders 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 the Takeda License Agreement. These losses have resulted in significant cash used in operations. For the nine months ended September 30, 2016, we used net cash in operating activities and purchases of equipment of approximately $62.9 million and expect to use additional cash of approximately $45 million through the end of 2016. 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 the 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.

With the termination of the Takeda License Agreement in October 2014, we will not receive milestone payments from Takeda and we will be responsible for the costs of developing ITI-214. On September 15, 2015, Takeda completed the transfer of the IND for ITI-214 to us. We intend to pursue the development of our PDE1 program, including ITI-214 for the treatment of several CNS and non-CNS conditions, and we expect a moderate increase in our operating expenses related to our PDE development programs through the end of 2016 and increasing further through 2017 as we enter into clinical activities and continue non-clinical activities of ITI-214.

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 currently have a universal shelf registration statement on Form S-3 that was declared effective by the Securities and Exchange Commission, or SEC, in September 2016 that allows us to issue up to $350 million of our common stock, preferred stock, various series of debt securities, warrants, rights and purchase contracts to purchase any of such securities, either individually or in units, from time to time at prices and on terms to be determined at the time of any such offering. This registration statement will remain in effect for up to three years from the initial effective date.

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 volatile nature of the financial markets, 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.

Table of Contents

To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our existing stockholders will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of our stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring debt, making capital expenditures or declaring dividends. If we raise additional funds through government or other third-party funding, marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us.

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, ITI-214, and 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 mutual funds, U.S. government agency securities, 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. We do not expect interest income to be a significant source of funding over the next several quarters. 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.

In March 2014, we entered into a long-term lease, which was amended in 2015, for 16,753 square feet of useable laboratory and office space located at 430 East 29th Street, New York, New York 10016. Due to the amortization of total lease payments, we have recognized approximately $1.6 million of deferred rent in the year ended December 31, 2015 and approximately $1.0 million in the nine months ended September 30, 2016. The deferred rent balance will incrementally increase over approximately the four months following September 30, 2016. We occupied these facilities as our headquarters in March 2015, replacing our previous laboratories and offices. The lease, as amended, has a term of 12 years. We expect that our facility related costs will increase moderately as a result of leasing this facility.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Table of Contents

Contractual Obligations and Commitments

Total contractual obligations as of September 30, 2016 are summarized in the following table (in thousands):

		Payments Due By Period			
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Operating Lease Obligations	$ 16,256	$ 945	$ 4,471	$ 3,208	$ 7,632

The table of Contractual Obligations and Commitments does not reflect that, under the License Agreement with BMS, we may be obligated to make future milestone payments to BMS totaling $12 million; to make other future milestone payments to BMS for each licensed product of up to an aggregate of approximately $14.75 million; to make tiered single digit percentage royalty payments on sales of licensed products; and to pay BMS a percentage of non-royalty payments made in consideration of any sublicense. On September 30, 2016, the Company borrowed $125 million under a secured line of credit. This amount was repaid on October 3, 2016 and the secured line of credit was terminated on October 6, 2016.

Critical Accounting Policies and Estimates

Our critical accounting policies are those policies which require the most significant judgments and estimates in the preparation of our consolidated financial statements. We evaluate our estimates, judgments, and assumptions on an ongoing basis. Actual results may differ from these estimates under different assumptions or conditions. A summary of our critical accounting policies is presented in Part II, Item 7, of our Annual Report on Form 10-K for the year ended December 31, 2015 and Note 2 to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q. There have been no material changes to our critical accounting policies during the nine months ended September 30, 2016.

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 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, stock-based compensation and clinical trial accruals. Actual results may differ from those estimates and under different assumptions or conditions.

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, 2015 filed on February 25, 2016. The significant accounting policies and bases of presentation from our consolidated financial statements are described in Note 2 Summary of Significant Accounting Policies to our

consolidated financial statements included in Item 1 of this Quarterly Report on Form 10-Q.

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, uses of cash, 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; the election by any collaborator to pursue research, development and commercialization activities; our ability to obtain future reimbursement and/or milestone payments from our collaborators; our ability to obtain and maintain intellectual property protection for our product candidates; our ability to successfully commercialize our product candidates;

Table of Contents

the performance of our third-party suppliers and manufacturers and our ability to obtain alternative sources of raw materials; our ability to obtain additional financing; our use of the proceeds from our securities offerings; 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 most recent Annual Report on Form 10-K, as updated from time to time in our subsequent periodic and current reports filed with the SEC.

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

Interest Rate Sensitivity. As of September 30, 2016, we had cash, cash equivalents and marketable securities of approximately $537.8 million consisting of cash deposited in a highly rated financial institution in the United States and in a short-term U.S. Treasury money market fund, as well as high-grade corporate bonds and commercial paper. The primary objective of our investment activities is to preserve our capital for the purpose of funding operations and we do not enter into investments for trading or speculative purposes. We believe that we do not have material exposure to high-risk investments such as mortgage-backed securities, auction rate securities or other special investment vehicles within our money-market fund investments. We believe that we do not have any material exposure to changes in fair value as a result of changes in interest rates. Declines in interest rates, however, would reduce future investment income.

Capital Market Risk. We currently have no product revenues and depend on funds raised through other sources. One possible source of funding is through further equity offerings. Our ability to raise funds in this manner depends in part upon capital market forces affecting our stock price.

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 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 September 30, 2016 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II: OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS

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

Table of Contents

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, 2015, filed with the Securities and Exchange Commission on February 25, 2016.

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

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

We must demonstrate that our drug candidates satisfy rigorous standards of safety and efficacy for their intended uses before the FDA and other regulatory authorities in the European Union and elsewhere will approve them for commercialization. Significant additional research, preclinical testing and clinical testing is required before we can file applications with the FDA or other regulatory authorities for premarket approval of our drug candidates. In addition, to compete effectively, our drugs must be easy to administer, cost-effective and economical to manufacture on a commercial scale. We may not achieve any of these objectives. Our lead product candidate, ITI-007, is in Phase 3 clinical development as a novel treatment for schizophrenia, bipolar depression and agitation associated with dementia, including Alzheimer s disease. In September 2016, we announced top-line results from the second Phase 3 clinical trial (ITI-007-302) of ITI-007 for the treatment of patients with schizophrenia. In this trial, neither dose of ITI-007 separated from placebo on the primary endpoint, change from baseline on the PANSS total score, in the pre-defined patient population, but we believe the ITI-007 late-stage clinical development program, including two large, well-controlled positive studies and supportive evidence from this second Phase 3 study, collectively provide evidence of the efficacy and safety of ITI-007 for the treatment of schizophrenia. We have requested a meeting with the FDA s Division of Psychiatry Products to discuss the submission of an NDA for ITI-007 in schizophrenia. In addition, we initiated Phase 3 development for the treatment of bipolar depression in the third quarter of 2015 and Phase 3 development for the treatment of agitation in patients with dementia, including Alzheimer s disease, in the second quarter of 2016. In addition, all rights with respect to ITI-214, which has advanced into Phase 1 clinical trials, that we previously granted to Takeda were returned to us in connection with the termination of the Takeda License Agreement. On September 15, 2015, Takeda completed the transfer of the IND for ITI-214 to us. We intend to pursue the development of our PDE program, including ITI-214 for the treatment of several CNS and non-CNS conditions, which may include cognition in Parkinson s disease, cognition in Alzheimer s disease, cognition in schizophrenia and in other non-CNS indications. We cannot be certain that the clinical development of these or any other drug candidates in preclinical testing or clinical development will be successful, that we will receive the regulatory approvals required to commercialize them or that any of our other research and drug discovery programs will yield a drug candidate suitable for investigation through clinical trials. Our commercial revenues from our product candidates currently in development, if any, will be derived from sales of drugs that will not become marketable for several years, if at all.

There is no guarantee that our planned clinical trials for ITI-007 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. In September 2015, we announced top-line clinical results from our first randomized, double-blind, placebo-controlled Phase 3 clinical trial in patients with an acutely exacerbated episode of schizophrenia. In this trial, a once-daily 60 mg dose of ITI-007 met the primary endpoint and demonstrated antipsychotic efficacy with statistically significant superiority over placebo at week 4 (study endpoint). In addition, the 60 mg dose of ITI-007 met the key secondary endpoint of statistically significant improvement on the CGI-S. In September 2016, we announced top-line results

from the second Phase 3 clinical trial of ITI-007 for the treatment of patients with schizophrenia. In this trial, neither dose of ITI-007 separated from placebo on the primary endpoint, change from baseline on the PANSS total score, in the pre-defined patient population. The active control, risperidone, did separate from placebo. In this trial, ITI-007 was statistically significantly better than risperidone on key safety and tolerability parameters and exhibited a safety profile similar to placebo. This replicates the safety and tolerability findings of our Phase 2 study in which the efficacy of ITI-007 60 mg and risperidone, the active control, were similar. We believe ITI-007 did not separate from placebo on the pre-specified primary endpoint in the ITI-007-302 study in part due to an unusually high placebo response at certain sites which disproportionately affected the trial results and contributed to the efficacy outcome of this study compared to our two previous positive efficacy studies. We believe the ITI-007 late-stage clinical development program, including two large, well-controlled positive studies and supportive evidence from this second Phase 3 study, collectively provide evidence of the efficacy and safety of ITI-007 for the treatment of schizophrenia. Across all three of our efficacy trials, ITI-007 60 mg improved symptoms of schizophrenia with the same magnitude of change from baseline in the primary endpoint, the PANSS total score. We have requested a meeting with the FDA s Division of Psychiatry Products to discuss the regulatory path for this first-in-class investigational agent. In addition, we initiated Phase 3 development for the treatment of bipolar depression in the third quarter of 2015 and Phase 3 development for the treatment of agitation in patients with dementia, including Alzheimer s disease, in the second quarter of 2016.

Table of Contents

The historical rate of failures for product candidates in clinical development and late-stage clinical trials is high. While we may be required to conduct further clinical trials in patients with schizophrenia and we plan to conduct further clinical trials in other indications, there is no guarantee that we will have the same level of success in these trials as we have had in certain of 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, intermittent explosive disorder, non-motor disorders associated with Parkinson s disease, obsessive compulsive disorder and anxiety disorders and post-traumatic stress disorder, we have never tested ITI-007 in Phase 2 clinical trials in the patient population for these other indications, except for ITI-007-200, a Phase 1/2 clinical trial designed to evaluate the safety, tolerability and pharmacokinetics of low doses of ITI-007 in healthy geriatric subjects and in patients with dementia, including Alzheimer s disease, for which we announced top-line data in the fourth quarter of 2014.

If we do not successfully complete clinical development of ITI-007, we will be unable to market and sell products derived from it and to generate product revenues. Even though we have successfully completed certain 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 recently completed our second Phase 3 clinical trial of ITI-007 for the treatment of schizophrenia. Although we previously 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 certain of the trials are 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 proceeded with our Phase 3 development program, in which we recently completed the second of two randomized, double-blind, placebo-controlled Phase 3 clinical trials of ITI-007 in patients with acutely exacerbated schizophrenia, with 450 patients enrolled in the first Phase 3 clinical trial and 696 patients enrolled in the second Phase 3 clinical trial. We completed enrollment of the first Phase 3 clinical trial in schizophrenia in the second quarter of 2015 and completed enrollment of the second Phase 3 clinical trial in schizophrenia in the second quarter of 2016. In the first Phase 3 trial, we randomized patients to two doses of ITI-007 (60mg or 40mg) or placebo over a 4-week treatment duration, and the primary outcome measure is change from baseline to Day 28 on the PANSS total score. In the second Phase 3 trial, we randomized patients to receive one of four treatments: 60 mg ITI-007, 20 mg ITI-007, 4 mg risperidone (active control) or placebo in a 1:1:1:1 ratio. The second Phase 3 trial was conducted for a 6-week treatment duration. We announced top-line results of the first Phase 3 clinical trial of ITI-007 in patients with schizophrenia in September 2015 and top-line results of the second Phase 3 clinical trial in September 2016. In the second Phase 3 clinical trial, neither dose of ITI-007 separated from placebo on the primary endpoint, change from baseline on the PANSS total score, in the pre-defined patient population. The active control, risperidone, did separate from placebo. In this trial, ITI-007 was statistically significantly better than risperidone on key safety and tolerability parameters and exhibited a safety profile similar to placebo. This replicates the safety and tolerability findings of our Phase 2 study in which the efficacy of ITI-007 60 mg and risperidone, the active control, were similar. We believe ITI-007 did not separate from placebo on the pre-specified primary endpoint in the ITI-007-302 study in part due to an unusually high placebo response at certain sites which disproportionately affected the trial results and contributed to the efficacy outcome of this study compared to our two previous positive

efficacy studies. Even though we believe that our recently completed Phase 3 trials and ongoing and planned clinical and non-clinical studies for ITI-007 in schizophrenia, if successful, will be sufficient to support our NDA, the FDA may not agree with our belief that the ITI-007 late-stage clinical development program, including two large, well-controlled positive studies and supportive evidence from this second Phase 3 study, collectively provide evidence of the efficacy and safety of ITI-007 for the treatment of schizophrenia. In addition, 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 other clinical 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 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

Table of Contents

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.

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

We have consumed substantial amounts of capital since our inception. Our cash, cash equivalents and investment securities totaled $537.8 million at September 30, 2016, which includes net proceeds of approximately $121.8 million from the public offering of shares of our common stock in March 2015, approximately $327.4 million from the public offering of shares of our common stock in September 2015 and $125 million that we borrowed under a secured line of credit that was repaid on October 3, 2016. Excluding the $125 million that we repaid under the secured line of credit, we had cash, cash equivalents and investment securities totaling $412.8 million at September 30, 2016. 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 the end of 2018, the amount and timing of our actual expenditures will depend upon numerous factors, including the ongoing status of our planned NDA submission for ITI-007 in patients with schizophrenia and the meeting that we have requested with the FDA regarding our clinical trial results; the ongoing status of our Phase 3 clinical trials of ITI-007 in patients with bipolar depression and dementia, including Alzheimer s disease; the continued development of our PDE program, including ITI-214 for the treatment of several CNS and non-CNS conditions; and our other planned clinical and non-clinical trials. We may require additional funds to obtain regulatory approval for ITI-007 for patients with bipolar disorder. Furthermore, we anticipate that we will need to secure additional funding to obtain regulatory approval for ITI-007 in patients with dementia, including Alzheimer s disease, for further development of ITI-007 in other programs including in patients with depressive disorders and other indications, and for development of our other product candidates. If the FDA requires that we perform additional preclinical studies or clinical trials, or we experience delays or other setbacks in our clinical trials, our expenses would further increase beyond what we currently expect and the anticipated timing of any potential NDA would likely be delayed.

With the remaining proceeds from our public offerings in February 2014, March 2015 and September 2015, we intend to fund the following: the completion of two Phase 3 clinical trials of ITI-007 in patients with acute exacerbated schizophrenia, one of which we announced top-line results in September 2015 and the second of which we announced top-line results in September 2016; the initiation of other planned clinical and non-clinical trials, including manufacturing, needed for anticipated regulatory approval of ITI-007 in patients with acute exacerbated schizophrenia and other potential additional indications; pre-launch activities for ITI-007 for the treatment of schizophrenia and, if it receives regulatory approval, to fund our initial commercialization efforts; the completion of our clinical trials of ITI-007 in bipolar disorder as a monotherapy and as an adjunctive therapy with lithium or valproate, a program we initiated in the third quarter of 2015; clinical trials of ITI-007 for the treatment of behavioral disturbances in dementia; pre-clinical and clinical development of our ITI-007 long acting injectable development program; other clinical trials of ITI-007; the continued clinical development of our PDE1 program, including ITI-214; and research and preclinical development of our other product candidates and the continuation of manufacturing activities in connection with the development of ITI-007. The remaining proceeds, if any, will be used to fund new and ongoing research and development activities, new business opportunities, general corporate purposes, including general and administrative expenses, capital expenditures and working capital. Accordingly, we will continue to require substantial additional capital beyond the net proceeds from these offerings to continue our clinical development and commercialization activities. Because successful development of our product candidates is uncertain, we are unable to estimate the actual funds we will require to complete research and development and commercialize our products under development.

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

- the results of the meeting that we have requested with the FDA regarding our Phase 3 clinical trial results of ITI-007 in patients with schizophrenia;

- the progress in, and the costs of, our preclinical studies and clinical trials and other research and development programs;

- the scope, prioritization and number of our research and development programs;

- the ability of any future collaborators and us to reach the milestones, and other events or developments, triggering payments under any future collaboration agreements or to otherwise make payments under such agreements;

- our ability to enter into new, and to maintain any existing, collaboration and license agreements;

- the extent to which any future collaborators are obligated to reimburse us for clinical trial costs under any future collaboration agreements;

- the costs involved in filing, prosecuting, enforcing and defending patent claims and other intellectual property rights;

- the costs of securing manufacturing arrangements for clinical or commercial production;

- the costs of preparing applications for regulatory approvals for our product candidates;

Table of Contents

the costs of preparing for and establishing, or contracting for, sales and marketing capabilities if we obtain regulatory clearances to market our product candidates; and

the costs associated with litigation.

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

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

We will need to satisfy our future cash needs through public or private sales of our equity securities, sales of debt securities, the incurrence of debt from commercial lenders, strategic collaborations, licensing a portion or all of our product candidates and technology and, to a lesser extent, grant funding. We filed a universal shelf registration statement on Form S-3 with the SEC, which was declared effective on September 14, 2016, on which we registered for sale up to $350 million of securities of any combination of common stock, preferred stock, debt securities, warrants, rights, purchase contracts and/or units from time to time and at prices and on terms that we may determine. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our existing stockholders will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of our stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring debt, making capital expenditures or declaring dividends. If we raise additional funds through collaboration and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or grant licenses on terms that are not favorable to us.

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

Unregistered Sales of Equity Securities

Not applicable.

Issuer Purchases of Equity Securities

We did not repurchase any of our equity securities during the three months ended September 30, 2016.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

Item 5. OTHER INFORMATION

On November 9, 2016, we amended our employment agreement with Michael I. Halstead, our Senior Vice President, General Counsel and Secretary, our employment agreement with Robert Davis, Ph.D., our Senior Vice President and Chief Scientific Officer, and our employment agreement with Kimberly E. Vanover, Ph.D., our Senior Vice President, Clinical Development, solely to remove the provision from each of their employment agreements that allows for the payment of cash severance and the acceleration of equity in the event that the executive terminates his or her employment with us for any reason within one month following a change in control.

Table of Contents

The summary of the amendments to our employment agreements with Mr. Halstead, Dr. Davis and Dr. Vanover is qualified in its entirety by reference to the full text of such amendments, copies of which are attached to this report as Exhibit 10.1, Exhibit 10.2 and Exhibit 10.3, respectively, and are incorporated herein by reference.

Table of Contents

Item 6. EXHIBITS

Exhibit Number	Exhibit Description	Filed Herewith	Incorporated by Reference herein from Form or Schedule	SEC File/ Filing Date Reg. Number
10.1*	Amendment No.1 to Employment Agreement dated as of November 9, 2016 by and between Michael I. Halstead and Intra-Cellular Therapies, Inc.*	X		
10.2*	Amendment No.1 to Employment Agreement dated as of November 9, 2016 by and between Robert Davis, Ph.D. and Intra-Cellular Therapies, Inc.*	X		
10.3*	Amendment No.1 to Employment Agreement dated as of November 9, 2016 by and between Kimberly Vanover, Ph.D. and Intra-Cellular Therapies, Inc.*	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 September 30, 2016, formatted in XBRL (eXtensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets as of September 30, 2016 (unaudited) and December 31, 2015 (audited), (ii) Condensed Consolidated Statements of Operations (unaudited) for the three and nine months ended September 30, 2016 and 2015, (iii) Condensed Consolidated Statements of Comprehensive Loss (unaudited) for the three and nine months ended September	X		

30, 2016 and 2015, (iv) Condensed Consolidated Statements of Cash Flows (unaudited) for the nine months ended September 30, 2016 and 2015, and (v) Notes to Condensed Consolidated Financial Statements (unaudited).

* Management contract or compensatory plan or arrangement.

Table of Contents

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: November 9, 2016

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

Date: November 9, 2016

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