
**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, 2017

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
(State or other jurisdiction of
incorporation or organization)

430 East 29th Street
New York, New York
(Address of principal executive offices)

36-4742850
(I.R.S. Employer
Identification No.)

10016
(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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company	<input type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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 8, 2017, the registrant had 54,577,626 shares of common stock outstanding.

[Table of Contents](#)

Intra-Cellular Therapies, Inc.

Index to Form 10-Q

PART I: FINANCIAL INFORMATION	1
Item 1. FINANCIAL STATEMENTS	1
Condensed Consolidated Balance Sheets as of September 30, 2017 (unaudited) and December 31, 2016 (audited)	1
Condensed Consolidated Statements of Operations (unaudited) for the three and nine months ended September 30, 2017 and 2016	2
Condensed Consolidated Statements of Comprehensive Loss (unaudited) for the three and nine months ended September 30, 2017 and 2016	3
Condensed Consolidated Statements of Cash Flows (unaudited) for the nine months ended September 30, 2017 and 2016	4
Notes to Condensed Consolidated Financial Statements (Unaudited)	5
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	28
Item 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS	29
Item 3. DEFAULTS UPON SENIOR SECURITIES	29
Item 4. MINE SAFETY DISCLOSURES	29
Item 5. OTHER INFORMATION	29
Item 6. EXHIBITS	30
SIGNATURES	31

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.

PART I: FINANCIAL INFORMATION**Item 1. FINANCIAL STATEMENTS**

Intra-Cellular Therapies, Inc. and Subsidiaries

Condensed Consolidated Balance Sheets

	September 30, 2017 <i>(Unaudited)</i>	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	\$ 52,340,519	\$ 48,642,225
Investment securities, available-for-sale	275,781,285	335,458,459
Accounts receivable	6,309	94,339
Prepaid expenses and other current assets	5,307,357	4,005,093
Total current assets	<u>333,435,470</u>	<u>388,200,116</u>
Property and equipment, net	679,606	627,614
Other assets	75,765	75,765
Total assets	<u>\$ 334,190,841</u>	<u>\$ 388,903,495</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 4,407,655	\$ 3,754,647
Accrued and other current liabilities	4,151,120	5,329,293
Accrued employee benefits	3,316,378	1,448,394
Total current liabilities	<u>11,875,153</u>	<u>10,532,334</u>
Long-term liabilities	<u>2,875,612</u>	<u>2,868,622</u>
Total liabilities	<u>14,750,765</u>	<u>13,400,956</u>
Stockholders' equity:		
Common stock, \$.0001 par value: 100,000,000 shares authorized; 43,427,344 and 43,292,906 shares issued and outstanding at September 30, 2017 and December 31, 2016, respectively	4,342	4,329
Additional paid-in capital	696,695,317	685,290,815
Accumulated deficit	(377,040,068)	(309,475,366)
Accumulated comprehensive loss	(219,515)	(317,239)
Total stockholders' equity	<u>319,440,076</u>	<u>375,502,539</u>
Total liabilities and stockholders' equity	<u>\$ 334,190,841</u>	<u>\$ 388,903,495</u>

See accompanying notes to these condensed consolidated financial statements.

Intra-Cellular Therapies, Inc. and Subsidiaries

Condensed Consolidated Statements of Operations (Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Revenues	\$ 30,754	\$ 4,362	\$ 240,782	\$ 232,807
Costs and expenses:				
Research and development	18,472,372	23,918,232	52,489,968	72,652,520
General and administrative	5,317,577	6,270,528	17,882,679	17,806,565
Total costs and expenses	23,789,949	30,188,760	70,372,647	90,459,085
Loss from operations	(23,759,195)	(30,184,398)	(70,131,865)	(90,226,278)
Interest expense	—	(12,260)	—	(12,260)
Interest income	884,763	763,949	2,564,747	2,129,927
Loss before provision for income taxes	(22,874,432)	(29,432,709)	(67,567,118)	(88,108,611)
Income tax benefit (expense)	4,016	(832,618)	2,416	(832,618)
Net loss	\$ (22,870,416)	\$ (30,265,327)	\$ (67,564,702)	\$ (88,941,229)
Net loss per common share:				
Basic & Diluted	\$ (0.53)	\$ (0.70)	\$ (1.56)	\$ (2.06)
Weighted average number of common shares:				
Basic & Diluted	43,424,387	43,253,429	43,410,072	43,229,087

See accompanying notes to these condensed consolidated financial statements.

Intra-Cellular Therapies, Inc. and Subsidiaries

Condensed Consolidated Statements of Comprehensive Loss (Unaudited)

	Three Months Ended September 30, 2017	2016	Nine Months Ended September 30, 2017	2016
Net loss	<u>\$ (22,870,416)</u>	<u>\$ (30,265,327)</u>	<u>\$ (67,564,702)</u>	<u>\$ (88,941,229)</u>
Other comprehensive loss:				
Unrealized gain (loss) on investment securities	<u>96,312</u>	<u>(230,935)</u>	<u>97,724</u>	<u>419,288</u>
Comprehensive loss	<u>\$ (22,774,104)</u>	<u>\$ (30,496,262)</u>	<u>\$ (67,466,978)</u>	<u>\$ (88,521,941)</u>

See accompanying notes to these condensed consolidated financial statements.

Intra-Cellular Therapies, Inc. and Subsidiaries
Condensed Consolidated Statements of Cash Flows

	(Unaudited)	
	Nine Months Ended September 30,	
	2017	2016
Cash flows provided by (used in) operating activities		
Net loss	\$ (67,564,702)	\$ (88,941,229)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	155,262	146,784
Share-based compensation expense	11,030,572	10,975,931
Issuance of common stock for services	143,159	171,059
Amortization of premiums on investment securities	401,056	420,275
Changes in operating assets and liabilities:		
Accounts receivable	88,030	29,351
Prepaid expenses and other assets	(1,302,264)	3,997,852
Accounts payable	653,008	3,784,546
Accrued liabilities	653,169	5,641,847
Deferred rent	43,632	966,704
Net cash used in operating activities	(55,699,078)	(62,806,880)
Cash flows provided by (used in) investing activities		
Purchases of investments	(274,674,730)	(320,098,309)
Maturities of investments	334,048,572	410,732,563
Purchases of property and equipment	(207,254)	(48,965)
Net cash provided by investing activities	59,166,588	90,585,289
Cash flows provided by financing activities		
Proceeds from secured line of credit	—	125,000,000
Proceeds from stock option exercises	230,784	450,308
Net cash provided by financing activities	230,784	125,450,308
Net increase in cash and cash equivalents	3,698,294	153,228,717
Cash and cash equivalents at beginning of period	48,642,225	47,159,303
Cash and cash equivalents at end of period	<u>\$ 52,340,519</u>	<u>\$ 200,388,020</u>

See accompanying notes to these condensed consolidated financial statements.

Intra-Cellular Therapies, Inc.

Notes to Condensed Consolidated Financial Statements (Unaudited)

September 30, 2017

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, lumateperone, is in Phase 3 clinical development as a novel treatment for schizophrenia, bipolar depression and agitation associated with dementia, including Alzheimer’s disease.

The Company was originally incorporated in the State of Delaware in August 2012 under the name “Oneida Resources Corp.” Prior to a reverse merger that occurred on August 29, 2013 (the “Merger”), Oneida Resources Corp. was a “shell” company registered under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), with no specific business plan or purpose until it began operating the business of ITI, through the Merger transaction on August 29, 2013. ITI was incorporated in Delaware in May 2001 to focus primarily on the development of novel drugs for the treatment of neuropsychiatric and neurologic diseases and other disorders of the CNS. Effective upon the Merger, a wholly-owned subsidiary of the Company merged with and into ITI, and ITI continues as the operating subsidiary of the Company.

In September 2016, the Company licensed certain intellectual property rights to its 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 consolidated statements of operations, the \$125 million of gain related to the transaction helped generate net taxable income for tax purposes in the U.S. and the Company utilized a portion of its available federal and state net operating loss carryforwards to offset the majority of this gain. Any taxes incurred related to intercompany transactions were treated as tax expense in the Company’s consolidated statement of operations. In addition to the license, the Company 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.

On October 2, 2017 and October 5, 2017, the Company completed a public offering of common stock in which the Company sold 11,129,032 shares of common stock, which included the exercise of the underwriters’ option to purchase an additional 1,451,613 shares, at an offering price of \$15.50 per share for aggregate gross proceeds of approximately \$172 million. After deducting underwriting discounts, commissions and offering expenses, the net proceeds to the Company were approximately \$162 million.

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, on which the Company registered for sale up to \$350 million of any combination of its common stock, preferred stock, debt securities, warrants, rights, purchase contracts and/or units from time to time and at prices and on terms that the Company may determine. After the public offering in October 2017, approximately \$178 million of securities remain available for issuance under this shelf registration statement. This registration statement will remain in effect for up to three years from the initial effective date.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements of Intra-Cellular Therapies, Inc. and its wholly own subsidiaries 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 set forth 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. The Company currently operates in one operating segment. Operating segments are defined as components of an enterprise about which separate discrete information is available for the chief operating decision maker, or decision making group, in deciding how to allocate resources and assessing performance. The Company views its operations and manages its business in one segment, which is discovering and developing drugs for the treatment of neurological and psychiatric disorders.

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.

Investment Securities

Investment securities consisted of the following (in thousands):

	September 30, 2017			
	Amortized Cost	Unrealized Gains	Unrealized (Losses)	Estimated Fair Value
	(unaudited)			
U.S. Government Agency Securities	\$ 89,980	\$ —	\$ (78)	\$ 89,902
FDIC Certificates of Deposit (1)	12,555	—	—	12,555
Certificates of Deposit	13,500	—	—	13,500
Commercial Paper	40,730	1	(18)	40,713
Corporate Notes/Bonds	119,236	5	(130)	119,111
	<u>\$276,001</u>	<u>\$ 6</u>	<u>\$ (226)</u>	<u>\$275,781</u>
	December 31, 2016			
	Amortized Cost	Unrealized Gains	Unrealized (Losses)	Estimated Fair Value
U.S. Government Agency Securities	\$ 67,199	\$ 1	\$ (74)	\$ 67,126
FDIC Certificates of Deposit (1)	20,740	1	—	20,741
Certificates of Deposit	64,500	—	—	64,500
Commercial Paper	67,352	11	(52)	67,311
Corporate Notes/Bonds	115,985	—	(205)	115,780
	<u>\$335,776</u>	<u>\$ 13</u>	<u>\$ (331)</u>	<u>\$335,458</u>

(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, 2017 and December 31, 2016, the Company held \$20.0 million and \$47.9 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 September 30, 2017, the Company had approximately \$41.3 million of investments that have been held for greater than one year which had a temporary impairment of approximately \$41,000. As of December 31, 2016, the Company had approximately \$25.5 million of investments that had been held for greater than one year which had a temporary impairment of approximately \$25,000.

The Company attributes the unrealized losses on the available-for-sale securities as of September 30, 2017 and December 31, 2016 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, 2017 and December 31, 2016. The carrying value of cash held in money market funds of approximately \$21.5 million as of September 30, 2017 and \$10.7 million as of December 31, 2016 is included in cash and cash equivalents and approximates market value based on quoted market price or Level 1 inputs.

[Table of Contents](#)

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

		Fair Value Measurements at Reporting Date Using		
	September 30, 2017	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money Market Funds	\$ 21,506	\$ 21,506	\$ —	\$ —
U.S. Government Agency Securities	89,902	—	89,902	—
FDIC Certificates of Deposit	12,555	—	12,555	—
Certificates of Deposit	26,000	—	26,000	—
Commercial Paper	40,713	—	40,713	—
Corporate Notes/Bonds	119,111	—	119,111	—
	<u>\$ 309,787</u>	<u>\$ 21,506</u>	<u>\$ 288,281</u>	<u>\$ —</u>

[Table of Contents](#)

	Fair Value Measurements at Reporting Date Using			
	December 31, 2016	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money Market Funds	\$ 10,724	\$ 10,724	\$ —	\$ —
U.S. Government Agency Securities	67,126	—	67,126	—
FDIC Certificates of Deposit	20,741	—	20,741	—
Certificates of Deposit	64,500	—	64,500	—
Commercial Paper	67,311	—	67,311	—
Corporate Notes/Bonds	115,780	—	115,780	—
	<u>\$ 346,182</u>	<u>\$ 10,724</u>	<u>\$ 335,458</u>	<u>\$ —</u>

Financial Instruments

The Company considers the recorded costs of its financial assets and liabilities, which consist of cash equivalents, accounts receivable, prepaid expenses, accounts payable and accrued liabilities, to approximate their fair value because of their relatively short maturities at September 30, 2017 and December 31, 2016. 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 not probable.

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, 2017 and December 31, 2016, as the Company has a history of collecting on all of its accounts, including those with government agencies and collaborations funding its research.

Property and Equipment

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

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

Revenue Recognition

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

The Company has entered into arrangements involving the delivery of more than one element. Each required deliverable is evaluated to determine whether it qualifies as a separate unit of accounting. For 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 and, as a result, any additional milestone payments could also be considered part of the consideration for the single unit of accounting and would be recognized as revenue as such performance obligations are performed under either the proportional performance or straight-line methods, as applicable.

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, manufacturing of drug product, outside services, providers, materials and consulting fees.

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.

[Table of Contents](#)

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, clinical sites, 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, 2017 and 2016, 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.

For all awards granted with time-based vesting conditions, expense is amortized using the straight-line attribution method. Share-based compensation expense recognized in the statements of operations for the three and nine months ended September 30, 2017 and 2016 is based on share-based awards ultimately expected to vest.

[Table of Contents](#)

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 a combination of the historical volatility of the common stock of comparable publicly traded entities and the limited historical information about the Company's common stock. The expected life of stock options is the period of time for which the stock options are expected to be outstanding. Given the limited historical exercise data, the expected life is determined using the "simplified method," which defines expected life as the midpoint between the vesting date and the end of the contractual term.

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

Prior to January 1, 2014, at which time 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 on or after January 1, 2014, 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 fair market value of the Company's common stock on the date of grant. The Company has granted RSUs that vest in three equal annual installments provided that the employee remains employed with the Company.

Beginning in the first quarter of 2016, the Company granted time based RSUs that vest in three equal annual installments. In the first quarter of 2017, the Company granted additional time-based RSUs as well as performance-based RSUs, which vest based on the achievement of certain milestones that include (i) the submission of a new drug application ("NDA") with the U.S. Food and Drug Administration (the "FDA"), (ii) the approval of the NDA by the FDA (the "Milestone RSU grants") and (iii) the achievement of certain comparative shareholder returns against the Company's peers (the "TSR RSU grants"). The Milestone RSU grants were valued at the closing price on March 8, 2017. The RSUs that vest upon the NDA submission will be amortized through December 31, 2018 based on the probable vesting date. The amortization of the expenses for RSUs related to the approval of the NDA will commence if and when the NDA filing has been approved through the last day of the calendar year in which the milestone is achieved. The TSR RSU grants were valued using the Monte Carlo Simulation method and will be amortized over the life of the RSU agreements which ends December 31, 2019. The Milestone RSU grants and TSR RSU grants are target based and the ultimate awards, if attained, could be the target amount or higher or lower than the target amount, depending on the timing or achievement of the goal. The Company is amortizing the expenses at the 100% targeted amount.

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, 2017 and 2016, 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 for services 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 required services 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.

[Table of Contents](#)

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, 2017 and 2016:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Stock options	513,781	1,528,266	513,781	1,528,266
RSUs	84,640	39,420	83,710	38,844

Recently Issued Accounting Standards

In May 2014, the FASB issued ASC Update No. 2014-09, Revenue from Contracts with Customers (Topic 606), which has been subsequently updated. The purpose of Update No. 2014-09 is to provide enhancements to the quality and consistency of how revenue is reported while also improving comparability in the financial statements of companies using U.S. GAAP and International Financial Reporting Standards. The core principle requires entities to recognize revenue in a manner that depicts the transfer of goods or services to customers in amounts that reflect the consideration to which an entity expects to be entitled in exchange for those goods or services. FASB ASC Topic 606, as amended, becomes effective for annual periods beginning after December 15, 2017, at which point the Company plans to adopt the standard. The Company currently plans to adopt the standard using the “modified retrospective method.” Under that method, the Company will apply the standard to contracts whose performance has not been completed as of January 1, 2018, and recognize the cumulative effect of initially applying the standard as an adjustment to the opening balance of retained earnings.

The Company does not expect the adoption of this standard to result in a material impact to its financial statements. Upon adopting FASB ASC Topic 606, the Company will provide additional disclosures in the notes to the consolidated financial statements related to the relevant aspects of any revenue generating contracts that the Company has or into which the Company expects to enter.

In 2017, the Company is implementing new internal controls as part of its efforts to adopt the new revenue recognition standard. These internal controls include providing training to the Company’s finance team and holding regular meetings with the Company’s management and the Audit Committee of the Company’s Board of Directors to review and approve key decisions. Upon adoption, the Company expects to implement new internal controls related to its accounting policies and procedures. The Company will require new internal controls to address risks associated with applying the five-step model. Additionally, the Company will establish monitoring controls to identify sales arrangements and changes in the Company’s business environment that could impact its current accounting assessment. The Company expects to finalize its impact assessment and redesign impacted processes, policies and controls.

In January 2016, the FASB issued ASU No. 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 consolidated financial statements.

In February 2016, the FASB issued ASU No. 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 Company is currently analyzing the impact of ASU 2016-02 and, at this time, has not yet determined the impact of the new standard, if any, on the Company’s consolidated financial statements.

In March 2016, the FASB issued ASU No. 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 December 31, 2016. As of January 1, 2017, the Company adopted ASU 2016-09 for the quarter ended March 31, 2017. Accordingly, the Company recognized previously unrecognized excess tax benefits of \$7 million recorded as deferred tax assets with a corresponding offsetting full valuation allowance at the beginning of 2017, which yielded no tax impact.

[Table of Contents](#)

3. Property and Equipment

Property and equipment consist of the following:

	September 30, 2017	December 31, 2016
Computer equipment	\$ 33,584	\$ 39,095
Furniture and fixtures	292,423	292,423
Scientific equipment	2,987,778	2,844,865
	<u>3,313,785</u>	<u>3,176,383</u>
Less accumulated depreciation	<u>(2,634,179)</u>	<u>(2,548,769)</u>
	<u>\$ 679,606</u>	<u>\$ 627,614</u>

Depreciation expense for the nine months ended September 30, 2017 and 2016 was \$155,262 and \$146,784, respectively.

4. Share-Based Compensation

The Company's Amended and Restated 2013 Equity Incentive Plan (the "Plan") provides 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. As of December 31, 2016, there were options to purchase 3,101,032 shares of common stock outstanding under the Plan. On June 16, 2015, the stockholders of the Company approved, at the Company's 2015 Annual Meeting of Stockholders, an amendment to the 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 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 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 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, 2017 and 2016, was comprised of the following:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Research and development	\$ 753,566	\$1,045,547	\$ 3,668,464	\$ 3,400,324
General and administrative	1,747,187	2,641,199	7,362,108	7,575,607
Total share-based compensation expense	<u>\$2,500,753</u>	<u>\$3,686,746</u>	<u>\$11,030,572</u>	<u>\$10,975,931</u>

The following table describes the weighted-average assumptions used for calculating the value of options granted during the nine months ended September 30, 2017 and September 30, 2016:

	2017	2016
Dividend yield	0%	0%
Expected volatility	87.4%-90.4%	80%
Weighted-average risk-free interest rate	2.1%	1.7%
Expected term	5.9 years	5.9 years

[Table of Contents](#)

Information regarding the stock options activity, including with respect to grants to employees, directors and consultants as of September 30, 2017 and changes during the nine-month period then ended, are summarized as follows:

	Number of Shares	Weighted- Average Exercise Price Per Share	Weighted- Average Contractual Life
Outstanding at December 31, 2016 (audited)	3,101,032	\$ 19.63	7.2 years
Options granted (unaudited)	738,195	\$ 15.21	9.3 years
Options exercised (unaudited)	(99,750)	\$ 2.55	3.4 years
Options canceled or expired (unaudited)	(128,830)	\$ 25.83	8.5 years
Outstanding at September 30, 2017 (unaudited)	3,610,647	\$ 18.97	7.0 years
Vested or expected to vest at September 30, 2017 (unaudited)	3,610,647	\$ 18.97	
Exercisable at September 30, 2017 (unaudited)	2,451,396	\$ 16.69	6.4 years

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, 2017 and changes during the nine-month period then ended, are summarized as follows:

	Number of Shares	Weighted-Average Grant Date Fair Value Per Share
Outstanding at December 31, 2016 (audited)	82,321	\$ 53.77
RSU's granted in 2017 (unaudited)	154,922	\$ 15.73
RSU's vested in 2017 (unaudited)	(26,256)	\$ 53.63
RSU's cancelled in 2017 (unaudited)	(18,297)	\$ 26.80
Outstanding at September 30, 2017 (unaudited)	192,690	\$ 25.77

Information related to the Company's Milestone RSU grants and the TSR RSU grants during the nine-month period ended September 30, 2017 are summarized as follows:

	Number of Shares	Weighted-Average Grant Date Fair Value Per Share
Outstanding at December 31, 2016 (unaudited)	—	\$ —
RSU's granted in 2017 (unaudited)	454,644	\$ 15.15
RSU's cancelled in 2017 (unaudited)	(38,838)	\$ 15.15
Outstanding at September 30, 2017 (unaudited)	415,806	\$ 15.15

The weighted average estimated fair value per share of the TSR RSUs granted in the nine months ended September 30, 2017 was \$17.08, which was derived from a Monte Carlo simulation. Significant assumptions utilized in estimating the value of the awards granted include an expected dividend yield of 0%, a risk free rate of 1.6%, and expected volatility of 95.4%. The TSR RSUs granted in the nine months ended September 30, 2017, will entitle the grantee to receive a number of shares of the Company's common stock determined over a three-year performance period ending and vesting on December 31, 2019, provided the grantee remains in the service of the Company on the settlement date. The Company expenses the cost of these awards ratably over the requisite service period. The number of shares for which the TSR RSUs will be settled will be a percentage of shares for which the award is targeted and will depend on the Company's total shareholder return (as defined below), expressed as a percentile ranking of the Company's total shareholder return as compared to the Company's peer group (as defined below). The number of shares for which the TSR RSUs will be settled vary depending on the level of achievement of the goal. Total shareholder return is determined by dividing the average share value of the Company's common stock over the 30 trading days preceding January 1, 2020 by the average share value of the Company's common stock over the 30 trading days beginning on March 8, 2017, with a deemed reinvestment of any dividends declared during the performance period. The Company's peer group includes 162 companies which comprise the Nasdaq Biotechnology Index, which was selected by the Compensation Committee of the Company's Board of Directors and includes a range of biotechnology companies operating in several business segments.

[Table of Contents](#)

The Company recognized non-cash stock-based compensation expense related to time based RSU's for the three and nine months ending September 30, 2017 of approximately \$368,000 and \$1.5 million, respectively, as compared to \$361,000 and \$1.1 million, respectively, for the three and nine months ending September 30, 2016. As of September 30, 2017, there was \$3.5 million of unrecognized compensation costs related to unvested time-based RSUs. Total expense for all RSUs, including the time-based and performance-based RSU grants for the three and nine months ending September 30, 2017 is approximately \$787,000 and \$2.6 million, respectively, as compared to \$361,000 and \$1.1 million, respectively, for the three and nine months ending September 30, 2016. As of September 30, 2017, there was \$5.4 million of unrecognized compensation costs related to unvested Milestone RSU grants and TSR RSU grants.

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 lumateperone and other specified compounds. The agreement was amended on November 3, 2010. The licensed rights are exclusive, except BMS retains rights in specified compounds in the fields of obesity, diabetes, metabolic syndrome and cardiovascular disease. However, BMS has no right to use, develop or commercialize lumateperone 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 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 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 lumateperone for patients with exacerbated 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 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 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 agreement.

7. Legal Matters

On May 12, 2017, a purported class action lawsuit was filed against the Company and certain of its executive officers alleging violations of the Exchange Act and Rule 10b-5 promulgated thereunder. On May 26, 2017, a second purported class action lawsuit was filed against the Company and certain of its executive officers alleging violations of the Exchange Act and Rule 10b-5 promulgated thereunder. Each of these lawsuits was premised upon allegations that the defendants made false and misleading statements and/or omissions by failing to earlier disclose findings related to toxicity in animals treated with lumateperone. Additionally, the complaints alleged that, as a result of the foregoing, certain of the defendants' statements about the Company's business, operations, and prospects were materially false and misleading and/or lacked a reasonable basis. In July 2017, these two actions were consolidated into a single action and a purported individual investor in the Company was appointed as lead plaintiff to represent the proposed class. In September 2017, the parties filed a request that the consolidated action be voluntarily dismissed without prejudice. On November 2, 2017, the United States District Court for the Eastern District of New York granted the parties' request to dismiss the action. The matter has now concluded.

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

You should read the following in conjunction with our unaudited condensed consolidated financial statements and the related notes thereto that appear elsewhere in this Quarterly Report on Form 10-Q and the audited consolidated financial statements and notes thereto and under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our Annual Report on Form 10-K filed on March 1, 2017. In addition to historical information, the following discussion and analysis includes forward-looking information that involves risks, uncertainties and assumptions. Our actual results and the timing of events could differ materially from those anticipated by these forward-looking statements as a result of many factors, including those discussed under “Risk Factors” in our Annual Report on Form 10-K filed on March 1, 2017, 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. Lumateperone (also known as 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, lumateperone combines potent serotonin 5-HT_{2A} receptor antagonism, dopamine receptor phosphoprotein modulation, or DPPM, glutamatergic modulation, and serotonin reuptake inhibition into a single drug candidate for the treatment of acute and residual schizophrenia and for the treatment of bipolar disorder, including bipolar depression. At dopamine D₂ receptors, lumateperone has been demonstrated to have dual properties and to act as both a pre-synaptic partial agonist and a post-synaptic antagonist. Lumateperone has also been demonstrated to have affinity for dopamine D₁ receptors and indirectly stimulate phosphorylation of glutamatergic NMDA GluN_{2B} 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 lumateperone may also be useful for the treatment of other psychiatric and neurodegenerative disorders, particularly behavioral disturbances associated with dementia, autism, and other CNS diseases. Lumateperone 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.

Lumateperone for the Treatment of Schizophrenia

In September 2015, we announced top-line clinical results from our first Phase 3 clinical trial of lumateperone 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, lumateperone had a favorable safety and tolerability profile as evidenced by motoric, metabolic, and cardiovascular characteristics similar to placebo, and

[Table of Contents](#)

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 lumateperone.

In September 2015, we also announced top-line data from an open-label positron emission tomography, or PET, study of lumateperone examining brain occupancy of striatal D2 receptors. This study was conducted in patients diagnosed with schizophrenia who were otherwise healthy and stable with respect to their psychosis. After washout from their previous antipsychotic medication for at least two weeks, PET was used to determine target occupancy in brain regions at baseline (drug-free) and again after two weeks of once daily lumateperone oral administration. In this trial, the 60 mg dose of ITI-007 was associated with a mean of approximately 40% striatal dopamine D2 receptor occupancy. As predicted by preclinical and earlier clinical data, lumateperone demonstrated antipsychotic effect at relatively low striatal D2 receptor occupancy, lower than the occupancy range required by most other antipsychotic drugs. Unlike any existing schizophrenia treatment, this dopamine receptor phosphoprotein modulator, or DPPM, acts as a pre-synaptic partial agonist and post-synaptic antagonist at D2 receptors. We believe this mechanism likely contributes to the favorable safety profile of lumateperone, 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 lumateperone confirmed the earlier Phase 2 results that we announced in December 2013, in which lumateperone 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, lumateperone 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 lumateperone for the treatment of patients with schizophrenia. In this trial, neither dose of lumateperone 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, lumateperone 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 lumateperone 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. In addition, we believe other confounding factors may have played a role in the efficacy outcome of ITI-007-302, including an expectation bias and the potential for functional unblinding. We believe the lumateperone 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 lumateperone 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.

As part of our ongoing dialogue with the U.S. Food and Drug Administration, or FDA, regarding our lumateperone development program in schizophrenia, we requested guidance from the FDA on the acceptability of the two positive well controlled clinical trials we have conducted (Study ITI-007-005 and Study ITI-007-301), with supportive evidence from Study ITI-007-302, as the basis for the submission of a new drug application, or NDA, for the treatment of schizophrenia. In connection with this request we provided extensive information and data analyses to the FDA relating to the three studies. The FDA has confirmed that the results of Study ITI-007-302 do not preclude us from submitting an NDA based on the efficacy studies we have conducted to date. We believe our schizophrenia clinical development program collectively provides evidence of the efficacy and safety of lumateperone for the treatment of schizophrenia.

In addition, the FDA had raised questions relating to certain findings observed in nonclinical toxicology studies of lumateperone in an animal species and requested additional information to confirm that the nonclinical findings are not indicative of a safety risk associated with long term exposure in humans. The data we presented supports the position that there are significant species differences in the metabolism of lumateperone. Based on the FDA's agreement that we presented adequate data indicating that the toxicity seen in the animal species is not relevant to humans, we are proceeding with our long-term safety study of lumateperone in patients with schizophrenia. Further, based on feedback from the FDA, we have incorporated additional monitoring in our long-term safety study for metabolites seen in animal species but not seen to date in humans, and also will continue to monitor for toxicities in our nonclinical studies. With over 2,000 people exposed to date, lumateperone has been well-tolerated with a safety profile similar to placebo. Accordingly, we are moving forward with our long-term safety study of lumateperone and intend to submit an NDA for the treatment of schizophrenia by mid-2018.

In September 2017, we announced positive topline data from the first part of an open-label safety switching study in which 302 patients with stable symptoms of schizophrenia were switched from standard-of-care antipsychotic medications to lumateperone (ITI-007 60 mg) with no dose titration of lumateperone required for a six-week treatment duration, then switched back to standard-of-care. Many currently available antipsychotic agents are associated with motor side effects and/or weight gain, cardiovascular liabilities, dyslipidemia, and hyperglycemia. In this study, lumateperone was generally well tolerated with a favorable safety profile. Statistically significant improvements from standard-of-care baseline were observed in body weight, cardiometabolic and endocrine parameters in patients with stable symptoms of schizophrenia when switched to lumateperone and worsened again when switched back to standard-of-care medication. Additionally, treatment with lumateperone was not associated with the motor or cardiovascular disturbances often associated with other antipsychotic medications. These data are consistent with previous study results reflecting a safety profile similar to placebo in placebo-controlled trials with lumateperone in patients with acutely exacerbated schizophrenia and extend this favorable safety profile to this stable patient population. Symptoms of schizophrenia did not worsen upon switch to lumateperone from standard-of-care. Rather, statistically significant improvement from baseline was observed in the PANSS mean total score. Notably, greater improvements were observed in subgroups of patients with elevated symptomatology such as those with comorbid symptoms of depression and those with prominent negative symptoms.

Lumateperone for the Treatment of Depressive Episodes Associated with Bipolar Disorder (Bipolar Depression)

Our bipolar depression program consists of three Phase 3 multi-center, randomized, double-blind, placebo-controlled clinical trials. In the ITI-007-401 and the ITI-007-404 trials lumateperone is being evaluated as a monotherapy and in the ITI-007-402 trial lumateperone is being evaluated as an adjunctive therapy with lithium or valproate. All three trials are evaluating lumateperone in patients with a clinical diagnosis of Bipolar I or Bipolar II disorder and who are experiencing a current major depressive episode. In the ITI-007-401 and the ITI-007-402 trials, patients are 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-007-404 trial patients are randomized to receive 40 mg ITI-007 or placebo in a 1:1 ratio orally once daily for 6 weeks. In the ITI-007-401 and the ITI-007-404 trials, patients receive lumateperone or placebo as a monotherapy. In the ITI-007-402 trial, patients receive lumateperone or placebo adjunctive to their existing mood stabilizer lithium or valproate. In each of these trials, we are employing a number of strategies designed to ensure we recruit appropriately diagnosed patients in an effort to reduce the risk of a high placebo response. Patient enrollment in the ITI-007-401 trial is expected to complete in the first half of 2018. Patient enrollment in the ITI-007-402 trial and the ITI-007-404 trial is expected to complete in the second half of 2018.

The primary endpoint for these 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 lumateperone. Safety and tolerability are also assessed in these clinical trials.

Lumateperone 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 lumateperone in healthy geriatric subjects and in patients with dementia, including AD. The completion of this study marked an important milestone in our strategy to develop low doses of lumateperone for the treatment of behavioral disturbances associated with dementia and related disorders. The ITI-007-200 trial results indicate that lumateperone is safe and well-tolerated across a range of low doses, has linear- and dose-related pharmacokinetics and may improve cognition in the elderly. The most frequent adverse event was mild sedation at the higher doses. We believe these results further position lumateperone as a development candidate for the treatment of behavioral disturbances in patients with dementia and other neuropsychiatric and neurological conditions.

In the second quarter of 2016, we initiated Phase 3 development of lumateperone 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

[Table of Contents](#)

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 the CGI-S. 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 Lumateperone

We are also pursuing clinical development of lumateperone for the treatment of additional CNS diseases and disorders. At the lowest doses, lumateperone has been demonstrated to act primarily as a potent 5-HT_{2A} 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-HT_{2A} 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 lumateperone 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-HT_{2A} 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 lumateperone, 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 lumateperone 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 lumateperone 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. 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. We believe 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, including cardiovascular disease. Following the positive safety and tolerability results in our Phase 1 program, we have initiated our development program for ITI-214 for Parkinson's disease and commenced patient enrollment in the third quarter of 2017 in a Phase 1/2 clinical trial of ITI-214 in patients with Parkinson's disease to evaluate safety and tolerability in this patient population, as well as motor and non-motor exploratory endpoints.

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, 2017, our accumulated deficit was \$377.0 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.

Recent Developments

On October 2, 2017 and October 5, 2017, we completed a public offering of common stock in which we sold 11,129,032 shares of common stock, which included the exercise of the underwriters' option to purchase an additional 1,451,613 shares, at an offering price of \$15.50 per share for aggregate gross proceeds of approximately \$172 million. After deducting underwriting discounts, commissions and offering expenses, the net proceeds to us were approximately \$162 million.

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 18 months. Our revenues for the three and nine months ended September 30, 2017 and 2016 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 with certainty to estimate either the costs or the timelines in which those costs will be incurred. The clinical development of lumateperone for the treatment of schizophrenia, for the treatment of bipolar depression and for the treatment of 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 lumateperone 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, including cardiovascular disease. We have initiated our development program for ITI-214 for Parkinson's disease and commenced patient enrollment in the third quarter of 2017 in a Phase 1/2 clinical trial of ITI-214 in patients with Parkinson's disease to evaluate safety and tolerability in this patient population, as well as motor and non-motor exploratory endpoints. 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 lumateperone. Any failure or delay in the advancement of lumateperone could require us to re-allocate resources from our other projects to the advancement of lumateperone, which could have a significant material adverse impact on the advancement of these other projects and on our results of operations. Our operating expenses are comprised of (i) research and development expenses and (ii) general and administrative expenses. Our research and development costs are comprised of:

- internal recurring costs, such as labor and fringe benefits, materials and supplies, facilities and maintenance costs; and
- fees paid to external parties who provide us with contract services, such as pre-clinical testing, manufacturing and related testing, clinical trial activities and license milestone payments.

General and administrative expenses are incurred in three major categories:

- salaries and related benefit costs;
- patent, legal, professional and pre-commercialization costs; and
- office and facilities overhead.

We expect that research and development expenses will increase as we proceed with our Phase 3 clinical trials of lumateperone for the treatment of bipolar disorder and for the treatment of agitation in patients with dementia, including AD, and as we proceed with

[Table of Contents](#)

increased manufacturing of drug product for clinical trials and pre-commercialization testing. We also expect that our general and administrative costs will increase from prior periods primarily due to costs to perform pre-product commercialization activities and the increased costs associated with being a public reporting entity, which could include hiring additional personnel. We granted options to purchase 487,121 shares of our common stock in 2016 and have granted options to purchase an additional 738,195 shares of our common stock in the nine months ended September 30, 2017. We also granted time based restricted stock units, or RSUs, for 78,806 shares of our common stock in 2016 and time based RSUs for 154,922 shares of our common stock in the nine months ended September 30, 2017. We will recognize expense associated with these RSUs and options over the next three years in both research and development expenses and general and administrative expenses. In the first quarter of 2017, we also granted performance based RSUs, which vest based on the achievement of certain milestones that include (i) the submission of a new drug application with the U.S. Food and Drug Administration, or the FDA, (ii) the approval of the NDA by the FDA, or the Milestone RSU grants, and (iii) the achievement of certain comparative shareholder returns against our peers, or the TSR RSU grants. The Milestone RSU grants were valued at the closing price on March 8, 2017. The RSUs related to the NDA submission will be amortized through December 31, 2018 based on the probable vesting date. The amortization of the expenses of the RSUs related to the approval of the NDA will commence if and when the filing has been approved through the last day of the calendar year in which the milestone is achieved. The TSR RSU grants were valued using the Monte Carlo Simulation method and will be amortized over the life of the RSU agreements which ends December 31, 2019. The Milestone RSU grants and the TSR RSU grants are target based and the ultimate awards, if attained, could be the target amount or higher or lower than the target amount, depending on the timing or achievement of the goal. We are amortizing the expenses at the 100% targeted amount. We expect this non-cash expense to be substantial 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.

The following table sets forth our revenues and operating expenses for the three and nine months ended September 30, 2017 and 2016 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
	<i>(Unaudited)</i>		<i>(Unaudited)</i>	
Revenues	\$ 31	\$ 4	\$ 241	\$ 232
Expenses				
Research and Development	18,472	23,918	52,490	72,653
General and Administrative	5,318	6,271	17,883	17,806
Total costs and expenses	23,790	30,189	70,373	90,459
Loss from operations	(23,759)	(30,185)	(70,132)	(90,227)
Interest Income, net	885	752	2,565	2,118
Income tax benefit (expense)	4	(832)	2	(832)
Net Loss	\$ (22,870)	\$ (30,265)	\$ (67,565)	\$ (88,941)

Comparison of Three and Nine Month Periods Ended September 30, 2017 and September 30, 2016

Revenues

Revenues increased for the three and nine months ended September 30, 2017 as compared to the three and nine months ended September 30, 2016 by approximately \$26,000 and \$8,000, respectively, due to revenue from a government grant.

Research and Development Expenses

Research and development expenses decreased to \$18.5 million for the three month period ended September 30, 2017 as compared to \$23.9 million for the three month period ended September 30, 2016, representing a decrease of approximately 23%. This change is due primarily to a decrease of approximately \$5.7 million of costs associated with outside clinical and non-clinical costs and an increase of approximately \$282,000 of internal costs in the three month period ended September 30, 2017 over the three month period ended September 30, 2016. In the three months ended September 30, 2017, the \$18.5 million of research and development costs were comprised primarily of development costs for lumateperone in patients with bipolar depression and dementia, including AD, of approximately \$7.1 million, clinical trials and development costs for lumateperone for the treatment of schizophrenia of approximately \$2.8 million, manufacturing expense of approximately \$2.3 million and other clinical and non-clinical expenses. In the three months ended September 30, 2016 the majority of the \$23.9 million of research and development costs were related to our development program for lumateperone for patients with schizophrenia that included \$8.1 million of manufacturing expenses and approximately \$4.8 million of expenses for our second Phase 3 schizophrenia trial. In addition there were approximately \$3.7 million of development costs for lumateperone in patients with bipolar depression and dementia, including AD, and other clinical and non-clinical expenses. Amounts payable to external parties comprised a significant portion of our research and development costs. In the three months ended September 30, 2017, we incurred approximately \$15.1 million of costs to external parties who performed clinical trial related activities, including manufacturing and testing

[Table of Contents](#)

lumateperone, as compared to \$20.9 million in the three month period ended September 30, 2016. Of these external costs, approximately \$14.4 million in the three months ended September 30, 2017 and approximately \$20.7 million in the three month period ended September 30, 2016 were for lumateperone related projects. The remaining external costs for each of these periods were spent on other projects. Internal costs are comprised primarily of costs relating to labor, fringe benefits, materials, stock based compensation, supplies and facilities and maintenance and were approximately \$3.2 million and \$3.0 million in the three months ended September 30, 2017 and 2016, respectively.

Research and development expenses decreased to \$52.5 million for the nine month period ended September 30, 2017 as compared to \$72.7 million for the nine month period ended September 30, 2016, representing a decrease of approximately 28%. This change is due primarily to a decrease of approximately \$21.8 million of costs associated with outside clinical and non-clinical costs, partially offset by an increase of approximately \$1.6 million of internal costs in the nine month period ended September 30, 2017 over the nine month period ended September 30, 2016. In the nine months ended September 30, 2017, the \$52.5 million of research and development costs were comprised primarily of development costs for lumateperone for the treatment of schizophrenia of approximately \$13.1 million, development costs for lumateperone in patients with bipolar depression and dementia, including AD of approximately \$15.0 million, manufacturing expense of approximately \$8.1 million and other clinical and non-clinical expenses. In the nine months ended September 30, 2016 the majority of the \$72.7 million of research and development costs were related to the second Phase 3 trial of lumateperone in patients with schizophrenia of approximately \$29.7 million, development costs for lumateperone in patients with bipolar depression and dementia, including AD, of approximately \$13.2 million, manufacturing expense of approximately \$9.5 million and other clinical and non-clinical expenses. Amounts payable to external parties comprised a significant portion of our research and development costs. In the nine months ended September 30, 2017, we incurred approximately \$41.5 million of costs to external parties who performed clinical trial related activities, including manufacturing and testing lumateperone, as compared to \$63.3 million in the nine month period ended September 30, 2016. Of these external costs, approximately \$40.1 million in the nine months ended September 30, 2017 and approximately \$62.8 million in the nine month period ended September 30, 2016 were for lumateperone related projects. The remaining external costs for each of these periods were spent on other projects. Internal costs are comprised primarily of costs relating to labor, fringe benefits, materials, stock based compensation, supplies and facilities and maintenance and were approximately \$11.0 million and \$9.4 million in the nine months ended September 30, 2017 and 2016, respectively.

As development of lumateperone progresses, we anticipate costs for lumateperone to increase due primarily to ongoing and planned clinical trials relating to our lumateperone programs in the remainder of 2017 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. As of September 30, 2017, we employed 30 full time personnel in our research and development group as compared to 28 full time personnel in our research and development group at September 30, 2016. 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 lumateperone, that are in the research and development stages, including in the treatment of neurological and neurodegenerative diseases, including Parkinson's and AD, among others and pain, substance use disorders and related psychiatric comorbidities including depression and anxiety. We have used internal resources and incurred expenses not only in relation to the development of lumateperone, but also in connection with these additional projects as well, including our PDE program. 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."

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;

Table of Contents

- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the active pharmaceutical ingredient, or API, and finished drug product are produced and tested to assess compliance with current Good Manufacturing Practices, or cGMPs;
- satisfactory completion of FDA inspections of clinical trial sites to assure that data supporting the safety and effectiveness of product candidates has been generated in compliance with Good Clinical Practices; and
- FDA review and approval of the NDA prior to any commercial marketing or sale of the drug in the United States.

The successful development of our product candidates and the approval process requires substantial time, effort and financial resources, and is uncertain and subject to a number of risks. We cannot be certain that any of our product candidates will prove to be safe and effective, will meet all of the applicable regulatory requirements needed to receive and maintain marketing approval, or will be granted marketing approval on a timely basis, if at all. Data from pre-clinical studies and clinical trials are susceptible to varying interpretations that could delay, limit or prevent regulatory approval or could result in label warnings related to or recalls of approved products. We, the FDA, or other regulatory authorities may suspend clinical trials at any time if we or they believe that the subjects participating in such trials are being exposed to unacceptable risks or if such regulatory agencies find deficiencies in the conduct of the trials or other problems with our product candidates. Other risks associated with our product candidates are described in the section entitled "Risk Factors" in our Annual Report on Form 10-K filed with the SEC on March 1, 2017, 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 decreased for the three month period ended September 30, 2017 as compared to the three month period ended September 30, 2016 by approximately \$953,000, representing a decrease of approximately 15%. The decrease is primarily the result of decreased stock option expense related to forfeited stock options and RSU's in the third quarter 2017 and legal fees incurred in the third quarter of 2016 for costs relating to the license of certain intellectual property by us to our wholly-owned subsidiary ITI Limited which was formed in the third quarter of 2016. Salaries, bonuses and related benefit costs for our executive, finance and administrative functions for the three months ended September 30, 2017 and 2016 constituted approximately 59% and 55% of our total general and administrative costs, respectively. The next major categories of general and administrative expenses are accounting, patent costs and, to a lesser extent, facilities and general office-related overhead.

General and administrative expenses increased for the nine month period ended September 30, 2017 as compared to the nine month period ended September 30, 2016 by approximately \$76,000, or 0.4%. The increase is primarily the result of professional fees in addition to increased labor and related costs, offset partially by lower pre-commercialization costs and lower stock option expense related to forfeited stock options and RSU's in the third quarter of 2017. Salaries, bonuses and related benefit costs for our executive, finance and administrative functions for the nine months ended September 30, 2017 and 2016 constituted approximately 63% and 62%, respectively, of our total general and administrative costs. The next major categories of expenses are accounting, patent costs, 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.

Liquidity and Capital Resources

Through September 30, 2017, we provided funds for our operations by obtaining approximately \$718 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. 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 addition, on October 2, 2017, we completed a public offering of 9,677,419 shares of our common stock for aggregate gross proceeds of approximately \$150 million and net proceeds of approximately \$140.6 million. On October 5, 2017, the underwriters exercised in full their option to purchase an additional 1,451,613 shares. All of the shares in the offering were sold by the Company, with gross proceeds to the Company of approximately \$172 million from the offering of an aggregate of 11,129,032 shares and net proceeds of approximately \$162 million, after deducting underwriting discounts and commissions and estimated offering expenses.

As of September 30, 2017, we had a total of approximately \$328.1 million in cash and cash equivalents and available-for-sale investment securities, and approximately \$11.9 million of short-term liabilities consisting entirely of liabilities from operations. In the nine months ended September 30, 2017, we spent approximately \$55.9 million in cash for operations and equipment and we received approximately \$2.6 million of interest income. We reduced working capital by approximately \$56.1 million for the nine months ended September 30, 2017. The use of cash was primarily for conducting clinical trials and non-clinical testing, including manufacturing related activities and funding recurring operating expenses.

[Table of Contents](#)

During the fourth quarter of 2017, subject to the timing of clinical trials, manufacturing and other development activities, we expect to spend up to \$35 million. We expect these expenditures to be due primarily to the development of lumateperone in patients with schizophrenia, behavioral disturbances in dementia, bipolar disorder and depressive disorders, 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 lumateperone, recurring expenses and costs to produce, develop and validate materials to be used in clinical and non-clinical studies related to lumateperone, expenses associated with the continued clinical development of our PDE program, including ITI-214, and expenses associated with our other development programs, pre-commercialization activities and general operations. We expect that cash expenditures will continue to increase after 2017 as we further expand the lumateperone clinical stage programs; 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; manufacturing and pre-commercial activities in connection with the development of lumateperone and the early stage pre-commercial launch activities for lumateperone. 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 middle of 2020.

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 lumateperone in patients with schizophrenia. With the remaining proceeds from our public offerings in March and September 2015 and October 2017, we believe that we have the funds to complete our ongoing clinical trials of lumateperone 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 also plan to fund additional clinical trials of lumateperone for the treatment of behavioral disturbances in dementia; preclinical and clinical development of ITI-007 long acting injectable development program; additional clinical trials of lumateperone; continued clinical development of our PDE program, including ITI-214; research and preclinical development of our other product candidates; and the continuation of manufacturing activities in connection with the development of lumateperone. We anticipate requiring additional funds to obtain regulatory approval for lumateperone in patients with dementia, including AD, for further development of lumateperone in patients with bipolar disorder, 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, 2017, we used net cash in operating activities and purchases of equipment of approximately \$55.9 million and expect to use additional cash of up to \$35 million during 2017. While we have several research and development programs underway, the lumateperone 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 lumateperone and our other product candidates, we expect the amount of cash to be used to fund operations to increase over the next several years.

With the termination of the Takeda License Agreement in October 2014, we are 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. We anticipate a moderate increase in our operating expenses related to our PDE development programs. Following the positive safety and tolerability results in our Phase 1 program, we have initiated our development program for ITI-214 for Parkinson's disease and commenced patient enrollment in the third quarter of 2017 in a Phase 1/2 clinical trial of ITI-214 in patients with Parkinson's disease to evaluate safety and tolerability in this patient population, as well as motor and non-motor exploratory endpoints. We expect these expenses to increase for 2018 and beyond.

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, 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. On September 2, 2016, we filed a universal shelf registration statement on Form S-3, which was declared effective by the SEC on September 14, 2016, on which we registered for sale up to \$350 million of any combination of our 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. After the public offering in October 2017, approximately \$178 million of securities remain available for issuance under this shelf registration statement. This registration statement will remain in effect for up to three years from the date it was declared effective.

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,

[Table of Contents](#)

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 lumateperone program could have a material adverse impact on our ability to raise additional capital.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our existing stockholders will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of our stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring debt, making capital expenditures or declaring dividends. If 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 lumateperone, 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 2014, we entered into a long-term lease, which was amended in December 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 \$3.0 million of deferred rent through September 30, 2017. 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 from year to year as a result of leasing this facility.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Contractual Obligations and Commitments

Total contractual obligations as of September 30, 2017 are summarized in the following table (in thousands):

	Payments Due By Period				
	Total	Less than 1 Year	1-3 Years	4-5 Years	More than 5 Years
Operating Lease Obligations	\$15,311	\$ 1,446	\$4,605	\$3,305	\$ 5,955

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.

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, 2016 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, 2017.

[Table of Contents](#)

The discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP. The preparation of these financial statements requires management to make estimates and assumptions that affect reported amounts of assets and liabilities as of the date of the balance sheet and reported amounts of revenues and expenses for the periods presented. Judgments must also be made about the disclosure of contingent liabilities. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Management makes estimates and exercises judgment in revenue recognition, 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. See Note 2, *Summary of Significant Accounting Policies*, in the notes to our unaudited financial statements for the three and nine months ended September 30, 2017, included in Part 1, Item 1 of this quarterly report on Form 10-Q for information on recent accounting pronouncements.

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, cash equivalents and investment securities, capital requirements and the need for additional financing; our beliefs about the extent to which the results of our clinical trials to date support an NDA filing for lumateperone for the treatment of schizophrenia; our belief that the toxicity findings observed in nonclinical animal toxicology studies of lumateperone are not indicative of a safety risk for humans; our ability to successfully complete our long-term safety study and to file an NDA with the FDA; 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 current and future product candidates; the election by any collaborator to pursue research, development and commercialization activities; our ability to obtain future reimbursement and/or milestone payments from our collaborators; our ability to obtain and maintain intellectual property protection for our product candidates; our ability to successfully commercialize our product candidates; the performance of our third-party suppliers and manufacturers and our ability to obtain alternative sources of raw materials; the potential outcome and cost of litigation; 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," "predict," "project," "likely," "will," "would," "could," "should," "continue" and words and terms of similar substance used in connection with any discussion 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, 2017, we had cash, cash equivalents and marketable securities of approximately \$328.1 million consisting of cash deposited in a highly rated financial institution in the United States, in a short-term U.S. Treasury money market fund, and in 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. 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, although the recent rise in interest rates has resulted in our unrealized loss on investments as of September 30, 2017 totaling approximately \$220,000. Since we plan on holding those investments to maturity, no recognition of impairment is required. 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 additional equity offerings. Our ability to raise funds in this manner depends 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, 2017 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

On May 12, 2017, a purported class action lawsuit was filed in the United States District Court for the Eastern District of New York against the Company, its Chief Executive Officer, its Chief Financial Officer and its Senior Vice President, Clinical Development, alleging violations of the Exchange Act and Rule 10b-5 promulgated thereunder. On May 26, 2017, a second purported class action lawsuit was filed in the United States District Court for the Eastern District of New York against the Company, its Chief Executive Officer, its Chief Financial Officer and its Senior Vice President, Clinical Development, alleging violations of the Exchange Act and Rule 10b-5 promulgated thereunder. Each of these lawsuits was premised upon allegations that the defendants made false and misleading statements and/or omissions by failing to earlier disclose findings related to toxicity in animals treated with lumateperone. Additionally, the complaints alleged that, as a result of the foregoing, certain of the defendants' statements about our business, operations, and prospects were materially false and misleading and/or lacked a reasonable basis. In July 2017, the United States District Court for the Eastern District of New York consolidated these two actions into a single action and a purported individual investor in the Company was appointed as lead plaintiff to represent the proposed class. In September 2017, the parties filed a request that the consolidated action be voluntarily dismissed without prejudice. On November 2, 2017, the United States District Court for the Eastern District of New York granted the parties' request to dismiss the action. The matter has now concluded.

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, 2016, filed with the Securities and Exchange Commission on March 1, 2017.

If we are unable to complete our long-term safety study or the results of our long-term safety study do not demonstrate the safety and tolerability of long-term use of lumateperone, we would not be able to file an NDA for lumateperone for a chronic condition such as schizophrenia.

The FDA had raised questions relating to certain findings observed in nonclinical toxicology studies of lumateperone in an animal species and requested additional information to confirm that the nonclinical findings are not indicative of a safety risk associated with

[Table of Contents](#)

long term exposure in humans. The data we presented supports the position that there are significant species differences in the metabolism of lumateperone. Based on the FDA's agreement that we presented adequate data indicating that the toxicity seen in the animal species is not relevant to humans, we are proceeding with our long-term safety study of lumateperone in patients with schizophrenia. Further, based on feedback from the FDA, we have incorporated additional monitoring in our long-term safety study for metabolites seen in animal species but not seen to date in humans, and also will continue to monitor for toxicities in its nonclinical studies. The results of the long-term safety study will be required to support an NDA approval for a chronic condition such as schizophrenia. If we are unable to complete our long-term study or the results of our long-term safety study do not demonstrate the safety and tolerability of long-term use of lumateperone, we would not be able to file an NDA for lumateperone for a chronic condition such as schizophrenia. Any failure to complete our long-term safety study or to file an NDA for lumateperone for schizophrenia or any other chronic condition would have a significant adverse effect on our business.

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, 2017.

Item 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

Item 5. OTHER INFORMATION

Not applicable.

Table of Contents

Item 6. EXHIBITS

<u>Exhibit Number</u>	<u>Exhibit Description</u>	<u>Filed Herewith</u>	<u>Incorporated by Reference herein from Form or Schedule</u>	<u>Filing Date</u>	<u>SEC File/Reg. Number</u>
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, 2017, formatted in XBRL (eXtensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets as of September 30, 2017 (unaudited) and December 31, 2016 (audited), (ii) Condensed Consolidated Statements of Operations (unaudited) for the three and nine months ended September 30, 2017 and 2016, (iii) Condensed Consolidated Statements of Comprehensive Loss (unaudited) for the three and nine months ended September 30, 2017 and 2016, (iv) Condensed Consolidated Statements of Cash Flows (unaudited) for the nine months ended September 30, 2017 and 2016, and (v) Notes to Condensed Consolidated Financial Statements (unaudited).	X			

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 8, 2017

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

Date: November 8, 2017

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

CERTIFICATIONS UNDER SECTION 302

I, Sharon Mates, Ph.D., certify that:

1. I have reviewed this quarterly report on Form 10-Q of Intra-Cellular Therapies, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 8, 2017

/s/ Sharon Mates, Ph.D.

Sharon Mates, Ph.D.

Chairman, President and Chief Executive Officer

(principal executive officer)

CERTIFICATIONS UNDER SECTION 302

I, Lawrence J. Hineline, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Intra-Cellular Therapies, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 8, 2017

/s/ Lawrence J. Hineline

Lawrence J. Hineline
Vice President of Finance and Chief Financial Officer
(principal financial officer)

CERTIFICATIONS UNDER SECTION 906

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), each of the undersigned officers of Intra-Cellular Therapies, Inc., a Delaware corporation (the "Company"), does hereby certify, to such officer's knowledge, that:

The Quarterly Report for the quarter ended September 30, 2017 (the "Form 10-Q") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 8, 2017

/s/ Sharon Mates, Ph.D.

Sharon Mates, Ph.D.

Chairman, President and Chief Executive Officer
(principal executive officer)

Dated: November 8, 2017

/s/ Lawrence J. Hinline

Lawrence J. Hinline

Vice President of Finance and Chief Financial Officer
(principal financial officer)