Intra-Cellular Therapies, Inc.
Form 10-Q
August 02, 2018
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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 June 30, 2018

or

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

For the transition period from _____ to _____

Commission File Number: 001-36274

INTRA-CELLULAR THERAPIES, INC.

(Exact name of registrant as specified in its charter)

Delaware	**36-4742850**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
430 East 29th Street	
New York, New York	**10016**
(Address of principal executive offices)	**(Zip Code)**

(646) 440-9333

(Registrant s telephone number, including area code)

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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		Accelerated filer
Non-accelerated filer	(Do not check if a smaller reporting company)	Smaller reporting company
		Emerging growth company

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 August 2, 2018, the registrant had 54,709,272 shares of common stock outstanding.

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

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PART I: FINANCIAL INFORMATION

Item 1. FINANCIAL STATEMENTS

Intra-Cellular Therapies, Inc. and Subsidiaries

Condensed Consolidated Balance Sheets

	June 30, 2018 *(Unaudited)*	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	**$ 69,767,045**	$ 37,790,114
Investment securities, available-for-sale	**333,997,440**	426,540,921
Prepaid expenses and other current assets	**5,896,583**	4,884,293
Total current assets	**409,661,068**	469,215,328
Property and equipment, net	**1,275,387**	1,137,171
Long term deferred tax asset, net	**1,058,435**	1,058,435
Other assets	**78,833**	75,765
Total assets	**$ 412,073,723**	$ 471,486,699
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	**$ 5,378,870**	$ 6,173,539
Accrued and other current liabilities	**10,462,217**	6,424,221
Accrued employee benefits	**3,094,280**	1,611,846
Total current liabilities	**18,935,367**	14,209,606
Long-term deferred rent	**2,750,914**	2,840,132
Total liabilities	**21,686,281**	17,049,738
Stockholders equity:		
Common stock, $.0001 par value: 100,000,000 shares authorized; 54,700,580 and 54,597,679 shares issued and outstanding at June 30, 2018 and December 31, 2017, respectively	**5,470**	5,460
Additional paid-in capital	**871,516,637**	862,479,505
Accumulated deficit	**(480,105,241)**	(407,248,780)
Accumulated comprehensive loss	**(1,029,424)**	(799,224)
Total stockholders equity	**390,387,442**	454,436,961
Total liabilities and stockholders equity	**$ 412,073,723**	$ 471,486,699

See accompanying notes to these condensed consolidated financial statements.

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Intra-Cellular Therapies, Inc. and Subsidiaries

Condensed Consolidated Statements of Operations (Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	**2018**	2017
Revenues	**$**	$ 114,741	**$**	$ 210,028
Costs and expenses:				
Research and development	**32,439,270**	12,478,638	**63,142,268**	34,017,596
General and administrative	**6,728,987**	6,254,616	**13,110,215**	12,565,102
Total costs and expenses	**39,168,257**	18,733,254	**76,252,483**	46,582,698
Loss from operations	**(39,168,257)**	(18,618,513)	**(76,252,483)**	(46,372,670)
Interest income	**1,793,474**	857,809	**3,397,622**	1,679,984
Loss before provision for income taxes	**(37,374,783)**	(17,760,704)	**(72,854,861)**	(44,692,686)
Income tax expense	**1,600**		**1,600**	1,600
Net loss	**$ (37,376,383)**	$ (17,760,704)	**$ (72,856,461)**	$ (44,694,286)
Net loss per common share:				
Basic & Diluted	**$ (0.68)**	$ (0.41)	**$ (1.33)**	$ (1.03)
Weighted average number of common shares:				
Basic & Diluted	**54,696,698**	43,419,798	**54,686,550**	43,402,796

See accompanying notes to these condensed consolidated financial statements.

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Intra-Cellular Therapies, Inc. and Subsidiaries

Condensed Consolidated Statements of Comprehensive Loss

	Three Months Ended June 30,		**Six Months Ended June 30,**	
	2018	2017	**2018**	2017
	(Unaudited)	*(Unaudited)*	*(Unaudited)*	*(Unaudited)*
Net loss	**$ (37,376,383)**	$ (17,760,704)	**$ (72,856,461)**	$ (44,694,286)
Other comprehensive loss:				
Unrealized gain (loss) on investment securities	**210,326**	(24,119)	**(230,200)**	1,412
Comprehensive loss	**$ (37,166,057)**	$ (17,784,823)	**$ (73,086,661)**	$ (44,692,874)

See accompanying notes to these condensed consolidated financial statements.

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Intra-Cellular Therapies, Inc. and Subsidiaries

Condensed Consolidated Statements of Cash Flows

	(Unaudited)	
	Six Months Ended June 30,	
	2018	2017
Cash flows used in operating activities		
Net loss	**$ (72,856,461)**	$ (44,694,286)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	**178,276**	101,801
Share-based compensation expense	**8,597,808**	8,529,819
Issuance of common stock for services	**95,408**	95,456
Net accretion of discounts and amortization of premiums of available-for-sale securities	**(234,256)**	314,826
Changes in operating assets and liabilities:		
Accounts receivable		32,404
Prepaid expenses and other assets	**(1,015,358)**	(2,139,726)
Accounts payable	**(794,669)**	(1,979,395)
Accrued liabilities	**5,451,351**	(1,616,227)
Deferred rent	**(20,139)**	68,477
Net cash used in operating activities	**(60,598,040)**	(41,286,851)
Cash flows provided by investing activities		
Purchases of investments	**(183,657,067)**	(206,034,513)
Maturities of investments	**276,204,604**	228,141,889
Purchases of property and equipment	**(316,492)**	(103,088)
Net cash provided by investing activities	**92,231,045**	22,004,288
Cash flows provided by financing activities		
Proceeds from stock option exercises	**343,926**	230,784
Net cash provided by financing activities	**343,926**	230,784
Net increase (decrease) in cash and cash equivalents	**31,976,931**	(19,051,779)
Cash and cash equivalents at beginning of period	**37,790,114**	48,642,225
Cash and cash equivalents at end of period	**$ 69,767,045**	$ 29,590,446

See accompanying notes to these condensed consolidated financial statements.

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Intra-Cellular Therapies, Inc.

Notes to Condensed Consolidated Financial Statements (Unaudited)

June 30, 2018

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 primarily 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 primarily for the treatment of neurological and psychiatric disorders.

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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):

	June 30, 2018			
	Amortized Cost	Unrealized Gains	Unrealized (Losses)	Estimated Fair Value
		(unaudited)		
U.S. Government Agency Securities	$ 123,718	$	$ (503)	$ 123,215
FDIC Certificates of Deposit (1)	2,695			2,695
Certificates of Deposit	31,000			31,000
Commercial Paper	48,142		(41)	48,101
Corporate Notes/Bonds	129,471		(485)	128,986
	$ 335,026	$	$ (1,029)	$ 333,997

	December 31, 2017			
	Amortized Cost	Unrealized Gains	Unrealized (Losses)	Estimated Fair Value
U.S. Government Agency Securities	$ 126,330	$	$ (348)	$ 125,982
FDIC Certificates of Deposit (1)	8,306			8,306
Certificates of Deposit	103,500			103,500
Commercial Paper	51,414		(61)	51,353
Corporate Notes/Bonds	137,790		(390)	137,400
	$ 427,340	$	$ (799)	$ 426,541

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

The Company has classified all of its investment securities available-for-sale, including those with maturities beyond one year, as current assets on the consolidated balance sheets based on the highly liquid nature of the investment securities and because these investment securities are considered available for use in current operations. As of June 30, 2018 and December 31, 2017, the Company held $98.8 million and $93.3 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 June 30, 2018, the aggregate related fair value of investments with unrealized losses was $305.3 million and the aggregate amount of unrealized losses was $1.0 million. Of the $305.3 million, $295.8 million have been held in a continuous unrealized loss position for less than 12 months and $9.5 million have

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been held in a continuous loss position for 12 months or longer. The total continuous unrealized loss for investments held for less than 12 months and for investments held for 12 months or longer is approximately $1.0 million and $13,000, respectively. As of December 31, 2017, the Company had approximately $37.3 million of investments with a continuous unrealized loss for 12 months or longer of approximately $42,000.

The Company attributes the unrealized losses on the available-for-sale securities as of June 30, 2018 and December 31, 2017 to the rise 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 June 30, 2018 and December 31, 2017. The carrying value of cash held in money market funds of approximately $43.7 million as of June 30, 2018 and $26.2 million as of December 31, 2017 is included in cash and cash equivalents and approximates market value based on quoted market price or Level 1 inputs. The carrying value of cash held in Certificates of Deposit and Commercial Paper of approximately $20.0 million and $5.0 million as of June 30, 2018, respectively, is included in cash and cash equivalents.

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

		Fair Value Measurements at Reporting Date Using		
	June 30, 2018	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money Market Funds	$ 43,744	$ 43,744	$	$
U.S. Government Agency Securities	123,215		123,215	
FDIC Certificates of Deposit	2,695		2,695	
Certificates of Deposit	51,000		51,000	
Commercial Paper	53,100		53,100	
Corporate Notes/Bonds	128,986		128,986	
	$ 402,740	$ 43,744	$ 358,996	$

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	December 31, 2017	Fair Value Measurements at Reporting Date Using Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money Market Funds	$ 26,181	$ 26,181	$	$
U.S. Government Agency Securities	125,982		125,982	
FDIC Certificates of Deposit	8,306		8,306	
Certificates of Deposit	103,500		103,500	
Commercial Paper	51,353		51,353	
Corporate Notes/Bonds	137,400		137,400	
	$ 452,722	$ 26,181	$ 426,541	$

Financial Instruments

The Company considers the recorded costs of its financial assets and liabilities, which consist of cash equivalents, prepaid expenses, accounts payable and accrued liabilities, to approximate their fair value because of their relatively short maturities at June 30, 2018 and December 31, 2017. At June 30, 2018, the Company has approximately $2.4 million as a prepaid related to a regulatory filing fee that is expected to be refunded within the next year. 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, cash and cash equivalents 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 June 30, 2018 and December 31, 2017, as the Company has a history of collecting on all its accounts including from 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.

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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 preclinical analytical testing, manufacturing of drug product, external 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.

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 external 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 six months ended June 30, 2018 and 2017, 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.

On December 22, 2017, President Trump signed into law the Tax Cuts and Jobs Act (TCJA) that significantly reforms the Internal Revenue Code of 1986, as amended (the Code). The TCJA, among other things, includes changes to U.S. federal tax rates, imposes significant additional limitations on the deductibility of interest and net operating loss carryforwards, allows for the expensing of capital expenditures, and puts into effect the migration from a worldwide system of taxation to a territorial system. In addition, the TCJA repealed the alternative minimum tax (AMT) and provides for a refund of taxes paid between 2018 and 2021. With the passing of the TCJA, the Company will receive a refund in future periods for AMT paid in prior years. The Company therefore has recognized a benefit of approximately $1.1 million for these taxes.

During December 2017, the SEC staff issued Staff Accounting Bulletin No. 118 (SAB 118) to address the application of U.S. GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the TCJA. The Company has recognized the provisional tax impacts related to the release of the valuation allowance with respect to AMT credits and the

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revaluation of deferred tax assets and liabilities and included these amounts in its consolidated financial statements for the year ended December 31, 2017. The Company continues to evaluate the effects of the TCJA and consider the amounts recorded to be provisional. Additional time is needed to ensure that the Company has fully analyzed and computed the tax effects of the TCJA on its tax accounts. The Company has not made any adjustments related to its provisional amounts recorded in this period, but continues to evaluate the provisions of the TCJA. The Company will complete its accounting during the measurement period provided under SAB 118 as the Company obtains further clarity on the application of the TCJA to its particular facts and report appropriately in 2018.

The Company recorded income tax expense of $1,600 for the three and six months ended June 30, 2018 and $0 and $1,600 for the three and six months ended June 30, 2017, respectively. The Company s effective tax rate for the three months ended June 30, 2018 and 2017 was approximately 0% for both periods, respectively. The Company s annual effective tax rate of approximately 0% is substantially lower than the U.S. statutory rate of 21% due to valuation allowances recorded on current year losses where the Company is not more likely than not to recognize a future tax benefit.

Comprehensive Income (Loss)

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

Share-Based Compensation

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

For all awards granted with time-based vesting conditions, expense is amortized using the straight-line attribution method. For awards that contain a performance condition, expense is amortized using the accelerated attribution method. Share-based compensation expense recognized in the statements of operations for the three and six months ended June 30, 2018 and 2017 is based on share-based awards ultimately expected to vest.

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. For stock options granted, 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 and in the first quarter of 2017 and 2018, the Company granted time-based RSUs that vest in three equal annual installments. In the first quarter of 2017, the Company granted 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 (collectively, the Milestone RSUs) and (iii) the achievement of certain comparative shareholder returns against the Company s peers (the TSR RSUs). The Milestone RSUs were valued at the

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closing price on March 8, 2017. The Milestone 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 Milestone RSUs related to the approval of the NDA will commence if and when the NDA submission has been approved through the last day of the calendar year in which the milestone is achieved. The TSR RSUs 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 RSUs and TSR RSUs 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 expense recognition related to these equity grants is based on the Company s best estimate.

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

Since the Company had net operating loss carryforwards as of June 30, 2018 and 2017, no excess tax benefits for the tax deductions related to share-based awards were recognized in the statements of operations. 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. 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 $9.7 million recorded as deferred tax assets with a corresponding offsetting full valuation allowance at the beginning of 2017, which yielded no tax impact.

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.

The following common stock equivalents were excluded in the calculation of diluted loss per share because their effect would be anti-dilutive as applied to the loss from operations for the three and six months ended June 30, 2018 and 2017:

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2018	2017	2018	2017

Stock options	797,638	483,782	797,560	483,782
RSUs	353,672	66,980	347,373	65,870
TSR RSUs	67,924	129,322	67,924	81,452

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 (as updated, ASC Topic 606). The purpose of ASC Topic 606 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. ASC Topic 606 became effective for annual periods beginning after December 15, 2017.

The Company adopted this standard using the modified retrospective method which did not result in an impact to its financial statements as the Company has not had product sales to date. Upon commercializing a product or executing any revenue generating contracts, 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.

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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 Company adopted ASU 2016-01 as of January 1, 2018 but the adoption did not have any 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 on the Company s consolidated financial statements.

In February 2018, the FASB issued ASU No. 2018-02, Income Statement-Reporting Comprehensive Income (Topic 220) Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income, to address a specific consequence of the TCJA by allowing a reclassification from accumulated other comprehensive income to retained earnings for stranded tax effects resulting from the TCJA s reduction of the U.S. federal corporate income tax rate. The ASU is effective for all entities for fiscal years beginning after December 15, 2018, with early adoption permitted, and is to be applied either in the period of adoption or retrospectively to each period in which the effect of the change in the U.S. federal corporate income tax rate in the TCJA is recognized. The Company does not have any stranded tax effects to which this ASU would apply. Therefore, there is no impact to the Company s consolidated financial statements.

In June 2018, the FASB issued ASU No. 2018-07, Compensation-Stock Compensation (Topic 718) Improvements to Nonemployee Share-Based Payment Accounting (ASU 2018-07). The standard allows for the entity to only remeasure equity-classified awards for which a measurement date has not been established through a cumulative-effect adjustment to retained earnings as of the beginning of the fiscal year of adoption. After adoption, the nonemployee share-based payment awards would be treated similar to employee share-based payment awards going forward. The ASU is effective for all entities for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. The Company is currently analyzing the impact of ASU 2018-07 and, at this time, has not yet determined the impact of the new standard on the Company s consolidated financial statements.

3. Property and Equipment

Property and equipment consist of the following:

	June 30, 2018	December 31, 2017
Computer equipment	**$ 47,738**	$ 33,584
Furniture and fixtures	**328,859**	301,509
Scientific equipment	**3,596,155**	3,494,866
Leasehold improvements	**149,470**	

	4,122,222	3,829,959
Less accumulated depreciation	**(2,846,835)**	(2,692,788)
	$ 1,275,387	$ 1,137,171

Depreciation expense for the six months ended June 30, 2018 and 2017 was $178,276 and $101,801, respectively.

4. Share-Based Compensation

On June 18, 2018, the Company s stockholders approved the 2018 Equity Incentive Plan (the 2018 Plan). The 2018 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. The 2018 Plan replaced the Company s Amended and Restated 2013 Equity Incentive Plan (the 2013 Plan). The Company will grant no further stock options or other awards under the 2013 Plan. Any options or other awards outstanding under the 2013 Plan remain outstanding in accordance with their terms and the terms of the 2013 Plan. As of June 30, 2018, the total number of shares reserved under all equity plans is 10,287,390 and the Company had 5,239,670 shares available for future issuance under the 2018 Plan. Stock options granted under the Plan may be either incentive

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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 the three and six months ended June 30, 2018 and 2017, was comprised of the following:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	**2018**	2017
Research and development	**$ 1,877,536**	$ 1,544,832	**$ 3,795,267**	$ 2,914,898
General and administrative	**2,433,169**	2,824,309	**4,802,541**	5,614,921
Total share-based compensation expense	**$ 4,310,705**	$ 4,369,141	**$ 8,597,808**	$ 8,529,819

The following table describes the weighted-average assumptions used for calculating the value of options granted during the six months ended June 30, 2018 and June 30, 2017:

	2018	2017
Dividend yield	**0%**	0%
Expected volatility	**85.2%-85.8%**	87.4%-90.4%
Weighted-average risk-free interest rate	**2.4%**	2.1%
Expected term	**6.0 years**	5.9 years

Information regarding the stock options activity, including with respect to grants to employees, directors and consultants as of June 30, 2018 and changes during the six-month period then ended, are summarized as follows:

	Number of Shares	**Weighted-Average Exercise Price**	**Weighted-Average Contractual Life**
Outstanding at December 31, 2017 (audited)	3,755,736	$ 18.75	7.0 years
Options granted (unaudited)	774,208	$ 16.02	9.6 years
Options exercised (unaudited)	(27,030)	$ 12.72	5.3 years
Options canceled or expired (unaudited)	(12,277)	$ 16.97	9.3 years
Outstanding at June 30, 2018 (unaudited)	4,490,637	$ 18.32	7.1 years

Vested or expected to vest at June 30, 2018 (unaudited)	4,490,637	$	18.32	
Exercisable at June 30, 2018 (unaudited)	2,967,178	$	18.11	6.1 years

The fair value of the time-based RSUs and the Milestone RSUs is based on the closing price of the Company s common stock on the date of grant. The fair value of the TSR RSUs was determined using the Monte Carlo simulation method.

Information regarding the time-based RSU activity and changes during the six-month period ended June 30, 2018 are summarized as follows:

	Number of Shares	Weighted-Average Grant Date Fair Value Per Share	
Outstanding at December 31, 2017 (audited)	190,933	$	25.48
RSU s granted in 2018 (unaudited)	504,198	$	16.89
RSU s vested in 2018 (unaudited)	(70,905)	$	28.34

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	Number of Shares	Weighted-Average Grant Date Fair Value Per Share
RSU s cancelled in 2018 (unaudited)	(4,683)	$ 15.93
Outstanding at June 30, 2018 (unaudited)	619,543	$ 18.24

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Information related to the Company s Milestone RSUs and the TSR RSUs during the six-month period ended June 30, 2018 are summarized as follows:

	Number of Shares	Weighted-Average Grant Date Fair Value Per Share
Outstanding at December 31, 2017	347,199	$ 15.35
RSU s granted in 2018		$
Outstanding at June 30, 2018	347,199	$ 15.35

The weighted average estimated fair value per share of the TSR RSUs granted in the three months ended March 31, 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 three months ended March 31, 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 192 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.

The Company recognized non-cash stock-based compensation expense related to time based RSU s for the three and six months ended June 30, 2018 of approximately $1.2 million and $2.3 million, respectively, as compared to $578,000 and $1.1 million for the three and six months ended June 30, 2017, respectively. Total expense for all RSUs, including the time-based and performance-based RSU grants for the three and six months ended June 30, 2018 was approximately $1.5 million and $3.0 million respectively as compared to $1.1 million and $1.8 million, respectively for the three and six months ended June 30, 2017, respectively. As of June 30, 2018, there was $8.4 million of unrecognized compensation costs related to unvested time-based RSUs. As of June 30, 2018, there was $3.5 million of unrecognized compensation costs related to unvested Milestone RSU grants and TSR RSU grants.

5. 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. Upon FDA acceptance of an NDA filing for lumateperone, the Company will be obligated to pay BMS a $2.0 million milestone payment. Based on the progress to date in the regulatory process, the Company believes that it is probable that this milestone will be achieved in 2018 and has therefore accrued the $2.0 million amount in the first quarter of 2018. Possible milestone payments remaining total $12.0 million including the $2.0 million milestone payment payable upon FDA acceptance of the NDA filing. 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.

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The agreement extends, and royalties are payable, on a country-by-country and product-by-product basis, through the later of 10 years after first commercial sale of a licensed product in such country, expiration of the last licensed patent covering a licensed product, its method of manufacture or use, or the expiration of other government grants providing market exclusivity, subject to certain rights of the parties to terminate the agreement on the occurrence of certain events. On termination of the agreement, the Company may be obliged to convey to BMS rights in developments relating to a licensed compound or licensed product, including regulatory filings, research results and other intellectual property rights.

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

6. Legal Matters

The Company is not currently a party to any material legal proceedings.

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, 2018. 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, 2018, 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 primarily 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 preclinical and clinical trials to date, lumateperone combines potent serotonin 5-HT2A receptor antagonism, dopamine receptor phosphoprotein modulation, or DPPM, glutamatergic modulation, and serotonin reuptake inhibition into a single drug candidate for the treatment of acute and residual schizophrenia and for the treatment of bipolar disorder, including bipolar depression. At dopamine 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 GluN2B receptors in a mesolimbic specific manner. We believe that this regional selectivity in brain areas thought to mediate the efficacy of antipsychotic drugs, together with serotonergic, glutamatergic, and dopaminergic interactions, may result in efficacy for a broad array of symptoms associated with schizophrenia and bipolar disorder with improved psychosocial function. The serotonin reuptake inhibition potentially allows for antidepressant activity in the treatment of schizoaffective disorder, other disorders with co-morbid depression, and/or as a stand-alone treatment for major depressive disorder. We believe 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. We had a pre-new drug application, or NDA, meeting with the U.S. Food and Drug Administration, or FDA, in the first quarter of 2018 and reached agreement on the timing and content of a rolling NDA submission for lumateperone for the treatment of schizophrenia. We initiated the rolling submission of our NDA with the FDA for lumateperone for the treatment of schizophrenia in the second quarter of 2018. We intend to complete this NDA submission mid-2018, by the end of the third quarter.

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-HT2A serotonin receptor antagonist. As the dose is increased, additional benefits are derived from the engagement of additional drug targets, including modest dopamine receptor modulation and modest inhibition of serotonin transporters. We believe that combined interactions at these receptors may provide additional benefits above and beyond selective 5-HT2A antagonism for treating agitation, aggression and sleep disturbances in diseases that include dementia, AD, Huntington s disease and autism spectrum disorders, while avoiding many of the side effects associated with more robust dopamine receptor antagonism. As the dose of lumateperone is further increased, leading to moderate

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dopamine receptor modulation, inhibition of serotonin transporters, and indirect glutamate modulation, these actions complement the complete blockade of 5-HT2A serotonin receptors. At a dose of 60 mg, ITI-007 has been shown effective in treating the symptoms associated with schizophrenia, and we believe this higher dose range will be useful for the treatment of bipolar disorder, depressive disorders and other neuropsychiatric diseases. Within the ITI-007 portfolio, we are also developing a long-acting injectable formulation to provide more treatment options to patients suffering from mental illness. Given the encouraging tolerability data to date with oral 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.

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. ITI-214 is our lead compound in this program. 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 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 anticipate top-line results from this trial will be available in the second half of 2018. In addition, in the first quarter of 2018, the investigational new drug application, or IND, went into effect for ITI-214 for the treatment of heart failure. We have initiated clinical conduct of the first clinical study in this program, a randomized, double-blind, placebo-controlled study of escalating single doses of ITI-214 to evaluate safety and hemodynamic effects in patients with systolic heart failure.

Our pipeline also includes preclinical 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, including our ITI-333 development program. ITI-333 is designed as a potential treatment for substance use disorders, pain and psychiatric comorbidities including depression and anxiety. There is a pressing need to develop new drugs to treat opioid addiction and safe, effective, non-addictive treatments to manage pain. We believe the potential exists for ITI-333 to address these challenges. Preclinical safety studies with ITI-333 are currently ongoing and we expect to initiate clinical studies in 2019.

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 until at least 2019, if ever. We had no revenues for the three and six months ended June 30, 2018 and revenues for the three and six months ended June 30, 2017 were 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

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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. In addition, in the first quarter of 2018, the IND went into effect for ITI-214 for the treatment of heart failure. We have initiated clinical conduct of the first clinical study in this program, a randomized, double-blind, placebo-controlled study of escalating single doses of ITI-214 to evaluate safety and hemodynamic effects in patients with systolic heart failure. Our other projects are still in the preclinical stages, and will require extensive funding not only to complete preclinical testing, but to commence 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 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 costs relating to labor and fringe benefits, materials, supplies, facilities and maintenance; 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 significantly 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 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 and acquiring additional facility space. We granted options to purchase 982,993 shares of our common stock in 2017 and have granted options to purchase an additional 774,208 shares of our common stock in the six months ended June 30, 2018. We also granted time based restricted stock units, or RSUs, for 154,922 shares of our common stock in 2017 and time based RSUs for 504,198 shares of our common stock in the six months ended June 30, 2018. 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 NDA with the FDA, (ii) the approval of the NDA by the FDA, or the Milestone RSUs, and (iii) the achievement of certain comparative shareholder returns against our peers, or the TSR RSUs. The Milestone RSUs were valued at the closing price on March 8, 2017. The Milestone

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 Milestone 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 and expires on December 31, 2019 if not achieved. The TSR RSUs 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 RSUs and the TSR RSUs 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 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.

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The following table sets forth our revenues and operating expenses for the three and six months ended June 30, 2018 and 2017 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	**2018**	2017
	(Unaudited)		*(Unaudited)*	
Revenues	**$**	$ 115	**$**	$ 210
Expenses				
Research and Development	**32,439**	12,479	**63,142**	34,017
General and Administrative	**6,729**	6,255	**13,110**	12,565
Total costs and expenses	**39,168**	18,734	**76,252**	46,582
Loss from operations	**(39,168)**	(18,619)	**(76,252)**	(46,372)
Interest Income	**1,794**	858	**3,398**	1,680
Income tax expense	**(2)**		**(2)**	(2)
Net Loss	**$ (37,376)**	$ (17,761)	**$ (72,856)**	$ (44,694)

Comparison of Three and Six Month Periods Ended June 30, 2018 and June 30, 2017

Revenues

Revenues for the three and six months ended June 30, 2018 were zero as compared to approximately $115,000 and $210,000 for the three and six months ended June 30, 2017, respectively. Revenues during the three and six month period ended June 30, 2017 were related to a government grant.

Research and Development Expenses

Research and development expenses increased to $32.4 million for the three month period ended June 30, 2018 as compared to $12.5 million for the three month period ended June 30, 2017, representing an increase of approximately 160%. This change is due primarily to an increase of approximately $18.7 million of costs associated with external clinical and non-clinical costs and an increase of approximately $1.2 million of internal costs in the three month period ended June 30, 2018 over the three month period ended June 30, 2017. In the three months ended June 30, 2018, the $32.4 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 $8.8 million, development costs for lumateperone for the treatment of schizophrenia of approximately $5.8 million, manufacturing expense of approximately $5.8 million and other clinical and non-clinical expenses. In the three months ended June 30, 2017, the $12.5 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 $4.4 million, development costs for lumateperone for the treatment of schizophrenia of approximately $1.5 million, manufacturing expense of approximately $1.3 million and other clinical and non-clinical expenses. Amounts incurred with external parties comprised a significant portion of our research and development costs. In the three months ended June 30, 2018, we incurred approximately $27.3 million of costs to external parties who performed clinical trial related activities, including manufacturing and testing lumateperone, as compared to $8.6 million in the three month period ended June 30, 2017. Of these external costs, approximately $24.3 million in the three months ended June 30, 2018

and approximately $8.1 million in the three month period ended June 30, 2017 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 $5.2 million and $3.9 million in the three months ended June 30, 2018 and 2017, respectively.

Research and development expenses increased to $63.1 million for the six month period ended June 30, 2018 as compared to $34.0 million for the six month period ended June 30, 2017, representing an increase of approximately 86%. This change is due primarily to an increase of approximately $24.6 million of costs associated with external clinical and non-clinical costs and by an increase of approximately $4.5 million of internal costs in the six month period ended June 30, 2018 over the six month period ended June 30, 2017. In the six months ended June 30, 2018, the $63.1 million of research and development costs were comprised primarily of development costs for lumateperone for the treatment of schizophrenia of approximately $12.4 million, development costs for lumateperone in patients with bipolar depression and dementia, including AD, of approximately $15.5 million, manufacturing expense of approximately $12.6 million and other clinical and non-clinical expenses. In the six months ended June 30, 2017, the $34.0 million of research and development costs were comprised primarily of development costs for lumateperone for the treatment of schizophrenia of approximately $10.4 million, development costs for lumateperone in patients with bipolar depression and dementia, including AD, of approximately $7.9 million, manufacturing expense of approximately $5.7 million and other clinical and non-clinical expenses. Amounts incurred with external parties comprised a significant portion of our research and development costs. In the six

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months ended June 30, 2018, we incurred approximately $51.0 million of costs to external parties who performed clinical trial related activities, including manufacturing and testing lumateperone, as compared to $26.4 million in the six month period ended June 30, 2017. Of these external costs, approximately $47.7 million in the six months ended June 30, 2018 and approximately $25.7 million in the six month period ended June 30, 2017 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 $12.1 million and $7.6 million in the six months ended June 30, 2018 and 2017, 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 2018 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 June 30, 2018, we employed 39 full time personnel in our research and development group as compared to 36 full time personnel at June 30, 2017. 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 areas of cognitive dysfunction and the treatment of neurodegenerative diseases, including AD, among others. We have used internal resources and incurred expenses not only in relation to the development of 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;

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, 2018, as updated from time to time in our other periodic and current reports filed with the SEC.

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General and Administrative Expenses

General and administrative expenses increased for the three month period ended June 30, 2018 as compared to the three month period ended June 30, 2017 by approximately $474,000, representing an increase of approximately 8%. The comparative increase is primarily due to increased labor of approximately $189,000 and pre-commercialization costs of approximately $785,000 and is offset in part by lower stock compensation expense of $394,000 and professional fees of approximately $263,000. Salaries, bonuses and related benefit costs for our executive, finance and administrative functions for the three months ended June 30, 2018 and 2017 constituted approximately 58% and 65%, respectively, of our total general and administrative costs. The next major categories of general and administrative expenses are patent costs and, to a lesser extent, facilities and general office-related overhead. We expect all general and administrative costs to increase significantly as we expand our operations and conduct pre-commercialization activities.

General and administrative expenses increased for the six month period ended June 30, 2018 as compared to the six month period ended June 30, 2017 by approximately $545,000, or 4%. The increase is primarily the result of an increase in labor costs of approximately $394,000 and pre-commercialization costs of approximately $1.1 million and is offset partially by lower stock compensation expense of approximately $812,000 and professional fees of approximately $316,000. Salaries, bonuses and related benefit costs for our executive, finance and administrative functions for the six months ended June 30, 2018 and 2017 constituted approximately 59% and 64%, respectively, of our total general and administrative costs. The next major categories of expenses were patent costs and, to a lesser extent, facilities and general office-related overhead.

Liquidity and Capital Resources

Through June 30, 2018, we provided funds for our operations by obtaining approximately $879.9 million of cash primarily through public and private offerings of our common stock and other securities, grants from government agencies and foundations and payments received under the terminated Takeda License Agreement. We do not believe that grant revenue will be a significant source of funding in the near future. 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, commissions and estimated offering expenses.

As of June 30, 2018, we had a total of approximately $403.8 million in cash and cash equivalents and available-for-sale investment securities, and approximately $18.9 million of short-term liabilities consisting entirely of liabilities from operations. In the first half of 2018, we spent approximately $64.3 million in cash for operations and equipment and we received approximately $3.4 million of interest income. We reduced working capital by approximately $64.3 million for the six months ended June 30, 2018. The use of cash was primarily for conducting clinical trials and non-clinical testing, including manufacturing related activities and funding recurring operating expenses.

For the remainder of the year 2018, subject to the timing of clinical trials, regulatory activities, manufacturing, precommercial and other development activities, we expect to spend up to $130 million. We expect these expenditures to be due primarily to the development of lumateperone in patients with schizophrenia, agitation associated with dementia, including AD, 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, including ITI-214, 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, and expenses associated with our other development programs, pre-commercialization activities and general operations. We expect that cash expenditures beyond 2018 will at least remain at the 2018 projected level of spending or increase moderately as we further expect to expand the lumateperone clinical stage programs; continue the ITI-007 long acting injectable development program through pre-clinical and early clinical development; expand our ITI-214 clinical stage development programs and the research and preclinical development of our other product candidates; and continue the 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 into 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 initial commercialization of lumateperone in patients with schizophrenia. With our existing cash, cash equivalents and available-for-sale investment securities, 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

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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 six months ended June 30, 2018, we used net cash in operating activities and purchases of equipment of approximately $64.3 million. This total does not include an offset for $3.4 million of interest income received. 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. In addition, in the first quarter of 2018, the IND went into effect for ITI-214 for the treatment of heart failure. We have initiated clinical conduct of the first clinical study in this program, a randomized, double-blind, placebo-controlled study of escalating single doses of ITI-214 to evaluate safety and hemodynamic effects in patients with systolic heart failure. We expect these expenses to increase for 2019 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, 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.

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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 $2.9 million of deferred rent through June 30, 2018. 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 June 30, 2018 are summarized in the following table (in thousands):

	Payments Due By Period				
	Total	**2018**	**2019-2020**	**2021-2023**	**After 2023**
Operating Lease Obligations	$ 14,229	$ 730	$ 3,046	$ 4,921	$ 5,532

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, 2017 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 six months ended June 30, 2018.

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. For the recently issued accounting standards that we believe may have an impact on our financial statements, see Recently Issued Accounting Pronouncements in our Annual Report on Form 10-K for the year ended December 31, 2017 filed on March 1, 2018.

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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; 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, or submit an application for regulatory approval, of our existing product candidates, any product candidates that we may develop, and any related restrictions, limitations, and/or warnings in the label of any approved product candidates; our plans to research, develop and commercialize our product candidates; the election by any collaborator to pursue research, development and commercialization activities; our ability to obtain future reimbursement and/or milestone payments from our collaborators; our ability to attract collaborators with development, regulatory and commercialization expertise; our ability to obtain and maintain intellectual property protection for our product candidates; our ability to successfully commercialize our product candidates; the performance of our third-party suppliers and manufacturers and our ability to obtain alternative sources of raw materials; our ability to obtain additional financing; our use of the proceeds from our securities offerings; our exposure to investment risk, interest rate risk and capital market risk; and our ability to attract and retain key scientific or management personnel.

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

In light of these assumptions, risks and uncertainties, the results and events discussed in the forward-looking statements contained in this Quarterly Report on Form 10-Q or in any document incorporated by reference might not occur. Stockholders are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the date of this Quarterly Report on Form 10-Q. We are not under any obligation, and we expressly disclaim any obligation, to update or alter any forward-looking statements, whether as a result of new information, future events or otherwise. All subsequent forward-looking statements attributable to the Company or to any person acting on its behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section.

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Sensitivity. As of June 30, 2018, we had cash, cash equivalents and marketable securities of approximately $403.8 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 June 30, 2018 and 2017 totaling approximately $1.0 million and $316,000, respectively. 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 further 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

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Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms, and is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate, to allow timely decisions regarding required disclosure.

(b) *Changes in Internal Controls*. There were no changes in our internal control over financial reporting identified in connection with the evaluation of such internal control that occurred during the three months ended June 30, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II: OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS

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

Item 1A. RISK FACTORS

There have been no material changes to the risk factors described in our Annual Report on Form 10-K for the year ended December 31, 2017, filed with the Securities and Exchange Commission on March 1, 2018.

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 June 30, 2018.

Item 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

Item 5. OTHER INFORMATION

Not applicable.

Item 6. EXHIBITS

Exhibit Number	Exhibit Description	Filed Herewith	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/ Reg. Number
10.1	Intra-Cellular Therapies, Inc. 2018 Equity Incentive Plan		Form 8-K (Exhibit 10.1)	6/21/2018	001-36274
10.2	Form of Stock Option Agreement under the 2018 Equity Incentive Plan		Form 8-K (Exhibit 10.2)	6/21/2018	001-36274

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Exhibit Number	Exhibit Description	Filed Herewith	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/ Reg. Number
10.3	Form of Director Stock Option Agreement under the 2018 Equity Incentive Plan		Form 8-K (Exhibit 10.3)	6/21/2018	001-36274
10.4	Form of Restricted Stock Unit Agreement under the 2018 Equity Incentive Plan		Form 8-K (Exhibit 10.4)	6/21/2018	001-36274
10.5	Form of Director Restricted Stock Unit Agreement under the 2018 Equity Incentive Plan		Form 8-K (Exhibit 10.5)	6/21/2018	001-36274
10.6	Non-Employee Director Compensation Policy, as Amended	X			
31.1	Certification of the Registrant s Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X			
31.2	Certification of the Registrant s Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X			
32	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X			
101	The following materials from the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2018, formatted in XBRL (eXtensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets as of June 30, 2018 (unaudited) and December 31, 2017 (audited), (ii) Condensed Consolidated Statements of Operations (unaudited) for the three and six months ended June 30, 2018 and 2017, (iii) Condensed Consolidated Statements of Comprehensive Loss (unaudited) for the three and six months ended June 30, 2018 and	X			

2017, (iv) Condensed Consolidated Statements of Cash Flows (unaudited) for the six months ended June 30, 2018 and 2017, and (v) Notes to Condensed Consolidated Financial Statements (unaudited).

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SIGNATURES

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

INTRA-CELLULAR THERAPIES, INC.

Date: August 2, 2018

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

Date: August 2, 2018

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