

---

---

**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 March 31, 2019

or

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 001-36274

---

**INTRA-CELLULAR THERAPIES, INC.**

(Exact name of registrant as specified in its charter)

---

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

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

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

**10016**  
(Zip Code)

**(646) 440-9333**

(Registrant's telephone number, including area code)

---

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 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

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 May 7, 2019, the registrant had 55,134,625 shares of common stock outstanding.

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	ITCI	The Nasdaq Global Select Market

## Table of Contents

### **Intra-Cellular Therapies, Inc.**

### **Index to Form 10-Q**

<u>PART I: FINANCIAL INFORMATION</u>	1
Item 1. <u>FINANCIAL STATEMENTS</u>	1
<u>Condensed Consolidated Balance Sheets as of March 31, 2019 (unaudited) and December 31, 2018 (audited)</u>	1
<u>Condensed Consolidated Statements of Operations (unaudited) for the three months ended March 31, 2019 and 2018</u>	2
<u>Condensed Consolidated Statements of Comprehensive Loss (unaudited) for the three months ended March 31, 2019 and 2018</u>	3
<u>Condensed Consolidated Statements of Stockholders' Equity (unaudited) for the three months ended March 31, 2019 and 2018</u>	4
<u>Condensed Consolidated Statements of Cash Flows (unaudited) for the three months ended March 31, 2019 and 2018</u>	5
<u>Notes to Condensed Consolidated Financial Statements (unaudited)</u>	6
Item 2. <u>MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	18
Item 3. <u>QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u>	26
Item 4. <u>CONTROLS AND PROCEDURES</u>	26
<u>PART II: OTHER INFORMATION</u>	27
Item 1. <u>LEGAL PROCEEDINGS</u>	27
Item 1A. <u>RISK FACTORS</u>	27
Item 2. <u>UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS</u>	27
Item 3. <u>DEFAULTS UPON SENIOR SECURITIES</u>	27
Item 4. <u>MINE SAFETY DISCLOSURES</u>	27
Item 5. <u>OTHER INFORMATION</u>	27
Item 6. <u>EXHIBITS</u>	28
<u>SIGNATURES</u>	29

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

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

Intra-Cellular Therapies, Inc. and Subsidiaries

Condensed Consolidated Balance Sheets

	March 31, 2019 <i>(Unaudited)</i>	December 31, 2018
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 64,091,080	\$ 54,947,502
Investment securities, available-for-sale	248,731,291	292,583,046
Prepaid expenses and other current assets	8,305,259	7,908,133
Total current assets	321,127,630	355,438,681
Property and equipment, net	1,125,606	1,159,766
Right of use assets, net	20,104,280	—
Long term deferred tax asset, net	529,218	529,218
Other assets	86,083	78,833
Total assets	<u>\$ 342,972,817</u>	<u>\$ 357,206,498</u>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 8,574,433	\$ 13,961,060
Accrued and other current liabilities	18,700,638	20,044,866
Lease liabilities, short-term	2,873,022	—
Accrued employee benefits	3,351,208	2,293,259
Total current liabilities	33,499,301	36,299,185
Long-term deferred rent	—	3,192,432
Long-term lease liabilities	20,859,089	—
Total liabilities	54,358,390	39,491,617
Stockholders' equity:		
Common stock, \$.0001 par value: 100,000,000 shares authorized; 55,131,125 and 54,895,295 shares issued and outstanding at March 31, 2019 and December 31, 2018, respectively	5,513	5,490
Additional paid-in capital	885,888,318	880,753,339
Accumulated deficit	(597,211,954)	(562,376,191)
Accumulated comprehensive loss	(67,450)	(667,757)
Total stockholders' equity	288,614,427	317,714,881
Total liabilities and stockholders' equity	<u>\$ 342,972,817</u>	<u>\$ 357,206,498</u>

*See accompanying notes to these condensed consolidated financial statements.*

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

	(Unaudited)	
	Three Months Ended March 31,	
	2019	2018
Revenues	\$ —	\$ —
Costs and expenses:		
Research and development	24,990,856	30,702,998
General and administrative	11,704,984	6,381,228
Total costs and expenses	<u>36,695,840</u>	<u>37,084,226</u>
Loss from operations	(36,695,840)	(37,084,226)
Interest income	1,860,077	1,604,148
Loss before provision for income taxes	<u>(34,835,763)</u>	<u>(35,480,078)</u>
Net loss	<u><u>\$(34,835,763)</u></u>	<u><u>\$(35,480,078)</u></u>
Net loss per common share:		
Basic & Diluted	\$ (0.63)	\$ (0.65)
Weighted average number of common shares:		
Basic & Diluted	55,113,226	54,676,175

*See accompanying notes to these condensed consolidated financial statements.*

## Intra-Cellular Therapies, Inc. and Subsidiaries

## Condensed Consolidated Statements of Comprehensive Loss

	<b>Three Months Ended March 31,</b>	
	<b>2019</b>	<b>2018</b>
	<i>(Unaudited)</i>	<i>(Unaudited)</i>
Net loss	<b><u>\$(34,835,763)</u></b>	<b><u>\$(35,480,078)</u></b>
Other comprehensive gain (loss):		
Unrealized gain (loss) on investment securities	<b>600,307</b>	<b>(440,526)</b>
Comprehensive loss	<b><u>\$(34,235,456)</u></b>	<b><u>\$(35,920,604)</u></b>

*See accompanying notes to these condensed consolidated financial statements.*

## Intra-Cellular Therapies, Inc. and Subsidiaries

## Condensed Consolidated Statements of Stockholders' Equity

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2017	54,597,679	\$ 5,460	\$862,479,505	\$(407,248,780)	\$ (799,224)	\$454,436,961
Exercise of stock options and issuances of restricted stock	94,773	9	337,787	—	—	337,796
Stock issued for services	2,266	—	47,669	—	—	47,669
Share-based compensation	—	—	4,287,103	—	—	4,287,103
Net loss	—	—	—	(35,480,078)	—	(35,480,078)
Other comprehensive loss	—	—	—	—	(440,526)	(440,526)
Balance at March 31, 2018	<u>54,694,718</u>	<u>\$ 5,469</u>	<u>\$867,152,064</u>	<u>\$(442,728,858)</u>	<u>\$ (1,239,750)</u>	<u>\$423,188,925</u>
	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2018	54,895,295	\$ 5,490	\$880,753,339	\$(562,376,191)	\$ (667,757)	\$317,714,881
Exercise of stock options and issuances of restricted stock	231,844	23	31,213	—	—	31,236
Stock issued for services	3,986	—	48,549	—	—	48,549
Share-based compensation	—	—	5,055,217	—	—	5,055,217
Net loss	—	—	—	(34,835,763)	—	(34,835,763)
Other comprehensive gain	—	—	—	—	600,307	600,307
Balance at March 31, 2019	<u>55,131,125</u>	<u>\$ 5,513</u>	<u>\$885,888,318</u>	<u>\$(597,211,954)</u>	<u>\$ (67,450)</u>	<u>\$288,614,427</u>

See accompanying notes to these condensed consolidated financial statements.

## Intra-Cellular Therapies, Inc. and Subsidiaries

## Condensed Consolidated Statements of Cash Flows

	(Unaudited)	
	Three Months Ended March 31,	
	2019	2018
<b>Cash flows used in operating activities</b>		
Net loss	\$(34,835,763)	\$ (35,480,078)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	101,353	82,498
Share-based compensation	5,055,217	4,287,103
Stock issued for services	48,549	47,699
Amortization of premiums and discounts on investment securities, net	(356,798)	(56,298)
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(526,089)	(1,265,302)
Accounts payable	(5,386,627)	3,865,311
Accrued liabilities and other	270,833	1,519,726
Deferred rent	—	15,342
Net cash used in operating activities	(35,629,325)	(26,983,999)
<b>Cash flows provided by investing activities</b>		
Purchases of investments	(14,327,684)	(91,870,300)
Maturities of investments	59,136,544	155,442,867
Purchases of property and equipment	(67,193)	(295,092)
Net cash provided by investing activities	44,741,667	63,277,475
<b>Cash flows provided by financing activities</b>		
Proceeds from exercise of stock options	31,236	337,796
Net cash provided by financing activities	31,236	337,796
Net increase in cash and cash equivalents	9,143,578	36,631,272
Cash and cash equivalents at beginning of period	54,947,502	37,790,114
Cash and cash equivalents at end of period	<u>\$ 64,091,080</u>	<u>\$ 74,421,386</u>
<b>Non-cash investing and financing activities</b>		
Right of use assets under operating leases	<u>\$ 219,703</u>	<u>\$ —</u>

*See accompanying notes to these condensed consolidated financial statements.* Intra-Cellular Therapies, Inc.

Notes to Condensed Consolidated Financial Statements (Unaudited)

March 31, 2019

**1. Organization**

Intra-Cellular Therapies, Inc. (the “Company”), through its wholly-owned operating subsidiaries, ITI, Inc. (“ITI”) and ITI Limited, is a biopharmaceutical company focused on the discovery and clinical development of innovative, small molecule drugs that address underserved medical needs in neuropsychiatric and neurological disorders by targeting intracellular signaling mechanisms within the central nervous system (“CNS”). The Company’s lead product candidate, lumateperone, is in Phase 3 clinical development as a novel treatment for schizophrenia and bipolar depression.

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 significant 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.

In October 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. The Company currently projects that its cash, cash equivalents and investments will be sufficient to fund operating expenses and capital expenditures into the second half of 2020, at which time the Company will require additional financing. 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 until September 14, 2019.

In the third quarter of 2018, the Company completed the rolling submission of its New Drug Application (“NDA”) to the U.S. Food and Drug Administration (“FDA”) for lumateperone, a once-daily, oral investigational medicine with a novel mechanism of action for the treatment of schizophrenia and in the fourth quarter of 2018 the FDA accepted the NDA for review. The NDA submission is supported by data from 20 clinical trials and more than 1,900 subjects exposed to lumateperone. Lumateperone received Fast Track designation from the FDA in November 2017 for the treatment of schizophrenia.

## 2. Summary of Significant Accounting Policies

### Basis of Presentation

The accompanying consolidated financial statements of Intra-Cellular Therapies, Inc. and its wholly own subsidiaries have been prepared in conformity with accounting principles generally accepted in the United States of America (“GAAP”). Any reference in these notes to applicable guidance is meant to refer to the authoritative United States generally accepted accounting principles set forth in the Accounting Standards Codification (“ASC”) and Accounting Standards Update (“ASU”) of the Financial Accounting Standards Board (“FASB”). All intercompany accounts and transactions have been eliminated in consolidation. The Company currently operates in one operating segment. Operating segments are defined as components of an enterprise about which separate discrete information is available for the chief operating decision maker, or decision making group, in deciding how to allocate resources and assessing performance. The Company views its operations and manages its business in one segment, which is discovering and developing drugs for the treatment of neurological and psychiatric disorders.

### Use of Estimates

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

### Cash and Cash Equivalents

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

### Investment Securities

Investment securities consisted of the following (in thousands):

	March 31, 2019			Estimated Fair Value
	Amortized Cost	Unrealized Gains	Unrealized (Losses)	
	(unaudited)			
U.S. Government Agency Securities	\$109,649	\$ 42	\$ (110)	\$109,581
FDIC Certificates of Deposit (1)	245	—	—	245
Certificates of Deposit	1,000	—	—	1,000
Commercial Paper	26,624	3	(8)	26,619
Corporate Notes/Bonds	111,281	86	(81)	111,286
	<u>\$248,799</u>	<u>\$ 131</u>	<u>\$ (199)</u>	<u>\$248,731</u>
	December 31, 2018			
	Amortized Cost	Unrealized Gains	Unrealized (Losses)	Estimated Fair Value
U.S. Government Agency Securities	\$124,691	\$ 24	\$ (289)	\$124,426
FDIC Certificates of Deposit (1)	245	—	—	245
Certificates of Deposit	1,000	—	—	1,000
Commercial Paper	41,317	—	(45)	41,272
Corporate Notes/Bonds	125,998	7	(365)	125,640
	<u>\$293,251</u>	<u>\$ 31</u>	<u>\$ (699)</u>	<u>\$292,583</u>

(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 March 31, 2019 and December 31, 2018, the Company held \$33.0 million and \$64.6 million, respectively, of available-for-sale investment securities with contractual maturity dates more than one year and less than two years.

## [Table of Contents](#)

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 March 31, 2019, the aggregate related fair value of investments with unrealized losses was \$170.5 million and the aggregate amount of unrealized losses was approximately \$200,000. Of the \$170.5 million, \$90.4 million has been held in a continuous unrealized loss position for less than 12 months and \$80.1 million has been held in a continuous loss position for 12 months or longer. The total continuous unrealized loss for investments held for 12 months or longer is approximately \$136,000 as of March 31, 2019. As of December 31, 2018, the Company had approximately \$180.4 million of investments with a continuous unrealized loss for 12 months or longer of approximately \$345,000.

The Company attributes the unrealized losses on the available-for-sale securities as of March 31, 2019 and December 31, 2018 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 March 31, 2019 and December 31, 2018. The carrying value of cash held in money market funds of approximately \$39.3 million as of March 31, 2019 and \$39.6 million as of December 31, 2018 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 of approximately \$24.0 million and \$7.5 million as of March 31, 2019 and December 31, 2018, respectively, is included in cash and cash equivalents and approximates market value based on quoted market price or Level 1 inputs.

## [Table of Contents](#)

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

	March 31, 2019	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	\$ 39,312	\$ 39,312	\$ —	\$ —
U.S. Government Agency Securities	109,581	—	109,581	—
FDIC Certificates of Deposit	245	—	245	—
Certificates of Deposit	25,000	—	25,000	—
Commercial Paper	26,619	—	26,619	—
Corporate Notes/Bonds	111,286	—	111,286	—
	<u>\$ 312,043</u>	<u>\$ 39,312</u>	<u>\$ 272,731</u>	<u>\$ —</u>

	December 31, 2018	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	\$ 39,591	\$ 39,591	\$ —	\$ —
U.S. Government Agency Securities	124,426	—	124,426	—
FDIC Certificates of Deposit	245	—	245	—
Certificates of Deposit	8,500	—	8,500	—
Commercial Paper	41,272	—	41,272	—
Corporate Notes/Bonds	125,640	—	125,640	—
	<u>\$ 339,674</u>	<u>\$ 39,591</u>	<u>\$ 300,083</u>	<u>\$ —</u>

### 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 March 31, 2019 and December 31, 2018. At March 31, 2019, the Company had approximately \$2.4 million as a prepaid expense related to a regulatory filing fee that was refunded in April 2019. 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 March 31, 2019 and December 31, 2018, as the Company has a history of collecting on all its accounts including from government agencies and collaborations funding its research. As of March 31, 2019 and December 31, 2018, the Company did not have accounts receivable.

### **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.

### **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, outside service 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 various clinical information provided by vendors and discussion with applicable personnel and external service providers as to the progress toward or state of completion 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 months ended March 31, 2019 and 2018, 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. 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.

## [Table of Contents](#)

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 recognized a benefit of approximately \$1.1 million for these taxes for the year ended December 31, 2017.

The Company’s effective tax rate for the three months ended March 31, 2019 and 2018 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 at 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. Share-based compensation expense recognized in the statements of operations for the three months ended March 31, 2019 and 2018 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 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. The Company recognizes forfeitures when they are incurred.

A restricted stock unit (“RSU”) is a stock-based 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 on the applicable vesting date.

In the first quarter of each fiscal year beginning in 2016, 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 (together, 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 closing price on March 8, 2017. The Milestone RSUs related to the NDA submission have been fully amortized through December 31, 2018. The NDA submission milestone was achieved in the third quarter of 2018, so the Milestone RSUs related to the NDA submission vested on

## [Table of Contents](#)

December 31, 2018. The amortization of the expenses for 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.

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 March 31, 2019 and 2018, no excess tax benefits for the tax deductions related to share-based awards were recognized in the statements of operations.

In June 2018, the Company's stockholders approved the Company's 2018 Equity Incentive Plan pursuant to which 4,750,000 additional shares of common stock were reserved for future equity grants.

### **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 months ended March 31, 2019 and 2018:

	Three Months Ended March 31,	
	2019	2018
Stock Options	359,053	724,978
RSUs	455,265	314,302
TSR RSUs	79,002	59,344

### **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.

In February 2016, the FASB issued ASU No. 2016-02, Leases ("ASU 2016-02"). ASU 2016-02 requires 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 adopted the standard on January 1, 2019 using the simplified transition method, allowing us to not restate comparative periods and apply ASC 842 on a prospective basis, resulting in a balance sheet presentation that is not comparable to the prior period in the first year of adoption. The Company elected the package of practical expedients permitted under the transition guidance within the new standard, which among other things, allowed the Company to carry forward the historical lease classification. The Company has not elected the hindsight practical expedient. The Company made an accounting policy election to keep leases with an initial term of 12 months or less off the balance sheet. The Company recognizes those lease payments in the consolidated statements of operations on a straight-line basis over the lease term.

## [Table of Contents](#)

The adoption of the standard resulted in recognition of additional net lease assets and lease liabilities of approximately \$20.2 million and \$23.4 million, respectively, as of January 1, 2019. The difference between these amounts represents the net deferred rent as of January 1, 2019 with no impact on the accumulated deficit. The adoption of the new lease standard was a non-cash transaction. The Company concluded the new standard did not have a material impact on its liquidity and income tax position.

In June 2016, the FASB issued ASU No. 2016-13, “Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments.” (ASU 2016-13) This guidance applies to all entities and impacts how entities account for credit losses for most financial assets and other instruments. For available-for-sale debt securities, entities will be required to recognize an allowance for credit losses rather than a reduction to the carrying value of the asset. For trade receivables, loans and held-to-maturity debt securities, entities will be required to estimate lifetime expected credit losses. This guidance is effective for fiscal years beginning after December 15, 2019 and interim periods therein. Early adoption is permitted for annual periods beginning after December 15, 2018 and interim periods therein. We are currently analyzing the impact of ASU 2016-13 on the condensed consolidated financial statements.

In February 2018, the FASB issued ASU 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. ASU 2018-02 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 August 2018, the SEC issued a final rule Release No. 33-10532, “Disclosure Update and Simplification,” to amend certain disclosure requirements now seen as redundant, duplicative, overlapping, outdated or superseded in wake of recent accounting pronouncements. The amended rules became effective November 5, 2018. We analyzed the release in preparation of this Form 10-Q, which resulted in the additional disclosure of changes to stockholders’ equity during interim periods, as presented within this Form 10-Q within the condensed consolidated statements of stockholders’ equity. We note that many of the amended requirements under this Release are not applicable to the Company, as we do not make dividend payments to stockholders, currently report our activities under a single business segment, and already provided all other significant disclosure requirements.

### 3. Property and Equipment

Property and equipment consist of the following:

	March 31, 2019	December 31, 2018
Computer equipment	\$ 60,377	\$ 44,427
Furniture and fixtures	366,808	341,582
Scientific equipment	3,681,613	3,658,209
Leasehold improvements	149,470	149,470
	<u>4,258,268</u>	<u>4,193,688</u>
Less accumulated depreciation	<u>(3,132,662)</u>	<u>(3,033,922)</u>
	<u>\$ 1,125,606</u>	<u>\$ 1,159,766</u>

Depreciation expense for the three months ended March 31, 2019 and 2018 was \$101,353 and \$82,498, respectively.

### 4. Right Of Use Assets and Lease Liabilities

In 2014, the Company entered into a long-term lease with a related party which, as amended, provided for a lease of 16,753 square feet of useable laboratory and office space located at 430 East 29th Street, New York, New York 10016. A member of the Company’s board of directors is the Executive Chairman of the parent company to the landlord under this lease. Concurrent with this lease, the Company entered into a license agreement to occupy certain vivarium related space in the same facility for the same term and rent escalation provisions as the lease. This license has the primary characteristics of a

## [Table of Contents](#)

lease and is treated as such for accounting purposes. In September 2018, the Company further amended the lease to obtain an additional 15,534 square feet of office space beginning October 1, 2018 and to extend the term of the lease for previously acquired space. The lease, as amended, has a term of 14.3 years ending in May 2029. The Company expects that its facility related costs will increase significantly as a result of leasing this additional space. In February 2019, the Company entered into a long-term lease for 3,164 square feet of office space in Towson, Maryland beginning March 1, 2019. The lease has a term of 3.2 years ending in April 2022 and includes a limited rent abatement and escalation provisions. The Company has no other significant leases. In addition, no identified leases require allocations between lease and non-lease components.

In adopting ASU 2016-02 as of January 1, 2019, the Company elected the package of practical expedients, which permit us not to reassess under the new standard the historical lease classification. The Company has not elected the hindsight practical expedient. The Company made an accounting policy election to keep leases with an initial term of 12 months or less off of the balance sheet. We also elected the lessee component election, allowing us to account for the lease and non-lease components as a single lease component. In determining whether a contract contains a lease, asset and service agreements are assessed at onset and upon modification for criteria of specifically identified assets, control and economic benefit. The Company recognized those lease payments in the consolidated statements of operations on a straight-line basis over the lease term. The Company uses the rate implicit in the contract whenever possible when determining the applicable discount rate. As the majority of our leases do not provide an implicit rate, we use our incremental borrowing rate based on the information available at the lease commencement date in determining the present value of lease payments. On the lease commencement dates, the Company estimated the lease liabilities and the right of use assets at present value using its applicable incremental borrowing rates of its two long term leases of 7.21% for our Maryland lease of 3.2 years and 9.1% for our New York leases of 14.3 years. On January 1, 2019, upon adoption of ASU 2016-02, the Company recorded right of use assets of approximately \$20.2 million, lease liabilities of \$23.4 million and eliminated deferred rent of \$3.2 million.

Right of use assets and lease liabilities for operating leases were \$20,104,280 and \$23,732,111 as of March 31, 2019, respectively.

Maturity analysis under the lease agreements are as follows:

Nine months December 31, 2019	\$ 2,195,207
Year ended December 31, 2020	3,346,376
Year ended December 31, 2021	3,448,323
Year ended December 31, 2022	3,491,166
Year ended December 31, 2023	3,566,466
Thereafter	21,302,235
Total	37,349,773
Less: Present value discount	(13,617,662)
Total Lease liability	\$ 23,732,111
Less: current portion	(2,873,022)
Long-term lease liabilities	\$ 20,859,089

Lease expense for the three months ended March 31, 2019 was approximately \$830,000.

## 5. 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 December 31, 2018, the total number of shares reserved under all equity plans is 10,287,390 and the Company had 4,807,323 shares available for future issuance under the 2018 Plan. Stock options granted under the 2018 Plan may be either incentive stock options ("ISOs") as defined by the Code, or non-qualified stock options. The Board of Directors determines who will receive options, the vesting periods (which are generally one to three years) and the exercise prices of such options. Options have a maximum term of 10 years. The exercise price of ISOs granted under the 2018 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 months ended March 31, 2019 and 2018, was comprised of the following:

[Table of Contents](#)

	Three Months Ended March 31,	
	2019	2018
Research and development	\$2,407,644	\$1,917,730
General and administrative	2,647,573	2,369,373
Total share-based compensation expense	<u>\$5,055,217</u>	<u>\$4,287,103</u>

The following table describes the weighted-average assumptions used for calculating the value of options granted during the three months ended March 31, 2019 and 2018:

	2019	2018
Dividend yield	0%	0%
Expected volatility	85.7%	85.8%
Weighted-average risk-free interest rate	2.52%	2.3%
Expected term (in years)	6.0	6.0

Information regarding the stock options activity, including with respect to grants to employees, directors and consultants as of March 31, 2019, and changes during the three-month period then ended, are summarized as follows:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Contractual Life
Outstanding at December 31, 2018 (audited)	4,748,391	\$ 18.75	7.0 years
Options granted (unaudited)	1,304,295	\$ 12.74	9.8 years
Options exercised (unaudited)	(11,400)	\$ 2.74	1.7 years
Options canceled or expired (unaudited)	(29,217)	\$ 19.20	8.4 years
Outstanding at March 31, 2019 (unaudited)	<u>6,012,069</u>	<u>\$ 17.09</u>	7.4 years
Vested or expected to vest at March 31, 2019 (unaudited)	<u>6,012,069</u>	<u>\$ 17.09</u>	
Exercisable at March 31, 2019 (unaudited)	<u>3,425,158</u>	<u>\$ 19.43</u>	6.0 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 three-month period ended March 31, 2019 are summarized as follows:

	Number of Shares	Weighted-Average Grant Date Fair Value Per Share
Outstanding at December 31, 2018 (audited)	647,411	\$ 18.16
RSU's granted in 2019 (unaudited)	886,802	\$ 12.73
RSU's vested in 2019 (unaudited)	(223,577)	\$ 19.44
RSU's cancelled in 2019 (unaudited)	(14,002)	\$ 14.97
Outstanding at March 31, 2019 (unaudited)	<u>1,296,634</u>	<u>\$ 14.26</u>

## Table of Contents

Information related to the Company's Milestone RSUs and the TSR RSUs during the three-month period ended March 31, 2019 are summarized as follows:

	Number of Shares	Weighted-Average Grant Date Fair Value Per Share
Outstanding at December 31, 2018	278,592	\$ 15.64
RSU's granted in 2019	—	\$ —
RSU's cancelled in 2019	(9,463)	\$ 15.64
Outstanding at March 31, 2019	<u>269,129</u>	<u>\$ 15.64</u>

The weighted average estimated fair value per share of the TSR RSUs granted in 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 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 January 1, 2017, with a deemed reinvestment of any dividends declared during the performance period. The Company's peer group includes 223 companies at December 31, 2018 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 months ended March 31, 2019 and 2018 of approximately \$1.9 million and \$1.1 million, respectively. Total expense for all RSUs, including the time based and performance based RSUs, is \$2.1 million and \$1.5 million for the three months ended March 31, 2019 and 2018, respectively. As of March 31, 2019, there was \$15.7 million of unrecognized compensation costs related to unvested time based RSUs. As of March 31, 2019, there was \$2.5 million of unrecognized compensation costs related to unvested Milestone RSUs and TSR RSUs.

## 6. Collaborations and License Agreements

### *The Bristol-Myers Squibb License Agreement*

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

Under the agreement, the Company made an upfront payment of \$1.0 million to BMS, a milestone payment of \$1.25 million in December 2013, and a milestone payment of \$1.5 million in December 2014 following the initiation of the Company's first Phase 3 clinical trial for lumateperone for patients with exacerbated schizophrenia. Upon FDA acceptance for review of an NDA submission for lumateperone, the Company was obligated to pay BMS a \$2.0 million milestone payment. This milestone was achieved in the third quarter of 2018. The Company accrued the \$2.0 million milestone payment obligation in 2018 and paid it in January 2019. Possible milestone payments remaining total \$10.0 million, including a \$5.0 million milestone payment payable upon an NDA approval. 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 ranging between 5 – 9% 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.

---

## [Table of Contents](#)

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.

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

*You should read the following in conjunction with our unaudited condensed consolidated financial statements and the related notes thereto that appear elsewhere in this Quarterly Report on Form 10-Q and the audited consolidated financial statements and notes thereto and under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K filed on February 27, 2019. In addition to historical information, the following discussion and analysis includes forward-looking information that involves risks, uncertainties and assumptions. Our actual results and the timing of events could differ materially from those anticipated by these forward-looking statements as a result of many factors, including those discussed under "Risk Factors" in our Annual Report on Form 10-K filed on February 27, 2019, 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-HT<sub>2A</sub> receptor antagonism, dopamine receptor phosphoprotein modulation, or DPPM, glutamatergic modulation, and serotonin reuptake inhibition into a single drug candidate for the treatment of acute and residual schizophrenia and for the treatment of bipolar disorder, including bipolar depression. At dopamine D<sub>2</sub> 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 D<sub>1</sub> receptors and indirectly stimulate phosphorylation of glutamatergic NMDA GluN<sub>2B</sub> 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, or MDD. 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. In the fourth quarter of 2018, the FDA accepted for review our new drug application, or NDA, for lumateperone for the treatment of schizophrenia, and assigned a Prescription Drug User Fee Act, or PDUFA, target action date of September 27, 2019. Lumateperone is also in Phase 3 clinical development as a novel treatment for bipolar depression.

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 completed this NDA submission in the third quarter of 2018 and the FDA accepted the NDA for review in the fourth quarter of 2018.

Our lumateperone bipolar depression Phase 3 clinical program consists of two monotherapy studies and one adjunctive study. We have completed patient enrollment in our first monotherapy study (Study 401) conducted in the U.S. and in the second monotherapy study (Study 404) conducted globally. Given the relative timing of these two events and to avoid introducing potential expectation bias in the ongoing Study 404, we anticipate reporting topline results from Study 401 and Study 404 simultaneously in the second quarter of 2019. The Study 401 dataset will remain locked and blinded until the Study 404 dataset is available and then both datasets will be analyzed concurrently. Subject to the outcome of these trials, we expect to submit for FDA regulatory approval for bipolar depression in the second half of 2019. Our global study evaluating adjunctive lumateperone in bipolar depression (Study 402) is ongoing.

In the second quarter of 2016, we initiated Phase 3 development of lumateperone for the treatment of agitation in patients with dementia, including AD. Our ITI-007-201 trial is a Phase 3 multi-center, randomized, double-blind, placebo-controlled clinical trial in patients with a clinical diagnosis of probable AD and clinically significant symptoms of agitation. In the fourth quarter of 2018, an independent data monitoring committee, or DMC, completed a pre-specified interim analysis of the ITI-007-201 trial, and concluded that the trial is not likely to meet its primary endpoint upon completion and therefore recommended the study should be stopped for futility. As a result, we determined to discontinue the ITI-007-201 trial. Lumateperone was generally well tolerated in the ITI-007-201 trial and the decision to discontinue the study was not related to safety. We are analyzing the data set from this trial and will determine the next steps in our program following completion of this analysis. We do not expect that these results will impact any of our other ongoing development programs.

## [Table of Contents](#)

We are also pursuing clinical development of lumateperone for the treatment of additional CNS diseases and disorders. At the lowest doses, lumateperone has been demonstrated to act primarily as a potent 5-HT<sub>2A</sub> serotonin receptor antagonist. As the dose is increased, additional benefits are derived from the engagement of additional drug targets, including modest dopamine receptor modulation and modest inhibition of serotonin transporters. We believe that combined interactions at these receptors may provide additional benefits above and beyond selective 5-HT<sub>2A</sub> antagonism for treating agitation, aggression and sleep disturbances in diseases that include dementia, AD, Huntington's disease and autism spectrum disorders, while avoiding many of the side effects associated with more robust dopamine receptor antagonism. As the dose of lumateperone is further increased, leading to moderate dopamine receptor modulation, inhibition of serotonin transporters, and indirect glutamate modulation, these actions complement the complete blockade of 5-HT<sub>2A</sub> 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 phosphodiesterase, or 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. In the fourth quarter of 2018, we announced that the Phase 1/2 clinical trial of ITI-214 has been completed and topline results demonstrated ITI-214 was generally well-tolerated with a favorable safety profile and clinical signs consistent with improvements in motor symptoms and dyskinesias. 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 a clinical program in late 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 the fourth quarter of 2019, if ever. We had no revenues for the three months ended March 31, 2019 and 2018, respectively. 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 and for the treatment of bipolar depression consumes and, together with our anticipated clinical development programs of lumateperone for depressive disorders and of ITI-214, 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.

## Table of Contents

Our ITI-002 program has a compound, ITI-214, in Phase 1/2 development. We intend to pursue the development of our PDE program, including ITI-214 for the treatment of several CNS and non-CNS conditions, including cardiovascular disease. We have initiated our development program for ITI-214 for Parkinson's disease. 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 moderately as we proceed with our Phase 3 clinical trials of lumateperone for the treatment of bipolar disorder and for the treatment of depressive disorders 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 significantly from prior periods primarily due to costs to perform pre-product commercialization activities and the increased costs associated with building infrastructure to support the anticipated commercial sales of lumateperone if it is approved for sale in the United States, which could include hiring additional personnel and the cost of additional facility space. On September 28, 2018, we signed a lease with a related party to acquire 15,534 square feet of additional office space in our current headquarters facility. We granted options to purchase 1,175,187 shares of our common stock in 2018 and have granted options to purchase an additional 1,304,295 shares of our common stock in the first quarter of 2019. We also granted time based restricted stock units, or RSUs, for 544,542 of our common stock in 2018 and time based RSUs for 886,802 shares of our common stock in the first quarter of 2019. 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 an 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 RSUs related to the NDA submission were amortized through December 31, 2018 based on the probable vesting date. The NDA submission milestone was achieved in the third quarter of 2018. The Milestone RSUs related to the NDA submission vested on December 31, 2018. 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 to continue to grant stock options and other stock-based awards in the future, which with our growing employee base will increase our stock-based compensation expense in future periods.

## [Table of Contents](#)

The following table sets forth our revenues, operating expenses, interest income and income tax expense for the three month periods ended March 31, 2019 and 2018 (in thousands):

	For the Three Months Ended March 31,	
	2019	2018
	(Unaudited)	
<b>Revenues</b>	\$ —	\$ —
<b>Expenses</b>		
Research and development	24,991	30,703
General and administrative	11,705	6,381
<b>Total costs and expenses</b>	<b>36,696</b>	<b>37,084</b>
<b>Loss from operations</b>	<b>(36,696)</b>	<b>(37,084)</b>
Interest income	1,860	1,604
Income tax expense	—	—
<b>Net loss</b>	<b><u>\$ (34,836)</u></b>	<b><u>\$ (35,480)</u></b>

### *Comparison of Three Month Periods Ended March 31, 2019 and March 31, 2018*

#### *Revenues*

Revenues for the three months ended March 31, 2019 and 2018 were zero.

#### *Research and Development Expenses*

The following tables set forth our research and development expenses for the three month periods ended March 31, 2019 and 2018 (in thousands):

	Three Months Ended March 31,	
	2019	2018
External Costs	\$ 17,809	\$ 23,730
Internal Costs	7,182	6,973
<b>Total Research and Development Expenses</b>	<b><u>\$ 24,991</u></b>	<b><u>\$ 30,703</u></b>

	Three Months Ended March 31,	
	2019	2018
Lumateperone costs	\$ 14,489	\$ 18,083
Manufacturing costs	5,860	6,802
Stock based compensation	2,408	1,918
Other projects and overhead	2,234	3,900
<b>Total Research and Development Expenses</b>	<b><u>\$ 24,991</u></b>	<b><u>\$ 30,703</u></b>

Research and development expenses decreased to \$25.0 million for the three month period ended March 31, 2019 as compared to \$30.7 million for the three month period ended March 31, 2018, representing a decrease of approximately 19%. This decrease is due primarily to a decrease of approximately \$7.7 million of costs associated with lumateperone clinical costs, a decrease of approximately \$942,000 in manufacturing expense, and a decrease of approximately \$1.7 million of non ITI-007 projects and overhead expenses, which is partially offset by an increase of approximately \$4.1 million in costs for lumateperone non-clinical efforts, and an increase of approximately \$490,000 in stock compensation expense. Internal costs increased by approximately \$209,000 for the period as we hired additional employees and increased our stock based compensation expense.

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 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 approvals for different indications.

## [Table of Contents](#)

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 February 27, 2019, as updated from time to time in our other periodic and current reports filed with the SEC.

### *General and Administrative Expenses*

General and administrative expenses increased by \$5.3 million for the three month period ended March 31, 2019 as compared to the three month period ended March 31, 2018, representing an increase of approximately 83%. The increase is primarily the result of an increase in pre-commercialization costs of approximately \$3.2 million, an increase in labor costs of approximately \$1.3 million, an increase in stock compensation expense of approximately \$278,000 and an increase in lease and rent expense of approximately \$402,000. Salaries, bonuses and related benefit costs for our executive, finance and administrative functions for the three months ended March 31, 2019 and 2018 constituted approximately 44% and 61%, respectively, of our total general and administrative costs. The next major categories of expenses were professional fees and general office-related overhead.

We expect general and administrative costs to increase significantly as we hire additional employees and expand our operations, in particular, the addition of a sales force and related commercial and other infrastructure as we prepare for potential commercial activities.

### **Liquidity and Capital Resources**

Through March 31, 2019, we provided funds for our operations by obtaining approximately \$880.3 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 our terminated license and collaboration agreement with Takeda Pharmaceutical Company Limited, or the Takeda License Agreement. We do not believe that grant revenue will be a significant source of funding in the near future.

## [Table of Contents](#)

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 March 31, 2019, we had a total of approximately \$312.8 million in cash and cash equivalents and available-for-sale investment securities, and approximately \$31.5 million of short-term liabilities consisting entirely of liabilities from operations, including approximately \$897,000 of short-term lease obligations. In the three months ended March 31, 2019, we spent approximately \$37.6 million in cash for operations and equipment, not including \$1.9 million of interest income. We reduced working capital by approximately \$29.5 million for the three months ended March 31, 2019. This 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 2019, subject to the timing of potential NDA approval, clinical trial conduct, regulatory activities, precommercial spending, manufacturing, and other development activities, we expect to spend between \$170 million and \$185 million. We expect these expenditures to be due primarily to the pre-commercialization activities, initial commercialization activities and related infrastructure expansion in connection with the potential commercialization of lumateperone for the treatment of schizophrenia; the development of lumateperone in our late stage clinical programs; the development of our other product candidates, including ITI-214 and ITI-333; the continuation of manufacturing activities in connection with the development of lumateperone; and general operations. We expect our existing cash and cash equivalents and investments will be sufficient to fund our operating expenses and capital expenditure requirements into the second half of 2020.

We will require significant additional financing in the future to continue to fund our operations. We believe that we have the funding in place to complete the additional clinical and non-clinical trials, manufacturing and pre-commercialization activities needed for potential regulatory approval and 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. We also plan to fund additional clinical trials of lumateperone for the treatment of behavioral disturbances in dementia and depressive disorders; 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 for further development of 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 three months ended March 31, 2019, we used net cash in operating activities and purchases of equipment of approximately \$37.6 million. This total does not include an offset for \$1.9 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, as well as commercialization efforts, we expect the amount of cash to be used to fund operations to increase over the next several years.

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

## [Table of Contents](#)

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 up to September 14, 2019.

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.

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 with a related party which, as amended, provided for a lease of 16,753 square feet of useable laboratory and office space located at 430 East 29th Street, New York, New York 10016. Concurrent with this lease, we entered into a license agreement to occupy certain vivarium related space in the same facility for the same term, rent and escalation provisions as the lease. This license has the primary characteristics of a lease and is treated as such for accounting purposes. In September 2018, we further amended the lease to obtain an additional 15,534 square feet of office space beginning October 1, 2018 and to extend the term of the lease for previously acquired space. The lease, as amended, has a term of 14.3 years ending in May 2029. We expect that our facility related costs will increase significantly as a result of leasing this additional space. In February 2019, we entered into a long-term lease for 3,164 square feet of office space in Towson, Maryland beginning March 1, 2019. The lease has a term of 3.2 years ending in April 2022.

### **Off-Balance Sheet Arrangements**

We do not have any off-balance sheet arrangements.

### **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, 2018 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 three months ended March 31, 2019.

## [Table of Contents](#)

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

### **Recently Issued Accounting Pronouncements**

We review new accounting standards to determine the expected financial impact, if any, that the adoption of each such standard will have. 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, 2018 filed on February 27, 2019.

### **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 current and future product candidates; the election by any collaborator to pursue research, development and commercialization activities; our ability to obtain future reimbursement and/or milestone payments from our collaborators; our ability to 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,” “predict,” “project,” “likely,” “will,” “would,” “could,” “should,” “continue” and words and terms of similar substance used in connection with any discussion of future operating or financial performance, identify forward-looking statements. All forward-looking statements are management’s present expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those described in the forward-looking statements. These risks include, but are not limited to, those set forth under the heading “Risk Factors” in our most recent Annual Report on Form 10-K, as updated from time to time in our subsequent periodic and current reports filed with the SEC.

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

**Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

*Interest Rate Sensitivity.* As of March 31, 2019, we had cash, cash equivalents and marketable securities of approximately \$312.8 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 March 31, 2019 and December 31, 2018 totaling approximately \$67,000 and \$668,000, 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 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.* Beginning January 1, 2019, we implemented ASU 2016-02, "Leases (Topic 842)." Although the adoption of the new accounting standard did not materially impact our consolidated statements of operations and had no impact on our consolidated cash flows for the three months ended March 31, 2019, we did implement new internal control procedures to support the new accounting and reporting processes associated with adopting the guidance. These procedures included performing a comprehensive lease scoping analysis to identify, disaggregate and evaluate each of our leases. There were no other 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 March 31, 2019 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 discussed in Item 1A. Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2018, filed with the Securities and Exchange Commission on February 27, 2019.

**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 quarter ended March 31, 2019.

**Item 3. DEFAULTS UPON SENIOR SECURITIES**

Not applicable.

**Item 4. MINE SAFETY DISCLOSURES**

Not applicable.

**Item 5. OTHER INFORMATION**

Not applicable.

## Table of Contents

### Item 6. EXHIBITS

<u>Exhibit Number</u>	<u>Exhibit Description</u>	<u>Filed Herewith</u>	<u>Incorporated by Reference herein from Form or Schedule</u>	<u>Filing Date</u>	<u>SEC File/Reg. Number</u>
31.1	<a href="#"><u>Certification of the Registrant's Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u></a>	X			
31.2	<a href="#"><u>Certification of the Registrant's Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u></a>	X			
32	<a href="#"><u>Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u></a>	X			
101	The following materials from the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2019, formatted in XBRL (eXtensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets as of March 31, 2019 (unaudited) and December 31, 2018 (audited), (ii) Condensed Consolidated Statements of Operations (unaudited) for the three months ended March 31, 2019 and 2018, (iii) Condensed Consolidated Statements of Comprehensive Loss (unaudited) for the three months ended March 31, 2019 and 2018, (iv) Condensed Consolidated Statements of Stockholders' Equity (unaudited) for the three months ended March 31, 2019 and 2018, (v) Condensed Consolidated Statements of Cash Flows (unaudited) for the three months ended March 31, 2019 and 2018, and (vi) Notes to Condensed Consolidated Financial Statements (unaudited).	X			

**SIGNATURES**

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

INTRA-CELLULAR THERAPIES, INC.

Date: May 8, 2019

By: /s/ Sharon Mates, Ph.D.

Sharon Mates, Ph.D.

Chairman, President and Chief Executive Officer

Date: May 8, 2019

By: /s/ Lawrence J. Hinline

Lawrence J. Hinline

Senior Vice President of Finance and Chief Financial Officer

## CERTIFICATIONS UNDER SECTION 302

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

1. I have reviewed this quarterly report on Form 10-Q of Intra-Cellular Therapies, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 8, 2019

/s/ Sharon Mates, Ph.D.

\_\_\_\_\_  
Sharon Mates, Ph.D.

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

## CERTIFICATIONS UNDER SECTION 302

I, Lawrence J. Hinline, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Intra-Cellular Therapies, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 8, 2019

/s/ Lawrence J. Hinline

---

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

## CERTIFICATIONS UNDER SECTION 906

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

The Quarterly Report for the quarter ended March 31, 2019 (the "Form 10-Q") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: May 8, 2019

/s/ Sharon Mates, Ph.D.

Sharon Mates, Ph.D.

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

Dated: May 8, 2019

/s/ Lawrence J. Hinline

Lawrence J. Hinline

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