Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2020

or

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

For the transition period from _____ to _____

Commission File Number: 001-36274

INTRA-CELLULAR THERAPIES, INC.
(Exact name of registrant as specified in its charter)

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

(646) 440-9333
(Registrant's telephone number, including area code)

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**

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 5, 2020, the registrant had 66,450,525 shares of common stock outstanding.

Table of Contents

Intra-Cellular Therapies, Inc.

Index to Form 10-Q

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, 2020 *(Unaudited)*	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	**$ 179,593,032**	$ 107,636,849
Investment securities, available-for-sale	**269,360,926**	116,373,335
Restricted cash	**1,400,000**	—
Accounts receivable, net	**1,351,013**	—
Inventory	**1,391,124**	—
Prepaid expenses and other current assets	**7,876,405**	6,313,785
Total current assets	**460,972,500**	230,323,969
Property and equipment, net	**2,132,987**	2,259,740
Right of use assets, net	**18,051,146**	18,252,074
Deferred tax asset, net	**—**	264,609
Other assets	**86,084**	86,084
Total assets	**$ 481,242,717**	$ 251,186,476
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	**$ 10,994,082**	$ 7,425,024
Accrued and other current liabilities	**10,667,765**	16,138,909
Lease liabilities, short-term	**3,211,234**	3,187,435
Accrued employee benefits	**6,203,283**	9,472,651
Total current liabilities	**31,076,364**	36,224,019
Lease liabilities	**19,718,023**	19,955,186
Total liabilities	**50,794,387**	56,179,205
Stockholders' equity:		
Common stock, $0.0001 par value: 100,000,000 shares authorized; 66,200,761 and 55,507,497 shares issued and outstanding at March 31, 2020 and December 31, 2019, respectively	**6,620**	5,551
Additional paid-in capital	**1,188,095,880**	904,971,772
Accumulated deficit	**(757,508,971)**	(710,098,369)
Accumulated comprehensive (loss) gain	**(145,199)**	128,317
Total stockholders' equity	**430,448,330**	195,007,271
Total liabilities and stockholders' equity	**$ 481,242,717**	$ 251,186,476

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,	
	2020	2019
Revenues		
Product sales, net	**$ 882,516**	$ —
Grant revenue	**200,963**	—
Total revenues	**1,083,479**	—
Operating expenses:		
Cost of product sales	**69,311**	—
Research and development	**16,003,326**	24,990,856
Selling, general and administrative	**34,096,366**	11,704,984
Total operating expenses	**50,169,003**	36,695,840
Loss from operations	**(49,085,524)**	(36,695,840)
Interest income	**1,678,203**	1,860,077
Loss before provision for income taxes	**(47,407,321)**	(34,835,763)
Income tax expense	**3,281**	—
Net loss	**$(47,410,602)**	$(34,835,763)
Net loss per common share:		
Basic & Diluted	**$ (0.73)**	$ (0.63)
Weighted average number of common shares:		
Basic & Diluted	**65,106,103**	55,113,226

See accompanying notes to these condensed consolidated financial statements.

Intra-Cellular Therapies, Inc. and Subsidiaries

Condensed Consolidated Statements of Comprehensive Loss (Unaudited)

	Three Months Ended March 31,	
	2020	2019
Net loss	**$(47,410,602)**	$(34,835,763)
Other comprehensive (loss) income:		
Unrealized (loss) gain on investment securities	**(273,516)**	600,307
Comprehensive loss	**$(47,684,118)**	$(34,235,456)

See accompanying notes to these condensed consolidated financial statements.

Intra-Cellular Therapies, Inc. and Subsidiaries

Condensed Consolidated Statements of Stockholders' Equity (Unaudited)

	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	55,131,125	$5,513	$885,888,318	$(597,211,954)	$ (67,450)	$288,614,427

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2019	**55,507,497**	**$5,551**	**$ 904,971,772**	**$(710,098,369)**	**$ 128,317**	**$195,007,271**
Common shares issued January 2020	**10,000,000**	**1,000**	**276,977,186**	**—**	**—**	**276,978,186**
Exercise of stock options and issuances of restricted stock	**689,781**	**69**	**589,092**	**—**	**—**	**589,161**
Stock issued for services	**3,483**	**—**	**53,533**	**—**	**—**	**53,533**
Share-based compensation	**—**	**—**	**5,504,297**	**—**	**—**	**5,504,297**
Net loss	**—**	**—**	**—**	**(47,410,602)**	**—**	**(47,410,602)**
Other comprehensive loss	**—**	**—**	**—**	**—**	**(273,516)**	**(273,516)**
Balance at March 31, 2020	**66,200,761**	**$6,620**	**$1,188,095,880**	**$(757,508,971)**	**$ (145,199)**	**$430,448,330**

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,	
	2020	2019
Cash flows used in operating activities		
Net loss	**$ (47,410,602)**	$(34,835,763)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	**148,802**	101,353
Share-based compensation	**5,504,297**	5,055,217
Stock issued for services	**53,533**	48,549
Amortization of premiums and discounts on investment securities, net	**(298,210)**	(356,798)
Changes in operating assets and liabilities:		
Accounts receivable, net	**(1,351,013)**	**—**
Inventory	**(1,391,124)**	**—**
Prepaid expenses and other assets	**(1,562,620)**	(526,089)
Long term deferred tax asset, net	**264,609**	**—**
Accounts payable	**3,569,058**	(5,386,627)
Accrued liabilities and other	**(8,740,512)**	270,833
Lease liabilities, net	**(12,436)**	—
Net cash used in operating activities	**(51,226,218)**	(35,629,325)
Cash flows (used in) provided by investing activities		
Purchases of investments	**(210,466,633)**	(14,327,684)
Maturities of investments	**57,503,736**	59,136,544
Purchases of property and equipment	**(22,049)**	(67,193)
Net cash (used in) provided by investing activities	**(152,984,946)**	44,741,667
Cash flows provided by financing activities		
Proceeds from exercise of stock options	**589,161**	31,236
Proceeds of public offering, net	**276,978,186**	—
Net cash provided by financing activities	**277,567,347**	31,236
Net increase in cash, cash equivalents, and restricted cash	**73,356,183**	9,143,578
Cash, cash equivalents, and restricted cash at beginning of period	**107,636,849**	54,947,502
Cash, cash equivalents, and restricted cash at end of period	**$ 180,993,032**	$ 64,091,080
Non-cash investing and financing activities		
Right of use assets under operating leases	**$ 97,234**	$ 219,703

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the condensed consolidated balance sheets that sum to the total of the same such amounts shown in the condensed consolidated statements of cash flows:

	March 31,	
	2020	2019
Cash and cash equivalents	**$179,593,032**	$64,091,080
Restricted cash	**1,400,000**	—
Total cash, cash equivalents and restricted cash	**$180,993,032**	$64,091,080

See accompanying notes to these condensed consolidated financial statements.

Intra-Cellular Therapies, Inc.

Notes to Condensed Consolidated Financial Statements (Unaudited)

March 31, 2020

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, clinical development and commercialization of innovative, small molecule drugs that address underserved medical needs primarily in neuropsychiatric and neurological disorders by targeting intracellular signaling mechanisms within the central nervous system ("CNS"). In December 2019, the Company announced that CAPLYTA™ (lumateperone) has been approved by the U.S. Food and Drug Administration ("FDA") for the treatment of schizophrenia in adults (42mg/day). The Company initiated the commercial launch of CAPLYTA in late March 2020 and announced that CAPLYTA is available to pharmacies in the United States (U.S.). As used in these Notes to Condensed Consolidated Financial Statements, "CAPLYTA" refers to lumateperone approved by the FDA for the treatment of schizophrenia in adults, and "lumateperone" refers to, where applicable, CAPLYTA as well as lumateperone for the treatment of indications beyond schizophrenia. Lumateperone is in Phase 3 clinical development as a novel treatment for bipolar depression.

On January 10, 2020, the Company completed a public offering of common stock in which the Company sold 10,000,000 shares of common stock at an offering price of $29.50 per share for aggregate gross proceeds of $295 million. After deducting underwriting discounts, commissions and offering expenses, the net proceeds to the Company were approximately $277 million.

In order to further its commercial activities and 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 for at least one year from the date that these financial statements are filed with the Securities and Exchange Commission (the "SEC"). 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 August 30, 2019, the Company filed a universal shelf registration statement on Form S-3, which was declared effective by the SEC on September 12, 2019, on which the Company registered for sale up to $350 million of any combination of its common stock, preferred stock, debt securities, warrants, rights and/or units from time to time and at prices and on terms that the Company may determine, which includes up to $75 million of common stock that the Company may issue and sell from time to time, through SVB Leerink LLC acting as its sales agent, pursuant to the sale agreement that the Company entered into with SVB Leerink on August 29, 2019 for the Company's "at-the-market" equity program. In addition, on January 6, 2020, the Company filed an automatic shelf registration statement on Form S-3 with the SEC, which became effective upon filing, on which the Company registered for sale an unlimited amount of any combination of its common stock, preferred stock, debt securities, warrants, rights, and/or units from time to time and at prices and on terms that the Company may determine, so long as the Company continues to satisfy the requirements of a "well-known seasoned issuer" under SEC rules. These registration statements will remain in effect for up to three years from the respective dates they became effective.

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 GAAP 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.

Revenue Recognition

Effective January 1, 2018, the Company adopted FASB ASC Topic 606, *Revenue from Contracts with Customers* ("ASC Topic 606"). The Company did not generate any product related revenue prior to the three months ended March 31, 2020, and therefore the adoption of ASC Topic 606 did not have an impact to the Company's financial statements for any prior periods or upon adoption. In accordance with ASC Topic 606, the Company recognizes revenue when the customer obtains control of a promised good or service, in an amount that reflects the consideration that the Company expects to receive in exchange for the good or service. The reported results for the three months ended March 31, 2020 reflect the application of ASC Topic 606.

To determine revenue recognition for arrangements that the Company determines are within the scope of ASC Topic 606, the Company performs the following five steps: (i) identify the contract(s) with a customer, (ii) identify the performance obligations in the contract, (iii) determine the transaction price, (iv) allocate the transaction price to the performance obligations in the contract, and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to arrangements that meet the definition of a contract under ASC Topic 606, including when it is probable that the Company will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC Topic 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. For a complete discussion of accounting for product sales, see *Product Sales, net* (below).

Product Sales, net

The Company sells CAPLYTA to a limited number of Customers which include a number of national and select regional distributors. These Customers subsequently resell the Company's products to specialty pharmacy providers, as well as other retail pharmacies and certain medical centers or hospitals. In addition to distribution agreements with Customers, the Company enters into arrangements with health care providers and payers that provide for government mandated and/or privately negotiated rebates, chargebacks, and discounts with respect to the purchase of the Company's products. As of March 31, 2020, the Company had executed agreements with its Customers in place; however, additional distribution agreements were signed subsequent to the quarter close. The Company recognizes revenue on product sales when the Customer obtains control of the Company's product, which occurs at a point in time (upon delivery). Product revenues are recorded net of applicable reserves for variable consideration, including discounts and allowances. If taxes should be collected from Customers relating to product sales and remitted to governmental authorities, they will be excluded from revenue.

Reserves for Variable Consideration

Revenues are calculated based on the wholesale acquisition cost that the Company charges to distributors for CAPLYTA less variable consideration for which reserves are established. Components of variable consideration may include trade discounts and allowances, product returns, provider chargebacks and discounts, government rebates, payer rebates, and other incentives, such as voluntary patient assistance, and other allowances that are offered within contracts between the Company and its Customers, payers, and other indirect customers relating to the Company's sales of its product.

These reserves, as detailed below, are based on the amounts earned, or to be claimed on the related sales, include estimates that take into consideration a range of possible outcomes which are either considered most likely or probability-weighted in accordance with the expected value method in ASC Topic 606 for relevant factors such as current contractual and statutory requirements, specific known market events and trends, forecasted customer buying and payment patterns. The Company's estimates regarding the payer mix for CAPLYTA and historical industry information regarding the payer mix for comparable pharmaceutical products and product portfolios, in particular, historical information related to similar products in their initial launch stages. Overall, these reserves reflect the Company's best estimates of the amount of consideration to which it is entitled based on the terms of the respective underlying contracts after considering whether revenue should be constrained under ASC 606.

The amount of variable consideration which is included in the transaction price may be constrained, and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized under the contract will not occur in a future period. The Company's analyses also contemplated application of the constraint in accordance with the guidance, under which it determined a material reversal of revenue would not occur in a future period for the estimates detailed below as of March 31, 2020 and, therefore, the transaction price was not reduced further during the three months ended March 31, 2020. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results in the future vary from the Company's estimates, the Company will adjust these estimates, which would affect net product sales and earnings in the period such variances become known.

Trade Discounts and Allowances— The Company generally provides Customers with discounts which include incentive fees that are explicitly stated in the Company's contracts and are recorded as a reduction of revenue in the period the related product revenue is recognized. In addition, the Company compensates (through trade discounts and allowances) its Customers for sales order management, data, and distribution services. However, the Company has determined such services received to date are not distinct from the Company's sale of products to the Customer and, therefore, these payments have been recorded as a reduction of net sales within the condensed consolidated statements of operations through March 31, 2020, as well as a reduction to trade receivables, net on the condensed consolidated balance sheets.

Product Returns— Consistent with industry practice, the Company generally offers Customers a limited right of return for product that has been purchased from the Company based on the product's expiration date, which lapses upon shipment to a patient. The Company estimates the amount of its product sales that may be returned by its Customers and records this estimate as a reduction of revenue in the period the related product revenue is recognized, as well as an accrued expenses and other current liabilities on the condensed consolidated balance sheets. The Company currently estimates product return liabilities using available industry data and its own sales information, including its visibility into the inventory remaining in the distribution channel. The Company has not received any returns to date.

Provider Chargebacks and Discounts— Chargebacks for fees and discounts to providers represent the estimated obligations resulting from contractual commitments to sell products to qualified healthcare providers at prices lower than the list prices charged to Customers who directly purchase the product from the Company. Customers charge the Company for the difference between what they pay for the product and the ultimate selling price to the qualified healthcare providers. These reserves are established in the same period that the related revenue is recognized, resulting in a reduction of product revenue and accounts receivables, net. Chargeback amounts are generally determined at the time of resale to the qualified healthcare provider by Customers, and the Company generally issues credits for such amounts within a few weeks of the Customer's notification to the Company of the resale. Reserves for chargebacks consist of credits that the Company expects to issue for units that remain in the distribution channel inventories at each reporting period-end that the Company expects will be sold to qualified healthcare providers, and chargebacks that Customers have claimed, but for which the Company has not yet issued a credit. For the three months ended March 31, 2020, these amounts were not significant.

Government Rebates— The Company is subject to discount obligations under state Medicaid and Medicare programs. These reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included in accrued expenses and other current liabilities on the condensed consolidated balance sheets. For Medicare, the Company also estimates the number of patients in the prescription drug coverage gap for whom the Company will owe an additional liability under the Medicare Part D program. The Company's liability for these rebates consists of estimates of claims under these programs for the current quarter, and estimated future claims under these programs that will be made for product that has been recognized as revenue, but which remains in the distribution channel inventories at the end of each reporting period.

Payer Rebates— The Company contracts with certain private payer organizations, primarily insurance companies and pharmacy benefit managers, for the payment of rebates with respect to utilization of its product. The Company estimates these rebates and records such estimates in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability recorded as an accrued expenses and other current liabilities on the condensed consolidated balance sheets.

Other Incentives— Other incentives which the Company offers include voluntary patient assistance programs, such as the co-pay assistance program, which are intended to provide financial assistance to qualified commercially-insured patients with prescription drug co-payments required by payers. The calculation of the accrual for co-pay assistance is based on an estimate of claims and the cost per claim that the Company expects to receive associated with product that has been recognized as revenue but remains in the distribution channel inventories at the end of each reporting period. The Company also has a voucher program whereby a patient can receive a prescription at no cost and whereby the Company reimburses the pharmacy for 100% of the sales price of the prescription. The Company estimates the number of claims through vouchers for product that is in the distribution channel inventories and reduces recognized revenue accordingly.

The adjustments are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included as a component of accrued expenses and other current liabilities on the condensed consolidated balance sheets.

Chargebacks, discounts, fees, and returns are recorded as reductions of trade receivables, net on the condensed consolidated balance sheets. Government and other rebates are recorded as a component of accrued expenses and other current liabilities on the condensed consolidated balance sheets.

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 condensed consolidated balance sheets.

Investment Securities, available-for-sale

Investment securities consisted of the following (in thousands):

	March 31, 2020			
	Amortized Cost	Unrealized Gains	Unrealized (Losses)	Estimated Fair Value
		(Unaudited)		
U.S. Government Agency Securities	$ 86,053	$ 187	$ (4)	$ 86,236
Commercial Paper	89,361	53	(22)	89,392
Corporate Notes/Bonds	94,092	120	(479)	93,733
	$ 269,506	$ 360	$ (505)	$269,361

	December 31, 2019			
	Amortized Cost	Unrealized Gains	Unrealized (Losses)	Estimated Fair Value
U.S. Government Agency Securities	$ 35,462	$ 35	$ (3)	$ 35,494
Certificates of Deposit	3,000	—	—	3,000
Commercial Paper	39,013	10	(5)	39,018
Corporate Notes/Bonds	38,770	91	—	38,861
	$ 116,245	$ 136	$ (8)	$116,373

The Company has classified all of its investment securities available-for-sale, including those with maturities beyond one year, as current assets on the condensed 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, 2020, and December 31, 2019, the Company held $91.3 million and $3.0 million, respectively, of available-for-sale investment securities with contractual maturity dates more than one year and less than two years.

The Company monitors its investment portfolio for overall risk, specifically credit risk loss, quarterly or more frequently if circumstances warrant. The Company would estimate the expected credit loss over the lifetime of the asset and record an allowance for the portion of the amortized cost basis of the financial asset that the Company does not expect to collect.

At March 31, 2020, the Company had 28 securities in an unrealized loss position and at December 31, 2019 the Company had six securities in an unrealized loss position. The aggregate related fair value of investments with unrealized losses as of March 31, 2020 was $113.4 million, which consisted of $16.7 million from U.S. Government agency securities, $26.7 million of Commercial paper, and $69.9 million of Corporate notes/bonds. The aggregate amount of unrealized losses as of March 31, 2020 was approximately $520,000, which consisted of $4,000 from U.S. Government agency securities, $22,000 from Commercial paper, and $494,000 from Corporate notes/bonds. Of the $113.4 million, $106.6 million has been held in a continuous unrealized loss position for less than 12 months and $6.8 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 $1,000 as of March 31, 2020. As of December 31, 2019, the Company had approximately $29.6 million of investments with a continuous unrealized loss for 12 months or longer of which approximately $12.5 million have been held in a continuous loss position for 12 months or longer.

The Company reviewed all of the investments which were in a loss position at the respective balance sheet dates, as well as reviewed the remainder of the portfolio. The Company has analyzed the unrealized losses and determined that market conditions were the primary factor driving these changes. After analyzing the securities in an unrealized loss position, the portion of these losses that relate to changes in credit quality is insignificant.

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, 2020 and December 31, 2019. The carrying value of money market funds of approximately $85.0 million as of March 31, 2020 and $49.9 million as of December 31, 2019 is included in cash and cash equivalents and approximates market value based on quoted market prices or Level 1 inputs. The carrying value of certificates of deposit of approximately $58.3 million and $47.6 million as of March 31, 2020 and December 31, 2019, respectively, is included in cash and cash equivalents and approximates market value based on quoted market prices or Level 2 inputs. The carrying value of commercial paper of approximately $3.0 million as of December 31, 2019 is included in cash and cash equivalents and approximates market value based on quoted market prices or Level 2 inputs. The carrying value of commercial paper of approximately $12.0 million and the carrying value of U.S. Government Agency Securities of approximately $20.0 million as of March 31, 2020 are included in cash and cash equivalents and approximates market value based on quoted market prices or Level 2 inputs.

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

		Fair Value Measurements at Reporting Date Using		
	March 31, 2020	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money Market Funds	$ 84,966	$ 84,966	$ —	$ —
U.S. Government Agency Securities	106,235	—	106,235	—
Certificates of Deposit	58,254	—	58,254	—
Commercial Paper	101,387	—	101,387	—
Corporate Notes/Bonds	93,733	—	93,733	—
Restricted Cash	1,400	1,400	—	—
	$ 445,975	$ 86,366	$ 359,609	$ —

	December 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	$ 49,882	$ 49,882	$ —	$ —
U.S. Government Agency Securities	35,494	—	35,494	—
Certificates of Deposit	50,622	—	50,622	—
Commercial Paper	42,015	—	42,015	—
Corporate Bonds/Notes	38,861	—	38,861	—
	$ 216,874	$ 49,882	$ 166,992	$ —

Financial Instruments

The Company considers the recorded costs of its financial assets and liabilities, which consist of cash equivalents, restricted cash, prepaid expenses, other assets, accounts payable, accrued liabilities, accrued employee benefits and lease liabilities, short-term, to approximate their fair value because of their relatively short maturities at March 31, 2020 and December 31, 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.

Accounts Receivable, net

The Company's accounts receivable, net, primarily arise from product sales. They are generally stated at the invoiced amount and do not bear interest. Revenues from product sales are recorded at the net sales price (transaction price), which includes estimates of variable consideration for which reserves are established and which result from wholesaler rebates chargebacks, prompt pay discounts, co-pay assistance and distribution fees.

The Company monitors the financial performance and creditworthiness of its customers so that it can properly assess and respond to changes in the customers' credit profiles. Of the first quarter 2020 sales, 96% were generated from three major industry wholesalers.

Concentration of Credit Risk

Financial instruments which potentially subject the Company to concentrations of credit risk consist of accounts receivable, net from customers and cash, cash equivalent and investments held at financial institutions. For the quarter ended March 31, 2020, the majority of the Company's accounts receivable, net arose from product sales in the U.S. and all customers have standard payment terms which generally require payment within 90 days. Three individual customers accounted for approximately 61.4%, 18% and 17% of product sales for the quarter ended March 31, 2020. As of March 31, 2020, the Company believes that such customers are of high credit quality.

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.

Restricted Cash

Restricted cash is collateral used under the letter of credit arrangement for the vehicle lease agreement. The Company adopted ASU No. 2016-18, Restricted Cash ("ASU 2016-18") and now includes restricted cash balances within the cash, cash equivalents and restricted cash balance on the statement of cash flows.

Inventory

The Company values its inventories at the lower of cost or estimated net realizable value. The Company determines the cost of its inventories, which includes amounts related to materials and manufacturing overhead, on a first-in, first-out ("FIFO") basis. The Company performs an assessment of the recoverability of capitalized inventory during each reporting period, and it writes down any excess and obsolete inventories to their estimated net realizable value in the period in which the impairment is first identified. Such impairment charges, if they occur, are recorded within cost of product sales.

The Company capitalizes inventory costs associated with the Company's products after regulatory approval when, based on management's judgment, future commercialization is considered probable and the future economic benefit is expected to be realized. Inventory acquired and manufactured prior to receipt of regulatory approval of a product candidate is expensed as research and development expense as incurred. Inventory that can be used in either the production of clinical or commercial product is expensed as research and development expense when selected for use in a clinical manufacturing campaign.

Shipping and handling costs for product shipments to customers are recorded as incurred in cost of product sales along with costs associated with manufacturing the product, and any inventory write-downs. Royalties due to Bristol-Myers Squibb Company ("BMS") under the Company's licensing agreement are included in cost of product sales.

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.

Cost of Product Sales

Our cost of product sales relates to sales of CAPLYTA. Cost of product sales primarily includes product royalty fees, overhead, and direct costs (inclusive of material, shipping, and manufacturing costs). Cost of product sales were approximately $69,000 and $0 for the three months ended March 31, 2020, and March 31, 2019, respectively, as there were no sales in 2019.

For the product royalty fees, the Company entered into an exclusive License Agreement with Bristol-Myers Squibb Company ("BMS"), for which the Company is obliged to make tiered single digit percentage royalty payments ranging between 5 – 9% on sales of licensed products. The related royalties are recorded within cost of product sales on the statement of operations.

Prior to FDA approval of CAPLYTA, the Company recorded $17.5 million of costs associated with the manufacturing of lumateperone as part of research and development expenses between 2017 and 2019. From December 20, 2019, the date of approval of CAPLYTA, through December 31, 2019 there was no production and no inventory costs were incurred. Therefore, at December 31, 2019, no inventory costs had been capitalized. The cost of product sales in the three months ended March 31, 2020 are lower than incurred because of previously expensed inventory.

Research and Development, Including Clinical Trial Expenses

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 services, providers, materials and consulting fees.

Costs for certain development activities, such as clinical trials, are recognized based on an evaluation of the progress to completion of specific tasks using data such as subject enrollment, clinical site activations or information provided to the Company by its vendors with respect to their actual costs incurred, among other factors. 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 or state of consummation of trials, or the services completed. During the course of a clinical trial, the Company adjusts its clinical expense recognition if actual results differ from its estimates. The Company makes estimates of its accrued expenses as of each balance sheet date based on the facts and circumstances known to it at that time. The Company's clinical trial accruals are dependent upon the timely and accurate reporting of contract research organizations, clinical sites and other third-party vendors. Although the Company does not expect its estimates to be materially different from amounts actually incurred, its understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in it reporting amounts that are too high or too low for any particular period. For the three months ended March 31, 2020 and 2019, there were no material adjustments to the Company's prior year estimates of accrued expenses for clinical trials.

Income Taxes

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

The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Valuation allowances are established when necessary to reduce net deferred tax assets to the amount expected to be realized. Income tax expense is the tax payable for the period and the change during the period in deferred tax assets and liabilities. The Company accounts for uncertain tax positions pursuant to ASC Topic 740 (previously included in FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes—an Interpretation of FASB Statement No. 109*). Financial statement recognition of a tax position taken or expected to be taken in a tax return is determined based on a more-likely-than-not threshold of that position being sustained. If the tax position meets this threshold, the benefit to be recognized is measured as the tax benefit having the highest likelihood of being realized upon ultimate settlement with the taxing authority. The Company recognizes interest accrued related to unrecognized tax benefits and penalties in the provision for income taxes.

The Company's effective tax rate for the three months ended March 31, 2020 and 2019 was approximately 0%. This effective tax rate is substantially lower than the U.S. statutory rate of 21% due to valuation allowances recorded on current year losses where the Company is not more-likely than not to recognize a future tax benefit.

On March 27, 2020, the United States enacted The Coronavirus Aid, Relief and Economic Security (CARES) Act which includes several significant business tax provisions that, among other things, would eliminate the taxable income limit for certain net operating losses (NOL) and allow businesses the option to carry back NOLs arising in 2018, 2019, and 2020 to the five prior tax years; accelerate refunds of previously generated corporate Alternative Minimum Tax (AMT) credits; generally loosen the business interest limitation under section 163(j) from 30 percent to 50 percent for years 2019 and 2020; and fix the "retail glitch" for qualified improvement property in the 2017 tax code overhaul known informally as the Tax Cuts and Jobs Act (TCJA, P.L. 115-97). Other technical corrections are also included in these tax provisions. The measure also adds an employee retention credit to encourage employers to maintain headcounts even if employees cannot report to work because of issues related to the coronavirus, a temporary provision allowing companies to defer remitting to the government the employee share of some payroll taxes, among other things. The Company reviewed the provisions and does not expect there to be a material tax impact on our financial statements for the period ending Mach 31, 2020. In particular, the Company reclassified its deferred tax asset related to the AMT tax credit carryforward of $265,000 to a current tax receivable as it anticipates receiving the refund upon the filing of its tax return for year ended December 31, 2019 as opposed to over the next few calendar years.

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, 2020 and 2019 accounts for forfeitures as they occur.

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 for quarterly periods prior to December 31, 2019 were based on a combination of the historical volatility of the common stock of comparable publicly traded entities and the limited historical information about the Company's common stock. In the fourth quarter of 2019, expected volatility rates are based entirely on the historical volatility of the Company's common stock. The expected life of stock options is the period of time for which the stock options are expected to be outstanding. Given the limited historical exercise data, the expected life is determined using the "simplified method," which defines expected life as the midpoint between the vesting date and the end of the contractual term.

The risk-free interest rates are based on the U.S. Treasury yield for a period consistent with the expected term of the option in effect at the time of the grant. The Company has not paid dividends to its stockholders since its inception and does not plan to pay cash dividends in the foreseeable future. Therefore, the Company has assumed an expected dividend rate of zero. For stock options granted, the exercise price was determined by using the closing market price of the Company's common stock on the date of grant.

A restricted stock unit ("RSU") is a stock award that entitles the holder to receive shares of the Company's common stock as the award vests. The fair value of each RSU is based on the fair market value of the Company's common stock on the date of grant. The Company has granted RSUs that vest in three equal annual installments provided that the employee remains employed with the Company.

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") to the FDA for lumateperone for the treatment of schizophrenia, (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 related to the NDA submission has 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 December 31, 2018. The Milestone RSU's related to the NDA approval was achieved in the fourth quarter of 2019, so the RSU's vested on December 31, 2019. The amortization of the expenses for Milestone RSUs related to the approval of the NDA was fully amortized on December 31, 2019. The TSR RSUs were valued using the Monte Carlo Simulation method and were amortized over the life of the RSUs based on the agreements which vested on January 24, 2020.

In the first quarter of 2020, the Company granted 86,000 shares performance-based RSUs, which vest based on the achievement of certain milestones that include (i) the approval of a planned NDA by the FDA and (ii) the achievement of certain comparative shareholder returns against the Company's peers (the "2020 TSR RSUs"). The 2020 TSR RSUs were valued using the Monte Carlo Simulation method and will be amortized over the life of the RSUs based on the agreements.

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 is 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, 2020 and 2019, no excess tax benefits for the tax deductions related to share-based awards were recognized in the condensed consolidated statements of operations.

Equity instruments issued to non-employees for services are accounted for under the provisions of ASC Topic 718 and ASC Topic 505-50, *Equity/Equity-Based Payments to Non-Employees*. Accordingly, the estimated fair value of the equity instrument is recorded on the earlier of the performance commitment date or the date the required services are completed and are marked to market during the service period.

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.

In December 2019, the Company adopted the Intra-Cellular Therapies, Inc. 2019 Inducement Award Plan (the "2019 Inducement Plan") without stockholder approval pursuant to Rule 5635(c)(4) of the Nasdaq Listing Rules. Pursuant to the 2019 Inducement Plan, the Company may grant stock options, RSUs, stock awards and other stock-based awards for up to a total of 1,000,000 shares of common stock to new employees of the Company. As of March 31, 2020, stock options and RSUs for 314,138 shares have been granted under the 2019 Inducement Plan.

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 could be anti-dilutive as applied to the loss from operations for the three months ended March 31, 2020 and 2019:

	Three Months Ended March 31,	
	2020	2019
Stock Options	6,408,389	6,012,069
RSUs	1,695,397	1,296,634
TSR RSUs	86,044	269,129

Recently Issued Accounting Standards

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. The Company adopted this standard on January 1, 2020. The Company evaluated the implications of the new standard, inclusive of the applicable financial statement disclosures required, as well as to its internal controls, business processes, and accounting policies, noting there was no significant impact to the financial statements as of January 1, 2020 and for the three-month period ended March 31, 2020.

3. Revenue

On December 20, 2019, the FDA approved CAPLYTA for the treatment of schizophrenia in adults. Subsequent to receiving FDA approval, the Company entered into its initial contracts with a limited number of Customers to distribute CAPLYTA. These contracts will be accounted for under ASC Topic 606, which was adopted in a prior period. Under ASC Topic 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to be entitled in exchange for those goods or services.

To date, the Company's only source of product sales has been from the U.S. sales of CAPLYTA, which it began shipping to Customers in March 2020. The product sales, net for the quarter ended March 31, 2020 were $882,516.

4. Inventory

Inventory consists of the following:

	March 31, 2020
Raw materials	$ —
Work in process	1,250,025
Finished goods	141,099
Total inventories	$1,391,124

Inventory acquired prior to receipt of the FDA approval on December 20, 2019 for CAPLYTA was expensed as research and development expense as incurred. No inventory was produced from the FDA approval date through the end of 2019; therefore, no inventory was capitalized on the consolidated balance sheet as of December 31, 2019.

5. Property and Equipment

Property and equipment consist of the following:

	March 31, 2020	December 31, 2019
Computer equipment	**$ 243,532**	$ 243,532
Furniture and fixtures	**423,097**	423,097
Scientific equipment	**3,883,276**	3,861,227
Leasehold improvements	**1,240,315**	1,240,315
	5,790,220	5,768,171
Less accumulated depreciation	**(3,657,233)**	(3,508,431)
	$ 2,132,987	$ 2,259,740

Depreciation expense for the three months ended March 31, 2020 and 2019 was $148,802 and $101,353, respectively.

6. Right of Use Assets and Lease Liabilities

Real Estate Leases

In 2014, the Company entered into a long-term lease with a related party which, as amended, provided for a lease of useable laboratory and office space located in New York, New York. 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 lease and is characterized as a lease in accordance with ASU 2016-02 for accounting purposes. In September 2018, the Company further amended the lease to obtain additional 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. In February 2019, the Company entered into a long-term lease for office space in Towson, Maryland beginning March 1, 2019. The lease has a term of 3.2 years ending in April 2022 and includes limited rent abatement and escalation provisions.

In adopting ASU 2016-02 as of January 1, 2019, the Company elected the package of practical expedients, which permit the Company not to reassess under the new standard the historical lease classification. The Company made an accounting policy election to keep leases with an initial term of 12 months or less off of the condensed consolidated balance sheets. The Company also elected the lessee component election, allowing the Company 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 the Company's leases do not provide an implicit rate, the Company uses its 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 7.2% for the Company's

Maryland lease of 3.2 years and 9.1% for the Company's 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. At the execution of the Maryland lease in 2019, the Company recorded a right of use asset and a lease liability of $0.2 million, which represented a non-cash transaction.

Maturity analysis under the lease agreements are as follows:

Nine months ending December 31, 2020	$ 2,515,636
Year ending December 31, 2021	3,448,323
Year ending December 31, 2022	3,491,166
Year ending December 31, 2023	3,566,466
Year ending December 31, 2024	3,675,196
Thereafter	17,627,041
Total	34,323,828
Less: Present value discount	(11,488,613)
Total Lease liability	$ 22,835,215
Less: Current portion	(3,211,234)
Long-term lease liabilities	$ 19,623,981

Lease expense for the three months ended March 31, 2020 and 2019 was approximately $818,000 and $830,000, respectively.

Vehicle Fleet Lease

On May 17, 2019, the Company entered into an agreement (the "Vehicle Lease") with a company (the Lessor) to acquire motor vehicles for certain employees. The Vehicle Lease provides for individual leases for the vehicles, which at each lease Commencement was determined to qualify for operating lease treatment. The Company began leasing vehicles under the Vehicle Lease in March 2020.

The contractual period of each lease is 12 months, followed by month-to-month renewal periods. The Company estimates the lease term for each vehicle to be 30 months based on industry standards. The lease permits either party to terminate the lease at any time via written notice to the other party. The Company neither acquires ownership, nor has the option to purchase the vehicles at any time. The Company is required to maintain an irrevocable $1.4 million letter of credit that the Lessor may draw upon in the event the Company defaults on the Vehicle Lease. The $1.4 million was recorded as restricted cash on the condensed consolidated balance sheet.

The nature of the lease is one commonly referred to as "TRAC" lease, as it contains a terminal rental adjustment clause, or "TRAC" clause." The TRAC clause limits lessee exposure, or likelihood of having a variable lease payment due at lease termination. This variable lease payment amount would be any difference between the vehicle stipulated (capitalized) cost and the sum of the reserve and net proceeds from disposal as described in the Vehicle Lease. Further, the Lessor guarantees that the net proceeds will not be less than 20% of the vehicle capitalized cost in the first 12 months, and 30% of the vehicle capitalized cost at the beginning of subsequent 12-month period increments.

Right of use asset and lease liability for the vehicle fleet lease were approximately $94,042 and $94,042, respectively, as of March 31, 2020 which represented a non-cash transaction. The operating cash outflows related to vehicle fleet operating lease obligations for the quarter ended March 31, 2020 were $3,335.

The following table presents the Vehicle Lease balances within the condensed consolidated balance sheet, weighted average remaining fleet lease term, and the weighted average discount rates related to the Vehicle Lease as of March 31, 2020:

Lease Assets and Liabilities – Fleet	Classification	March 31, 2020
Assets		
Right of use assets, net	Operating lease right of use assets	$ 94,042
		$ 94,042
Liabilities		
Current		
Lease liabilities, short-term	Operating lease liabilities	$ —
Non-Current		
Lease liabilities	Non-current operating lease liabilities	94,042
Total lease liabilities		$ 94,042
Weighted average remaining lease term		2.4 years
Weighted average discount rate		1.80%

The following table presents the maturity of the Company's fleet lease liability as of March 31, 2020:

Nine months ending December 31, 2020	$ 20,555
Year ending December 31, 2021	27,407
Year ending December 31, 2022	49,797
Year ending December 31, 2023	—
Year ending December 31, 2024	—
Thereafter	—
Total	97,759
Less: Present value discount	(3,717)
Total operating lease liabilities	$ 94,042
Less: Current portion	—
Long-term lease liabilities	$ 94,042

Right of use assets and lease liabilities for operating leases were approximately $18.1 million and $22.9 million, respectively, as of March 31, 2020.

7. 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. In December 2019, the Company adopted the 2019 Inducement Plan for the grant of equity awards of up to 1,000,000 shares of common stock to newly hired employees.

As of December 31, 2019, the total number of shares reserved under all equity plans was 11,287,390 and the Company had 2,208,317shares available for future issuance under the 2018 Plan and the 2019 Inducement Plan. Stock options granted under the 2018 Plan and the 2019 Inducement 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 and the 2019 Inducement 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, 2020 and 2019, was comprised of the following:

	Three Months Ended March 31,	
	2020	2019
Inventoriable costs	**$ 293,384**	$ —
Research and development	**2,006,855**	2,407,644
General and administrative	**3,204,058**	2,647,573
Total share-based compensation expense	**$5,504,297**	$5,055,217

The following table describes the weighted-average assumptions used for calculating the value of options granted during the three months ended March 31, 2020 and 2019:

	2020	**2019**
Dividend yield	**0%**	0%
Expected volatility	**91.6-92.5%**	85.7%
Weighted-average risk-free interest rate	**1.42%**	2.52%
Expected term (in years)	**6.0**	6.0

Information regarding stock option awards under the 2019 Inducement Plan, including with respect to grants to employees as of March 31, 2020, 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, 2019	—	$ —	
Options granted in 2020	39,728	$ 17.18	10.0 years
Outstanding at March 31, 2020	39,728	$ 17.18	10.0 years
Vested or expected to vest at March 31, 2020	39,728	$ 17.18	
Exercisable at March 31, 2020	—	$ —	

Information regarding RSU awards under the 2019 Inducement Plan time and changes during the three-month period ended March 31, 2020 are summarized as follows:

	Number of Shares	**Weighted-Average Exercise Price**	**Weighted-Average Contractual Life**
Outstanding at December 31, 2019	—	$ —	
Time based RSUs granted in 2020	274,410	$ 16.01	10.0 years
Outstanding at March 31, 2020	274,410	$ 16.01	10.0 years
Vested or expected to vest at March 31, 2020	274,410	$ 16.01	
Exercisable at March 31, 2020	—	$ —	

As of March 31, 2020, the Company issued options and time based RSUs totaling 314,138 shares in the 2019 Inducement Award Plan.

Information regarding the stock options activity, including with respect to grants to employees, directors and consultants as of March 31, 2020, 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, 2019	6,039,945	$ 16.81	7.0 years
Options granted	656,433	$ 23.94	9.9 years
Options exercised	(211,961)	$ 7.81	4.0 years
Options canceled or expired	(115,756)	$ 16.01	8.8 years
Outstanding at March 31, 2020	6,368,661	$ 17.86	7.1 years
Vested or expected to vest at March 31, 2020	6,368,661	$ 17.86	
Exercisable at March 31, 2020	3,869,771	$ 18.95	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, 2020 are summarized as follows:

	Number of Shares	Weighted-Average Grant Date Fair Value Per Share	Weighted-Average Contractual Life
Outstanding at December 31, 2019	1,268,679	$ 13.60	1.7 years
Time based RSUs granted in 2020	698,336	$ 23.94	2.9 years
Time based RSUs vested in 2020	(466,657)	$ 13.82	1.3 years
Time based RSUs cancelled in 2020	(79,371)	$ 16.25	1.9 years
Outstanding at March 31, 2020	1,420,987	$ 18.46	2.4 years

Information related to the Company's Milestone RSUs and TSR RSUs during the three-month period ended March 31, 2020 are summarized as follows:

	Number of Shares	Weighted-Average Grant Date Fair Value Per Share	Weighted-Average Contractual Life
Outstanding at December 31, 2019	67,080	$ 17.08	0.2 years
Milestone RSUs and TSR RSUs granted in 2020	86,044	$ 33.47	2.9 years
Milestone RSUs and TSR RSUs vested in 2020	(67,080)	$ 17.08	0.2 years
Outstanding at March 31, 2020	86,044	$ 33.47	2.9 years

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 remained in the service of the Company on the settlement date. The Company expensed the cost of these awards ratably over the requisite service period. The number of shares for which the TSR RSUs was settled was a percentage of shares for which the award is targeted and depended 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 were be settled varied depending on the level of achievement of the goal. Total shareholder return was 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 included 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, 2020 and 2019 of approximately $2.4 million and $1.9 million, respectively. Total expense for all RSUs, including the time based and performance based RSUs, is $2.5 million and $2.1 million for the three months ended March 31, 2020 and 2019, respectively. As of March 31, 2020, there was $28.0 million of unrecognized compensation costs related to unvested time based RSUs. As of March 31, 2020, there was $1.3 million of unrecognized compensation costs related to unvested Milestone RSUs and TSR RSUs.

8. Collaborations and License Agreements

The Bristol-Myers Squibb License Agreement

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

Under the agreement, the Company made an upfront payment of $1.0 million to BMS, a milestone payment of $1.25 million in December 2013, and a milestone payment of $1.5 million in December 2014 following the initiation of the Company's first Phase 3 clinical trial for lumateperone for patients with exacerbated schizophrenia. Upon FDA acceptance of an NDA filing for lumateperone, the Company was obligated to pay BMS a $2.0 million milestone payment. The Company achieved the acceptance in the third quarter of 2018 and has therefore accrued the $2.0 million milestone liability, which was paid in January 2019. The FDA approved the NDA filing on December 23, 2019 and as a result the Company accrued an additional milestone liability of $5.0 million in the fourth quarter of 2019 which was paid in January 2020. Possible milestone payments remaining total $5.0 million. Under the agreement, the Company may be obliged to make other milestone payments to BMS for each licensed product of up to an aggregate of approximately $14.75 million. The Company is also obliged to make tiered single digit percentage royalty payments 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.

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. With the initial recognition of product sales revenue in the first quarter of 2020, the Company accrued approximately $44,000 in royalties to satisfy its obligation 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 March 2, 2020. In addition to historical information, the following discussion and analysis includes forward-looking information that involves risks, uncertainties and assumptions. Our actual results and the timing of events could differ materially from those anticipated by these forward-looking statements as a result of many factors, including those discussed under "Risk Factors" in our Annual Report on Form 10-K filed on March 2, 2020, 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, clinical development and commercialization 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. In December 2019 CAPLYTA (lumateperone) was approved by the FDA for the treatment of schizophrenia in adults (42mg/day) and we initiated the commercial launch of CAPLYTA in late March of 2020. In support of our commercialization efforts, we hired a national sales force consisting of approximately 240 sales representatives. The launch price for CAPLYTA is in line with other currently marketed branded antipsychotics indicated for the treatment of schizophrenia. As used in this report, "CAPLYTA" refers to lumateperone approved by the FDA for the treatment of schizophrenia in adults, and "lumateperone" refers to, where applicable, CAPLYTA as well as lumateperone for the treatment of indications beyond schizophrenia.

Lumateperone is also in Phase 3 clinical development as a novel treatment for bipolar depression. Our lumateperone bipolar depression Phase 3 clinical program currently consists of three monotherapy studies and one adjunctive study. In the first quarter of 2020 we initiated our third monotherapy Phase 3 study, Study 403, evaluating lumateperone as monotherapy in the treatment of major depressive episodes associated with Bipolar I or Bipolar II disorder. While patient enrollment in Study 403 in the U.S. has been impacted by the coronavirus (COVID-19) pandemic, country regulatory review processes and other preparatory activities outside the U.S. continue to progress. Subject to patient enrollment rates returning to our projected levels within our expected timelines, we anticipate reporting topline results from Study 403 in the second half of 2021. On July 8, 2019, we announced topline results from our first monotherapy study, Study 401, conducted in the U.S., and our second monotherapy study, Study 404, conducted globally, evaluating lumateperone as monotherapy in the treatment of major depressive episodes associated with Bipolar I or Bipolar II disorder. In Study 404, lumateperone 42 mg met the primary endpoint for improvement in depression as measured by change from baseline versus placebo on the MADRS total score ($p<0.0001$; effect size = 0.56). Study 401 tested two doses of lumateperone, 42 mg and 28mg along with placebo. In this trial, neither dose of lumateperone met the primary endpoint of statistical separation from placebo as measured by change from baseline on the MADRS total score. There was a high placebo response in this trial. Lumateperone was generally well-tolerated in both bipolar depression studies, with a favorable safety profile. The rates of discontinuation due to treatment emergent adverse events for both doses of lumateperone were low. We completed patient enrollment in our global study evaluating adjunctive lumateperone in bipolar depression, Study 402, and we anticipate reporting topline results from this study in mid-2020. Subject to the results of Study 402 and our interactions with the FDA regarding our bipolar depression program, in late 2020 we expect to submit a supplemental new drug application, or sNDA, to the FDA for potential regulatory approval of lumateperone for the treatment of bipolar depression.

We are also pursuing clinical development of lumateperone for the treatment of additional CNS diseases and disorders. We believe lumateperone may have utility for treating agitation, aggression and sleep disturbances in diseases that include dementia, Alzheimer's disease, or AD, Huntington's disease and autism spectrum disorders. At a dose of 42 mg, lumateperone has been shown effective in treating the symptoms associated with schizophrenia, and we believe this dose may merit further investigation for the treatment of bipolar disorder, depressive disorders and other neuropsychiatric diseases.

Within the lumateperone portfolio, we are also developing a long-acting injectable formulation to provide more treatment options to patients suffering from mental illness. We have completed the preclinical development of a long-acting injectable formulation and plan to initiate a Phase 1 clinical trial in 2020. 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.

We may investigate the use of lumateperone, either on our own or with a partner, as a treatment for 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 inhibit the enzyme phosphodiesterase type 1, or PDE1. PDE1 enzymes are highly active in multiple disease states and our PDE1 inhibitors are designed to reestablish normal function in these disease states. Abnormal PDE1 activity is associated with cellular proliferation and activation of inflammatory cells. Our PDE1 inhibitors ameliorate both of these effects in animal models. We intend to pursue the development of our phosphodiesterase, or PDE, program, for the treatment of several CNS and non-CNS conditions with a focus on diseases where excessive PDE1 activity has been demonstrated and increased inflammation is an important contributor to disease pathogenesis. Our potential disease targets include heart failure, immune system regulation, neurodegenerative diseases, and other non-CNS disorders. 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. Following the favorable 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. The first clinical study in this program, is a randomized, double-blind, placebo-controlled Phase 1/2 study of escalating single doses of ITI-214 to evaluate safety and hemodynamic effects in patients with systolic heart failure and we anticipate reporting topline results from this study in the first half of 2020.

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. Preclinical safety studies with ITI-333 are currently ongoing and we expect to initiate a clinical program in 2020.

We have assembled a management team with significant industry experience to lead the discovery, development and commercialization of our product candidates. We complement our management team with a group of scientific and clinical advisors that includes recognized experts in the fields of schizophrenia and other CNS disorders.

Results of Operations

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

Revenues

Net revenues from product sales consist of sales of CAPLYTA, which was approved by the FDA on December 2019. We initiated the commercial launch of CAPLYTA in late March 2020 and generated approximately $882,500 in net revenue from product sales in the quarter ended March 31, 2020. In addition, we had approximately $201,000 of grant revenues for the three months ended March 31, 2020 compared to no grant revenue for the three months ended March 31, 2019. 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, developing and commercializing 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 costs associated with the commercialization of CAPLYTA will be substantial and will be incurred prior to our generating sufficient revenue to offset these costs. Costs for the clinical development of lumateperone for the treatment of bipolar depression consumes and, together with our anticipated clinical development programs for depressive disorders and 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.

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 and our clinical development program for this indication is ongoing. 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) costs of product sales; (ii) research and development expenses; (iii) general and administrative and (iv) selling expenses.

Costs of product sales are comprised of:

- Direct costs of formulating, manufacturing and packaging drug product

- Overhead costs consisting of labor, customs, stock based compensation, shipping, outside inventory management and other miscellaneous operating costs; and
- Royalty payments on product sales.

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, and professional costs; and
- office and facilities overhead.

Selling expenses are incurred in three major categories:

- salaries and related benefit costs of a dedicated sales force;
- sales operation costs; and
- marketing and promotion expenses.

Product sold through March 31, 2020 generally consisted of drug product that was previously charged to research and development expense prior to FDA approval of CAPLYTA. Because the Company previously expensed drug product the cost of drug product sold is lower than it would have been and has a positive impact on our cost of product sales and related product gross margins for the three months ended March 31, 2020. The Company's reported cost of product sales as a percentage of product sales, net was 7.9% or approximately $69,000 for the three months ended March 31, 2020. Had direct and overhead costs not been previously recognized into research and development expense, the percentage would have been 14.7% or approximately $130,000.

We will continue to have these favorable results until our sales of CAPLYTA include drug product that is manufactured after the FDA approval. We are currently unable to estimate how long it will be until we begin selling product manufactured post FDA approval.

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 depression and depressive disorders, other clinical trials, increased manufacturing of drug product for clinical trials and pre-clinical development activities. We also expect that our general and administrative costs will increase from prior periods primarily due to costs associated with building infrastructure to support the anticipated commercial sales of CAPLYTA, which will 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 1,833,102 shares of our common stock in 2019 and have granted options to purchase an additional 696,161 shares of our common stock in the first quarter of 2020. We also granted time based restricted stock units, or RSUs, for 950,449 of our common stock in 2019 and time based RSUs for 972,746 shares of our common stock in the first quarter of 2020. We will recognize expense associated with these RSUs and options over 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 for lumateperone for the treatment of schizophrenia, (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 NDA approval milestone was achieved in the fourth quarter of 2019. The Milestone RSUs related to the NDA approval vested on December 31, 2019. The TSR RSUs were valued using the Monte Carlo simulation method and were amortized over the life of the RSU's which vested on January 24, 2020. In the first quarter of 2020, we also granted performance based RSUs, which vest based on the achievement of certain milestones that include (i) the approval of a planned NDA by the FDA, or the 2020 Milestone RSUs, and (ii) the achievement of certain comparative shareholder returns against our peers, or the 2020 TSR RSUs. The 2020 Milestone RSUs were valued at the closing price on February 18, 2020. The 2020 TSR RSUs were valued using the Monte Carlo simulation method. 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.

The following table sets forth our revenues, operating expenses, interest income and income tax expense for the three-month periods ended March 31, 2020 and 2019 (in thousands):

	For the Three Months Ended March 31,	
	2020	2019
	(Unaudited)	
Revenues		
Product sales, net	**$ 882**	$ —
Grant revenue	**201**	—
Total revenues, net	**1,083**	—
Expenses		
Cost of product sales	**69**	—
Research and development	**16,003**	24,991
General and administrative	**34,097**	11,705
Total costs and expenses	**50,169**	36,696
Loss from operations	**(49,086)**	(36,696)
Interest income	**1,678**	1,860
Income tax expense	**(3)**	—
Net loss	**$ (47,411)**	$ (34,836)

Comparison of Three-Month Periods Ended March 31, 2020 and March 31, 2019

Revenues

Revenues for the three months ended March 31, 2020 and 2019 were $1,083,479 and zero, respectively. Net product sales were approximately $882,500 for the three months ended March 31, 2020 and were comprised of sales of CAPYLTA, which was approved by the FDA on December 20, 2019 and became available to wholesalers in March 2020. No similar net product sales were recognized during the three months ended March 31, 2019. In addition, revenue from a government grant was approximately $201,000 for the three months ended March 31, 2020.

Cost of Product Sales

Cost of product sales was approximately $69,000 for the three months ended March 31, 2020. Cost of product sales consisted primarily of product royalty fees, overhead and minimal direct costs. Product sold during the three months ended March 31, 2020 generally consisted of drug product that was previously charged to research and development expense prior to FDA approval of CAPLYTA. This minimal cost drug product had a positive impact on our cost of product sales and related product gross margins for the three months ended March 31, 2020. We will continue to have a lower cost of product sales that excludes the cost of the drug product that was incurred prior to FDA approval until our sales of CAPLYTA include drug product that is manufactured after the FDA approval. We expect that this will be the case for the near-term and as a result, our cost of product sales will be less than we anticipate it will be in future periods. No similar cost of product sales was recognized during the three months ended March 31, 2019.

Research and Development Expenses

The following tables set forth our research and development expenses for the three-month periods ended March 31, 2020 and 2019 (in thousands):

	Three Months Ended March 31,	
	2020	2019
External costs	**$ 9,007**	$ 17,809
Internal costs	**6,996**	7,182
Total research and development expenses	**$ 16,003**	$ 24,991

	Three Months Ended March 31,	
	2020	2019
Lumateperone costs	**$ 7,046**	$ 14,489
Manufacturing costs	**2,673**	5,860
Stock based compensation	**2,300**	2,408
Other projects and overhead	**3,984**	2,234
Total research and development expenses	**$ 16,003**	$ 24,991

Research and development expenses decreased to $16.0 million for the three month period ended March 31, 2020 as compared to $25.0 million for the three month period ended March 31, 2019, representing a decrease of approximately 36%. This decrease is due primarily to a decrease of approximately $4.6 million of costs associated with lumateperone clinical costs, a decrease of approximately $3.2 million in manufacturing expense, a decrease of $2.8 million of costs associated with lumateperone non-clinical costs, a decrease of approximately $0.1 million for stock compensation expense, all of which are partially offset by an increase of approximately $1.7 million of non lumateperone related projects.

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 approval. We received FDA approval on December 20, 2019 for lumateperone as a treatment for schizophrenia.

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 for the year ended December 31, 2019, as updated by the section entitled "Risk Factors" in this Quarterly Report on Form 10-Q and from time to time in our other periodic and current reports filed with the SEC.

Selling, General and Administrative Expenses

Selling, general and administrative costs for the three-month period ended March 31, 2020 were $34.1 million as compared to $11.7 million in the three-month period ended March 31, 2019 which represents an increase of 191%. Below is a breakout of these expenses into selling and general administrative costs for the periods.

General and administrative expenses were $13.3 million in 2020 as compared to $6.5 million for the same period in 2019, an increase of 103%. This increase is due to increased professional fees of $2.1 million, labor and bonus expense of $1.5 million, information technology services of $1.5 million, stock compensation expense of approximately $0.6 million, and the remainder on insurance, lease expense, and other administrative expenses. Salaries, bonuses and related benefit costs for our general and administrative functions for the three months ended March 31, 2020 and 2019 constituted approximately 47% and 64%, respectively, of our general and administrative costs.

Selling costs were $20.8 million for the three-month period ended March 31, 2020 as compared to pre-commercialization costs of $5.2 million in the same period in 2019, or an increase of 304%. This increase is primarily due to an increase in sales related labor costs of $9.9 million and commercialization costs of $5.8 million. Salaries, bonuses and related benefit costs for our sales and marketing functions for the three months ended March 31, 2020 and 2019 constituted approximately 53% and 23%, respectively, of our selling costs.

We expect selling, general and administrative costs to increase significantly from the first quarter 2020 as the onboarding of our sales force was completed during the three months ended March 31, 2020 and we are expanding post approval marketing and market access efforts as well as our administrative infrastructure.

Liquidity and Capital Resources

Through March 31, 2020, we provided funds for our operations by obtaining a total of approximately $1.2 billion 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 a terminated license and collaboration agreement. We do not believe that grant revenue will be a significant source of funding in the near future.

On January 10, 2020, we completed a public offering of 10,000,000 shares of our common stock. All of the shares in the offering were sold by the Company, with gross proceeds to the Company of $295.0 million and net proceeds of approximately $277.0 million, after deducting underwriting discounts, commissions and offering expenses.

As of March 31, 2020, we had a total of approximately $450.4 million in cash and cash equivalents, available-for-sale investment securities, restricted cash and approximately $31.1 million of short-term liabilities consisting entirely of liabilities from operations, including approximately $3.2 million of short-term lease obligations. In the three months ended March 31, 2020, we spent approximately $52.9 million in cash for operations and equipment, not including an offset of $1.7 million of interest income. We reduced working capital by approximately $41.2 million for the three months ended March 31, 2020. The use of cash was primarily for selling and marketing costs in connection with our commercial launch of CAPLYTA, conducting clinical trials and non-clinical testing, product manufacturing, and funding recurring operating expenses.

Based on our current operating plans, we expect that our existing cash, cash equivalents and marketable securities will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months from the filing date of this quarterly report. During that time, we expect that our expenses will increase substantially due primarily to our commercialization activities and related infrastructure expansion in connection with the commercialization of CAPLYTA 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; the continuation of manufacturing activities for anticipated future sales of product and in connection with the development of lumateperone; and general operations.

For the remainder of the year 2020, we expect to spend up to $230 million primarily related to the marketing and commercialization of CAPLYTA, lumateperone clinical development including clinical trial conduct, regulatory activities, manufacturing, expansion of our administrative infrastructure and other development activities. Our other development activities will include efforts related to the ITI-214 and ITI-333 programs, among others. However, the COVID-19 pandemic may negatively impact our commercialization of CAPLYTA, our ability to complete our ongoing or planned preclinical and clinical trials, our ability to obtain approval of any product candidates from the FDA or other regulatory authorities, and our workforce and therefore our research, development and commercialization activities. This may ultimately have a material adverse effect on our liquidity, although we are unable to make any prediction with certainty given the rapidly changing nature of the pandemic and governmental and other responses to it.

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 commercialize CAPLYTA 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 our 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 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 a license agreement that has been terminated. These losses have resulted in significant cash used in operations. For the three months ended March 31, 2020, we used net cash in operating activities and purchases of equipment of approximately $52.9 million. This total does not include an offset for $1.7 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 beyond schizophrenia 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 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. 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, is ongoing. We expect these expenses to increase in the next several years.

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 August 30, 2019, we filed a universal shelf registration statement on Form S-3, which was declared effective by the SEC on September 12, 2019, on which we registered for sale up to $350 million of any combination of our common stock, preferred stock, debt securities, warrants, rights and/or units from time to time and at prices and on terms that we may determine, which includes up to $75 million of common stock that we may issue and sell from time to time, through SVB Leerink LLC acting as our sales agent, pursuant to the sale agreement that we entered into with SVB Leerink on August 29, 2019 for our “at-the-market” equity program. In addition, on January 6, 2020, we filed an automatic shelf registration statement on Form S-3 with the SEC, which became effective upon filing, on which we registered for sale an unlimited amount of any combination of its common stock, preferred stock, debt securities, warrants, rights, and/or units from time to time and at prices and on terms that we may determine, so long as we continue to satisfy the requirements of a “well-known seasoned issuer” under SEC rules. These registration statements will remain in effect for up to three years from the respective dates they became effective.

We cannot be sure that future funding will be available to us when we need it on terms that are acceptable to us, or at all. We sell securities and incur debt when the terms of such transactions are deemed favorable to us and as necessary to fund our current and projected cash needs. The amount of funding we raise through sales of our common stock or other securities depends on many factors,

including, but not limited to, the magnitude of sales of CAPLYTA, 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. Additionally, the continued spread of COVID-19 and uncertain market conditions may limit our ability to access any financing. In addition, any unfavorable results in the commercialization of CAPLYTA and 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 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 characterized as a lease in accordance with ASU 2016-02 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. 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. We anticipate acquiring additional space in 2020 to accommodate our commercial and infrastructure expansion which could result in a moderate increase in facility costs. On May 17, 2019, we entered into a vehicle fleet lease with a company to acquire motor vehicles for certain employees. The vehicle fleet lease provides for individual leases for the vehicles, which at each lease commencement was determined to qualify for operating lease treatment. We began leasing vehicles under the vehicle fleet lease in March 2020.

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, 2019 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, 2020. With the launch of product sales this quarter, the accounting policy for revenue recognition, which was previously developed, was implemented.

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 research and development, including 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 Standards" in Note 2 to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q, and "Recently Issued Accounting Standards" in Note 2 to our audited consolidated financial statements and "Recently Issued Accounting Pronouncements" in our Annual Report on Form 10-K for the year ended December 31, 2019 filed on March 2, 2020.

Certain Factors That May Affect Future Results of Operations

The SEC encourages companies to disclose forward-looking information so that investors can better understand a company's future prospects and make informed investment decisions. This Quarterly Report on Form 10-Q contains such "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These statements involve known and unknown risks, uncertainties and other important factors which may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. Forward-looking statements include, but are not limited to, statements about: the accuracy of our estimates regarding expenses, future revenues, uses of cash, cash equivalents and investment securities, capital requirements and the need for additional financing; our expectations regarding our commercialization of CAPLYTA, including the impact of COVID-19 on the commercialization of CAPLYTA and our ability to adapt our approach as appropriate; the supply and availability of and demand for our product, the initiation, cost, timing, progress and results of our development activities, non-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 lumateperone and our other 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 lumateperone and our other 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 lumateperone and our other 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, the following: there are no guarantees that CAPLYTA will be commercially successful; we may encounter issues, delays or other challenges in launching or commercializing CAPLYTA; the COVID-19 pandemic may negatively impact our commercial plans and sales for CAPLYTA; the COVID-19 pandemic may negatively impact the conduct of, and the timing of enrollment, completion and reporting with respect to, our clinical trials, whether CAPLYTA receives adequate reimbursement from third-party payers; the degree to which CAPLYTA receives acceptance from patients and physicians for its approved indication; challenges associated with execution of our sales activities, which in each case could limit the potential of our product; results achieved in CAPLYTA in the treatment of schizophrenia following commercialization may be different than observed in clinical trials, and may vary among patients; any other impacts on our business as a result of or related to the COVID-19 pandemic; risks associated with our current and planned clinical trials; we may encounter unexpected safety or tolerability issues with CAPLYTA for the treatment of schizophrenia or in ongoing or future trials and other development activities; our other product candidates may not be successful or may take longer and be more costly than anticipated; product candidates that appeared promising in earlier research and clinical trials may not demonstrate safety and/or efficacy in larger-scale or later clinical trials; our proposals with respect to the regulatory path for our product candidates may not be acceptable to the FDA; our reliance on collaborative partners and other third parties for development of our product candidates; and the other risk factors detailed under the heading "Risk Factors" in our most recent Annual Report on Form 10-K, as updated under the heading "Risk Factors" 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, 2020, we had cash, cash equivalents, marketable securities and restricted cash of approximately $450.4 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 the recent changes in interest rates or through potential changes in the credit worthiness of the issuers of our available-for-sale securities. The recent changes the market place resulted in an unrealized loss of approximately $145,000 for the three months ended March 31, 2020, compared to an unrealized gain of approximately $128,000 for the year ended of December 31, 2019. We have the ability and plan to hold these investments to maturity. Declines in interest rates, however, would reduce future investment income.

Capital Market Risk. We currently have limited 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 at a reasonable assurance level 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, 2020, we implemented ASU No. 2016-13, "Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments" ("ASU 2016-13"). Although the adoption of the new accounting standard did not materially impact our condensed consolidated balance sheet, statements of operations and cash flows as of and for the three months ended March 31, 2020, we did implement new internal control procedures to support the new accounting and reporting processes associated with adopting the guidance. Prior to the launch of product sales this quarter, we implemented internal controls and business processes around revenue recognition and inventory. 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, 2020 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

Except as set forth below, 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, 2019, filed with the Securities and Exchange Commission on March 2, 2020.

The outbreak of the novel strain of coronavirus, SARS-CoV-2, or similar public health crises, could have a material adverse impact on our business, financial condition and results of operations, including our commercial operations and sales, clinical trials and preclinical studies.

Public health crises, such as pandemics or similar outbreaks, could adversely impact our business. In December 2019, a novel strain of coronavirus, SARS-CoV-2, which causes coronavirus disease 2019 (COVID-19), surfaced in Wuhan, China. Since then, SARS-CoV-2 and COVID-19 have spread to multiple countries, including the United States. The COVID-19 pandemic is evolving, and to date has led to the implementation of various responses, including government-imposed quarantines, travel restrictions and other public health safety measures. In response to the spread of SARS-CoV-2 and COVID-19, we have instructed the majority of our office-based employees to work from home. Our increased reliance on personnel working from home may negatively impact productivity, or disrupt, delay, or otherwise adversely impact our business. In addition, this could increase our cyber security risk, create data accessibility concerns, and make us more susceptible to communication disruptions, any of which could adversely impact our business operations or delay necessary interactions with local and federal regulators, ethics committees, manufacturing sites, research or clinical trial sites and other important agencies and contractors. In connection with our commercial launch of CAPLYTA, which is approved by U.S. Food and Drug Administration for the treatment of schizophrenia in adults, our commercial organization and sales force and medical organization are having significantly reduced personal interactions with physicians and customers and increasingly conduct promotional activities virtually, and we have elected to cease in-person interactions with physicians and customers entirely for some period of time in the interest of employee and community safety. As a result of the COVID-19 outbreak, or similar pandemics, we may experience disruptions that could severely impact our business, including our ability to successfully commercialize our only commercial product, CAPLYTA, in the U.S., and these disruptions could negatively impact our sales of CAPLYTA. Business interruptions from the current or future pandemics may also adversely impact the third parties we rely on to sufficiently manufacture CAPYLTA and to produce our product candidates in quantities we require, which may impair the commercialization and our research and development activities.

We are currently conducting clinical trials for our product candidates in many countries, including the United States, Europe and Russia and may expand to other geographies. Timely enrollment of, completion of and reporting on our clinical trials is dependent upon these global clinical trial sites which are, or in the future may be, adversely affected by the COVID-19 outbreak or other pandemics. Some factors from the COVID-19 outbreak that may adversely affect the timing and conduct of our clinical trials and adversely impact our business generally, include but are not limited to delays or difficulties in clinical site initiation, diversion of healthcare resources away from clinical trials to pandemic concerns, limitations on travel, regulatory delays and supply chain disruptions.

The COVID-19 outbreak continues to rapidly evolve, and the extent to which the outbreak impacts our business, including our commercial results, clinical trials, and preclinical studies will depend on future developments, which are highly uncertain.

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, 2020.

Item 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

Item 5. OTHER INFORMATION

Not applicable.

Item 6. EXHIBITS

Exhibit Number	Exhibit Description	Filed Herewith	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/ Reg. Number
10.1	Non-Employee Director Compensation Policy, as amended.*		Form 10-K (Exhibit 10.28)	3/2/2020	001-36274
31.1	Certification of the Registrant's Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X			
31.2	Certification of the Registrant's Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X			
32	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X			
101	The following materials from the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2020, formatted in Inline XBRL (eXtensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets as of March 31, 2020 (unaudited) and December 31, 2019 (audited), (ii) Condensed Consolidated Statements of Operations (unaudited) for the three months ended March 31, 2020 and 2019, (iii) Condensed Consolidated Statements of Comprehensive Loss (unaudited) for the three months ended March 31, 2020 and 2019, (iv) Condensed Consolidated Statements of Stockholders' Equity (unaudited) for the three months ended March 31, 2020 and 2019, (v) Condensed Consolidated Statements of Cash Flows (unaudited) for the three months ended March 31, 2020 and 2019, and (vi) Notes to Condensed Consolidated Financial Statements (unaudited).	X			
104	Cover Page Interactive Date File (formatted as Inline XBRL and contained in Exhibit 101).	X			

* Management contract or compensatory plan or arrangement.

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 7, 2020

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

Date: May 7, 2020

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

Exhibit 31.1

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 7, 2020

/s/ Sharon Mates, Ph.D.

Sharon Mates, Ph.D.
Chairman, President and Chief Executive Officer
(principal executive officer)

Exhibit 31.2

CERTIFICATIONS UNDER SECTION 302

I, Lawrence J. Hineline, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: May 7, 2020

/s/ Lawrence J. Hineline

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

Exhibit 32

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, 2020 (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 7, 2020

/s/ Sharon Mates, Ph.D.

Sharon Mates, Ph.D.
Chairman, President and Chief Executive Officer
(principal executive officer)

Dated: May 7, 2020

/s/ Lawrence J. Hineline

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