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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 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 November 6, 2020, the registrant had 80,157,554 shares of common stock outstanding.

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Intra-Cellular Therapies, Inc.

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

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PART I: FINANCIAL INFORMATION

Item 1. FINANCIAL STATEMENTS

Intra-Cellular Therapies, Inc. and Subsidiaries

Condensed Consolidated Balance Sheets

	September 30, 2020 (Unaudited)	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	**$ 300,988,981**	$ 107,636,849
Investment securities, available-for-sale	**420,958,509**	116,373,335
Restricted cash	**1,400,000**	—
Accounts receivable, net	**7,480,604**	—
Inventory	**2,947,138**	—
Prepaid expenses and other current assets	**11,090,774**	6,313,785
Total current assets	**744,866,006**	230,323,969
Property and equipment, net	**2,049,552**	2,259,740
Right of use assets, net	**24,292,167**	18,252,074
Deferred tax asset, net	**—**	264,609
Other assets	**86,084**	86,084
Total assets	**$ 771,293,809**	$ 251,186,476
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	**$ 8,569,148**	$ 7,425,024
Accrued and other current liabilities	**12,186,380**	16,138,909
Lease liabilities, short-term	**5,267,258**	3,187,435
Accrued employee benefits	**12,005,931**	9,472,651
Total current liabilities	**38,028,717**	36,224,019
Lease liabilities	**23,869,557**	19,955,186
Total liabilities	**61,898,274**	56,179,205
Stockholders' equity:		
Common stock, $0.0001 par value: 100,000,000 shares authorized; 80,142,797 and 55,507,497 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	**8,014**	5,551
Additional paid-in capital	**1,585,023,637**	904,971,772
Accumulated deficit	**(876,404,854)**	(710,098,369)
Accumulated comprehensive income	**768,738**	128,317
Total stockholders' equity	**709,395,535**	195,007,271
Total liabilities and stockholders' equity	**$ 771,293,809**	$ 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 September 30, 2020	2019	Nine Months Ended September 30, 2020	2019
Revenues				
Product sales, net	**$ 7,368,594**	$ —	**$ 10,126,999**	$ —
Grant revenue	**—**	—	**231,710**	—
Total revenues, net	**7,368,594**	—	**10,358,709**	—
Operating expenses:				
Cost of product sales	**556,107**	—	**753,957**	—
Research and development	**10,275,368**	21,339,792	**51,483,551**	70,059,113
Selling, general and administrative	**52,473,573**	15,036,444	**128,015,496**	42,184,078
Total operating expenses	**63,305,048**	36,376,236	**180,253,004**	112,243,191
Loss from operations	**(55,936,454)**	(36,376,236)	**(169,894,295)**	(112,243,191)
Interest income	**752,829**	1,513,837	**3,591,091**	5,105,464
Loss before provision for income taxes	**(55,183,625)**	(34,862,399)	**(166,303,204)**	(107,137,727)
Income tax expense	**—**	—	**3,281**	1,600
Net loss	**$ (55,183,625)**	$ (34,862,399)	**$(166,306,485)**	$(107,139,327)
Net loss per common share:				
Basic & Diluted	**$ (0.79)**	$ (0.63)	**$ (2.48)**	$ (1.94)
Weighted average number of common shares:				
Basic & Diluted	**69,530,039**	55,207,400	**67,030,991**	55,155,854

See accompanying notes to these condensed consolidated financial statements.

Intra-Cellular Therapies, Inc. and Subsidiaries

Condensed Consolidated Statements of Comprehensive Loss (Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	**2020**	2019
Net loss	**$ (55,183,625)**	$ (34,862,399)	**$(166,306,485)**	$(107,139,327)
Other comprehensive income (loss):				
Unrealized gain (loss) on investment securities	**(399,361)**	(33,396)	**640,421**	866,805
Comprehensive loss	**$ (55,582,986)**	$ (34,895,795)	**$(165,666,064)**	$(106,272,522)

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) Income	Total Stockholders' Equity
	Shares	Amount				
Balance at June 30, 2019	55,186,745	$5,519	$ 891,183,518	$(634,653,119)	$ 232,444	$ 256,768,362
Exercise of stock options and issuances of restricted stock	54,332	6	152,373	—	—	152,379
Stock issued for services	6,502	—	48,571	—	—	48,571
Share-based compensation	—	—	4,806,768	—	—	4,806,768
Net loss	—	—	—	(34,862,399)	—	(34,862,399)
Other comprehensive loss	—	—	—	—	(33,396)	(33,396)
Balance at September 30, 2019	55,247,579	$5,525	$ 896,191,230	$(669,515,518)	$ 199,048	$ 226,880,285

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Comprehensive (Loss) Income	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	338,054	34	442,792	—	—	442,826
Stock issued for services	14,230	1	145,690	—	—	145,691
Share-based compensation	—	—	14,849,409	—	—	14,849,409
Net loss	—	—	—	(107,139,327)	—	(107,139,327)
Other comprehensive gain	—	—	—	—	866,805	866,805
Balance at September 30, 2019	55,247,579	$5,525	$ 896,191,230	$(669,515,518)	$ 199,048	$ 226,880,285

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Comprehensive (Loss) Income	Total Stockholders' Equity
	Shares	Amount				
Balance at June 30, 2020	**66,777,737**	**$6,678**	**$ 1,199,576,320**	**$(821,221,229)**	**$ 1,168,099**	**$ 379,529,868**
Common shares issued	**13,179,458**	**1,318**	**370,137,298**	**—**	**—**	**370,138,616**
Common shares receivable collected	**—**	**—**	**5,705,186**	**—**	**—**	**5,705,186**
Exercise of stock options and issuances of restricted stock	**183,516**	**18**	**2,650,587**	**—**	**—**	**2,650,605**
Stock issued for services	**2,086**	**—**	**53,527**	**—**	**—**	**53,527**
Share-based compensation	**—**	**—**	**6,900,719**	**—**	**—**	**6,900,719**
Net loss	**—**	**—**	**—**	**(55,183,625)**	**—**	**(55,183,625)**
Other comprehensive loss	**—**	**—**	**—**	**—**	**(399,361)**	**(399,361)**
Balance at September 30, 2020	**80,142,797**	**$8,014**	**$ 1,585,023,637**	**$(876,404,854)**	**$ 768,738**	**$ 709,395,535**

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Comprehensive (Loss) Income	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	**23,409,458**	**2,341**	**652,709,670**	**—**	**—**	**652,712,011**
Exercise of stock options and issuances of restricted stock	**1,218,188**	**121**	**7,829,463**	**—**	**—**	**7,829,584**
Stock issued for services	**7,654**	**1**	**160,582**	**—**	**—**	**160,583**
Share-based compensation	**—**	**—**	**19,352,150**	**—**	**—**	**19,352,150**
Net loss	**—**	**—**	**—**	**(166,306,485)**	**—**	**(166,306,485)**
Other comprehensive gain	**—**	**—**	**—**	**—**	**640,421**	**640,421**
Balance at September 30, 2020	**80,142,797**	**$8,014**	**$ 1,585,023,637**	**$(876,404,854)**	**$ 768,738**	**$ 709,395,535**

See accompanying notes to these condensed consolidated financial statements.

Intra-Cellular Therapies, Inc. and Subsidiaries

Condensed Consolidated Statements of Cash Flows (Unaudited)

	Nine Months Ended September 30,	
	2020	**2019**
Cash flows used in operating activities		
Net loss	**$(166,306,485)**	$(107,139,327)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	**402,146**	335,461
Share-based compensation	**19,352,150**	14,849,409
Stock issued for services	**160,583**	145,691
Amortization of premiums and discounts on investment securities, net	**(177,374)**	(871,412)
Changes in operating assets and liabilities:		
Accounts receivable, net	**(7,480,604)**	—
Inventory	**(2,947,138)**	—
Prepaid expenses and other assets	**(4,776,989)**	4,020,430
Long term deferred tax asset, net	**264,609**	—
Accounts payable	**1,144,124**	(7,730,137)
Accrued liabilities and other	**(1,419,249)**	3,462,560
Lease liabilities, net	**(45,899)**	—
Net cash used in operating activities	**(161,830,126)**	(92,927,325)
Cash flows (used in) provided by investing activities		
Purchases of investments	**(488,524,539)**	(58,332,886)
Maturities of investments	**184,757,160**	199,383,553
Purchases of property and equipment	**(191,958)**	(1,350,688)
Net cash (used in) provided by investing activities	**(303,959,337)**	139,699,979
Cash flows provided by financing activities		
Proceeds from exercise of stock options	**7,829,584**	442,826
Proceeds of public offerings, net	**652,712,011**	—
Net cash provided by financing activities	**660,541,595**	442,826
Net increase in cash, cash equivalents, and restricted cash	**194,752,132**	47,215,480
Cash, cash equivalents, and restricted cash at beginning of period	**107,636,849**	54,947,502
Cash, cash equivalents, and restricted cash at end of period	**$ 302,388,981**	$ 102,162,982
Non-cash investing and financing activities		
Right of use assets under operating vehicle fleet leases	**$ 7,750,959**	$ —
Right of use assets under operating real estate leases	$ —	$ 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:

	September 30,	
	2020	2019
Cash and cash equivalents	**$300,988,981**	$102,162,982
Restricted cash	**1,400,000**	—
Total cash, cash equivalents and restricted cash	**$302,388,981**	$102,162,982

See accompanying notes to these condensed consolidated financial statements.

Intra-Cellular Therapies, Inc.

Notes to Condensed Consolidated Financial Statements (Unaudited)

September 30, 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) had 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. 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 $295.0 million. After deducting underwriting discounts, commissions and offering expenses, the net proceeds to the Company were approximately $277.0 million. On September 15, 2020, the Company completed a public offering of common stock in which the Company sold 12,666,667 shares of common stock at an offering price of $30.00 per share for aggregate gross proceeds of $380.0 million. After deducting underwriting discounts, commissions and offering expenses, the net proceeds to the Company were approximately $357.8 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. On September 10, 2020, the Company terminated the "at-the-market" equity program sales agreement with SVB Leerink LLC. Through the date of the termination of the sales agreement on September 10, 2020, the Company had issued an aggregate 742,791 shares of common stock under the Company's "at-the-market" equity program which resulted in the Company receiving net proceeds of $17.9 million.

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 condensed 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 ("U.S. GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative U.S. 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, developing and commercializing drugs for the treatment of neurological and psychiatric disorders.

Use of Estimates

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

Cash and Cash Equivalents

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

Investment Securities

Investment securities consisted of the following (in thousands):

	September 30, 2020			
	Amortized Cost	Unrealized Gains	Unrealized (Losses)	Estimated Fair Value
	(Unaudited)			
U.S. Government Agency Securities	$159,237	$ 12	$ (32)	$159,217
Certificates of Deposit	10,500	—	—	10,500
Commercial Paper	78,788	138	(2)	78,924
Corporate Notes/Bonds	171,665	782	(129)	172,318
	$420,190	$ 932	$ (163)	$420,959

	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 as 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 September 30, 2020, and December 31, 2019, the Company held $197.3 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.

The aggregate related fair value of investments with unrealized losses as of September 30, 2020 was $192.8 million, which consisted of $110.4 million from U.S. government agency securities, $10.0 million of commercial paper, and $72.4 million of corporate notes/bonds. The aggregate amount of unrealized losses as of September 30, 2020 was approximately $163,000, which consisted of $32,000 from U.S. government agency securities, $2,000 from commercial paper, and $129,000 from corporate notes/bonds. The $192.8 million aggregate fair value of investments with unrealized losses as of September 30, 2020 has been held in a continuous unrealized loss position for less than 12 months. 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 had 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 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 September 30, 2020 or December 31, 2019. The carrying value of cash held in money market funds of approximately $224.2 million as of September 30, 2020 and $49.9 million as of December 31, 2019 is included in cash and cash equivalents on the condensed consolidated balance sheet and approximates market value based on quoted market prices or Level 1 inputs. The carrying value of certificates of deposit of approximately $47.6 million as of December 31, 2019 is also included in cash and cash equivalents on the condensed consolidated balance sheet 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 on the condensed consolidated balance sheet 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		
	September 30, 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	$ 224,239	$ 224,239	$ —	$ —
U.S. Government Agency Securities	159,217	—	159,217	—
Certificates of Deposit	10,500	—	10,500	—
Commercial Paper	78,924	—	78,924	—
Corporate Notes/Bonds	172,318	—	172,318	—
	$ 645,198	**$ 224,239**	**$ 420,959**	**$ —**

	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 Notes/Bonds	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, accounts receivable, 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 September 30, 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.

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.

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 chargebacks, prompt pay discounts, 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. For the three and nine months ended September 30, 2020, 96% of sales were generated from three major industry wholesalers, respectively.

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 nine months ended September 30, 2020, all 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 39%, 29%, and 28% of product sales for the three months ended September 30, 2020 as well as accounted for approximately 41%, 27% and 27% of product sales for the nine months ended September 30, 2020. As of September 30, 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.

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. Inventory that is used in the production of sample product is reclassified to prepaid and other current assets and is then expensed to selling, general and administrative expenses when the sample product is distributed.

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.

Property and Equipment

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

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

Revenue Recognition

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 January 1, 2020, and therefore the adoption of ASC Topic 606 did not have an impact in the Company's financial statements for any prior periods. 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 and nine months ended September 30, 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 additional discussion of accounting for product sales, see *Product Sales, net* (below).

To date, the Company's only source of product sales has been from sales of CAPLYTA in the U.S., which the Company began shipping to customers in March 2020.

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. 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 rebates, discounts and allowances, among others. 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 more 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 September 30, 2020 and, therefore, the transaction price was not reduced further during the three and nine months ended September 30, 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 September 30, 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 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 and nine months ended September 30, 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 invoices received for claims from prior quarters that have not been paid or for which an invoice has not yet been received, estimates of claims for the current quarter, and estimated future claims 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.

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).

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 expensed all costs associated with the manufacturing of lumateperone as part of research and development expenses. 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 nine months ended September 30, 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 for use in clinical and nonclinical trials, 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 nine-months ended September 30, 2020, the Company recorded a change in estimate of approximately $3.3 million of accrued expenses for clinical trials related to the first and second quarter of 2020 which resulted in an increase of clinical trial expense in the nine month period ending September 30, 2020. For the three and nine months ended September 30, 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 and nine months ended September 30, 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, of which the immediate relevance to the Company is the acceleration of refunds of previously generated corporate Alternative Minimum Tax ("AMT") credits. The CARES Act 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 there was not a material tax impact on its financial statements for the three and nine months ended September 30, 2020. The Company did reclassify its deferred tax asset related to the AMT tax credit carryforward of $265,000 to a current tax receivable in the first quarter of 2020 upon the filing of its tax return for year ended December 31, 2019 and received the refund in July 2020.

Comprehensive Income (Loss)

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

Share-Based Compensation

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

For all awards granted with time based vesting conditions, expense is amortized using the straight-line attribution method. Share-based compensation expense recognized in the statements of operations for the three and nine months ended September 30, 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 were fully amortized on 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 Milestone RSUs related to the approval of the NDA were 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 performance-based RSUs for 86,000 shares of common stock, 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 has losses and also maintains a full valuation allowance to cover its deferred tax assets as of September 30, 2020 and 2019, excess tax benefits, if any, recognized for the tax deductions related to share-based awards will add to the Company's net operating loss deferred tax asset and covered by valuation allowances.

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 May 2020, the Company's stockholders approved the Company's 2018 Amended and Restated Equity Incentive Plan pursuant to which 6,500,000 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 share-based awards for up to a total of 1,000,000 shares of common stock to new employees of the Company. As of September 30, 2020, stock options and RSUs for 314,138 shares have been granted under the 2019 Inducement Plan. The Company does not intend to make additional grants 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 awards 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 and nine months ended September 30, 2020 and 2019:

	Three and Nine Months Ended September 30,	
	2020	2019
Stock options	5,964,135	6,330,914
RSUs	1,702,538	1,425,459
TSR RSUs	43,022	134,170

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 and nine month period ended September 30, 2020.

3. Inventory

Inventory consists of the following:

	September 30, 2020
Raw materials	$ —
Work in process	1,597,413
Finished goods	1,349,725
	$ 2,947,138

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.

4. Property and Equipment

Property and equipment consist of the following:

	September 30, 2020	December 31, 2019
Computer equipment	$ 243,532	$ 243,532
Furniture and fixtures	423,097	423,097
Scientific equipment	4,053,185	3,861,227
Leasehold improvements	1,240,315	1,240,315
	5,960,129	5,768,171
Less accumulated depreciation	(3,910,577)	(3,508,431)
	$ 2,049,552	$ 2,259,740

Depreciation expense for the three and nine months ended September 30, 2020 was $121,044 and $402,146, respectively, as compared to approximately $129,052 and $335,461, respectively, for the three and nine months ended September 30, 2019.

5. 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, provides 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:

Three months ending December 31, 2020	$ 845,566
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	17,627,040
Total	32,653,757
Less: Present value discount	(10,463,196)
Total Lease liability	22,190,561
Less: Current portion	(3,259,966)
Long-term lease liabilities	$ 18,930,595

Lease expense for the three and nine months ended September 30, 2020 was approximately $0.8 million and $2.5 million, respectively, as compared to approximately $0.8 million and $2.5 million, respectively, for the three and nine months ended September 30, 2019.

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 of, 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 is 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 $6.9 million and $6.9 million, respectively, as of September 30, 2020. The vehicle leases entered into since March 2020 represent non-cash transactions. The total operating lease cost for the nine months ended September 30, 2020 was $585,490. The operating cash outflows related to vehicle fleet operating lease obligations for the nine months ended September 30, 2020 were $585,490.

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 September 30, 2020:

Lease Assets and Liabilities – Fleet	Classification	September 30, 2020
Assets		
Right of use assets, net	Operating lease right of use assets	$ 6,946,254
		$ 6,946,254
Liabilities		
Current		
Lease liabilities, short-term	Operating lease liabilities	$ 2,007,292
Non-Current		
Lease liabilities	Non-current operating lease liabilities	4,938,962
Total lease liabilities		$ 6,946,254
Weighted average remaining lease term		2.2 years
Weighted average discount rate		1.85%

The following table presents the maturity of the Company's fleet lease liability as of September 30, 2020:

Time Period	
Three months ending December 31, 2020	$ 530,799
Year ending December 31, 2021	2,112,506
Year ending December 31, 2022	3,207,898
Year ending December 31, 2023	1,273,867
Thereafter	—
Total	7,125,070
Less: Present value discount	(178,816)
Total operating lease liabilities	6,946,254
Less: Current portion	(2,007,292)
Long-term lease liabilities	$ 4,938,962

Right of use assets and lease liabilities for all operating leases were approximately $24.3 million and $29.1 million, respectively, as of September 30, 2020.

6. Share-Based Compensation

On June 18, 2018, the Company's stockholders approved the 2018 Equity Incentive Plan (the "2018 Plan"). The 2018 Plan provided for the granting of share-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. On May 27, 2020, the Company's stockholders approved the Amended and Restated 2018 Equity Incentive Plan (the "Amended 2018 Plan"), which amended and restated the 2018 Plan. The Amended 2018 Plan provides for the granting of up to 6,500,000 additional share-based awards, such as stock options, restricted common stock, RSUs and stock appreciation rights to employees, directors and consultants as determined by the Board of Directors. In December 2019, the Company adopted the 2019 Inducement Award Plan (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 2,208,317 shares available for future issuance under the Amended 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 Internal Revenue Code of 1986, as amended, 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 stock options granted under the Amended 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 share-based compensation expense related to all of the Company's share-based awards, including stock options and RSUs to employees, directors and consultants, recognized during the three and nine months ended September 30, 2020 and 2019, was comprised of the following:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Inventoriable costs	**$ 345,460**	$ —	**$ 996,802**	$ —
Research and development	**2,402,865**	2,023,700	**6,792,498**	$ 6,785,280
General and administrative	**4,152,394**	2,783,068	**11,562,850**	8,064,129
Total share-based compensation expense	**$ 6,900,719**	$ 4,806,768	**$ 19,352,150**	$ 14,849,409

The following table describes the weighted-average assumptions used for calculating the value of options granted during the nine months ended September 30, 2020 and 2019:

	2020	2019
Dividend yield	**0%**	0%
Expected volatility	**91.6%-92.7%**	83.7%-85.7%
Weighted-average risk-free interest rate	**1.31%**	2.32%
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 September 30, 2020, and changes during the nine 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	9.5 years
Outstanding at September 30, 2020	39,728	$ 17.18	9.5 years
Vested or expected to vest at September 30, 2020	39,728	$ 17.18	
Exercisable at September 30, 2020	—	$ —	

Information regarding RSU awards under the 2019 Inducement Plan during the nine month period ended September 30, 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	—	$ —	
Time based RSUs granted in 2020	274,410	$ 16.01	2.6 years
Time based RSUs cancelled in 2020	(15,064)	$ 15.81	2.5 years
Outstanding at September 30, 2020	259,346	$ 16.01	2.6 years
Vested or expected to vest at September 30, 2020	259,346	$ 16.01	
Exercisable at September 30, 2020	—	$ —	

As of September 30, 2020, the Company issued options and time based RSUs totaling 314,138 shares in the 2019 Inducement Plan. The Company does not intend to issue any additional equity awards under the 2019 Inducement Plan.

Information regarding the stock options activity, including with respect to grants to employees, directors and consultants as of September 30, 2020, and changes during the nine 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	742,509	$ 23.85	9.4 years
Options exercised	(696,936)	$ 12.79	4.8 years
Options canceled or expired	(161,111)	$ 21.70	7.9 years
Outstanding at September 30, 2020	5,924,407	$ 18.03	6.8 years
Vested or expected to vest at September 30, 2020	5,924,407	$ 18.03	
Exercisable at September 30, 2020	3,620,984	$ 18.85	5.7 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 nine month period ended September 30, 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	728,596	$ 23.05	2.7 years
Time based RSUs vested in 2020	(506,546)	$ 13.78	0.9 years
Time based RSUs cancelled in 2020	(90,559)	$ 17.03	1.5 years
Outstanding at September 30, 2020	1,400,170	$ 18.69	1.9 years

Information related to the Company's Milestone RSUs and TSR RSUs during the nine month period ended September 30, 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	$ 32.56	2.4 years
Milestone RSUs and TSR RSUs vested in 2020	(67,080)	$ 17.08	0.2 years
Outstanding at September 30, 2020	86,044	$ 32.56	2.4 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 entitled the grantee to receive a number of shares of the Company's common stock determined over a three-year performance period ended and vested 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 was 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 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 originally included 223 companies that comprised the Nasdaq Biotechnology Index at December 31, 2018, which was selected by the Compensation Committee of the Company's Board of Directors and included a range of biotechnology companies operating in several business segments.

The weighted average estimated fair value per share of the TSR RSUs granted in 2020 was $32.56, 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 1.4%, and expected volatility of 91.3%. The TSR RSUs granted in 2020 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, 2022, provided the grantee remained in the service of the Company on the settlement date. The Company is expensing the cost of these awards ratably over the requisite service period. The number of shares for which the TSR RSUs will be settled is a percentage of shares for which the award is targeted and depends on the Company's total shareholder return, expressed as a percentile ranking of the Company's total shareholder return as compared to the Company's peer group, which is consistent with the TSR RSUs granted in 2017. The number of shares for which the TSR RSUs will be settled will vary depending on the level of achievement of the goal. Total shareholder return will be determined by dividing the average share value of the Company's common stock over the 30 trading days preceding January 1, 2023 by the average share value of the Company's common stock over the 30 trading days beginning on January 1, 2020, with a deemed reinvestment of any dividends declared during the performance period. The Company's peer group included companies that compromised the Nasdaq Biotechnology Index at December 31, 2019.

The Company recognized non-cash share-based compensation expense related to time based RSU's for the three and nine months ended September 30, 2020 of approximately $3.2 million and $8.9 million, respectively, as compared to $1.7 million and $5.6 million for the three and nine months ended September 30, 2019, respectively. Total expense for all RSUs, including the time based and performance based RSUs, is $3.4 million and $9.2 million for the three and nine months ended September 30, 2020, respectively, as

compared to $1.9 million and $6.1 million for the three and nine months ended September 30, 2019, respectively. As of September 30, 2020, there was $21.6 million of unrecognized compensation costs related to unvested time based RSUs. As of September 30, 2020, there was $1.0 million and $1.1 million of unrecognized compensation costs related to unvested Milestone RSUs and TSR RSUs, respectively.

7. 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 in 2005, 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, 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 nine months ended September 30, 2020, the Company expensed approximately $506,000 in cost of product sales 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 2020. In support of our commercialization efforts, we hired a national sales force consisting of approximately 240 sales representatives. 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 clinical program consists of three monotherapy studies and one adjunctive study. In September 2020, we announced positive topline results from Study 402, conducted globally, evaluating lumateperone as adjunctive therapy to lithium or valproate in the treatment of major depressive episodes associated with Bipolar I or Bipolar II disorder. In Study 402, once daily lumateperone 42 mg met the primary endpoint for improvement in depression as measured by change from baseline versus placebo on the Montgomery-Åsberg Depression Rating Scale, or MADRS, total score ($p=0.0206$; effect size = 0.27). Lumateperone 42 mg also met the key secondary endpoint, the Clinical Global Impression Scale for Bipolar for Severity of Illness, or CGI-BP-S, Depression Score ($p=0.0082$; effect size = 0.31). The lower lumateperone dose, 28 mg, showed a trend for a dose-related improvement in symptoms of depression but the results did not reach statistical significance. 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. Following the positive results in Study 402, we amended Study 403 to evaluate major depressive episodes with mixed features in bipolar disorder in patients with Bipolar I or Bipolar II disorder and mixed features in patients with major depressive disorder (“MDD”). We expect to complete Study 403 in 2022 and following completion we intend to discuss the results with the FDA to determine whether Study 403, as amended, will constitute a registration trial in support of a potential future regulatory filing for this indication.

In July 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). These benefits were statistically significant in both Bipolar I and Bipolar II patients. Study 404 also met its key secondary endpoint, Clinical Global Impression Scale for Bipolar for Severity of Illness (CGI-BP-S) Total Score ($p<0.001$; effect size = 0.46). 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 all three 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.

In addition, while our Phase 3 bipolar depression trials were powered for the overall patient population and not powered for subpopulation analyses, statistically significant benefit versus placebo was seen in the subgroup of patients with Bipolar I and Bipolar II disorder in Study 404 and in patients with Bipolar I disorder in Study 402, but the Bipolar II subgroup was not statistically significant in Study 402. Based on the results of Study 402 and Study 404, 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 in patients with Bipolar I or II disorder as monotherapy and adjunctive therapy early in the first quarter of 2021 and, assuming the sNDA submission is accepted by the FDA, we anticipate an FDA target action date in the second half of 2021.

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. We have commenced our Phase 3 clinical program evaluating lumateperone as an adjunctive therapy to antidepressants for the treatment of MDD and we expect to initiate clinical conduct in two Phase 3 trials in 2021.

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. Following discussions with the FDA, we plan to initiate a Phase 1 clinical trial by the end of 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 certain 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 second quarter of 2020, we announced topline results from Study ITI-214-104, a Phase 1/2 translational study of single ascending doses of ITI-214 in patients with chronic systolic heart failure with reduced ejection fraction. In this study, ITI-214 improved cardiac output by increasing heart contractility and decreasing vascular resistance. Agents that both increase heart contractility (inotropism) and decrease vascular resistance (vasodilation) are called inodilators. Inodilators in current clinical use are associated with the development of arrhythmias, which are abnormal heart rhythms that when serious can impair heart function and lead to mortality. ITI-214, which acts through a novel mechanism of action, was not associated with arrhythmias in this study and was generally well tolerated in all patients.

Our pipeline also includes programs that are focused on advancing drugs for symptomatic and disease modifying treatments for schizophrenia, Parkinson's disease, AD and other neuropsychiatric and neurodegenerative disorders. We have an ongoing early stage clinical program evaluating a new molecule as a potential treatment for behavioral disturbances in patients with dementia. We have completed single and multiple ascending dose studies in healthy volunteers and are currently evaluating safety and pharmacokinetics in a healthy elderly population.

We also have a development program with our ITI-333 compound as a potential treatment for substance use disorders, pain and psychiatric comorbidities including depression and anxiety. There is a pressing need to develop new drugs to treat opioid addiction and safe, effective, non-addictive treatments to manage pain. We have initiated a clinical program with ITI-333. Following a pre-IND meeting with the FDA, we expect to initiate a single ascending dose safety and tolerability in late 2020 or early 2021. We have received a grant from the National Institute on Drug Abuse under the Helping to End Addiction Long-term Initiative, or NIH HEAL Initiative, that we expect will fund a significant portion of the early stage clinical development costs associated with this program.

We have assembled a management team with significant industry experience to lead the discovery, development and potential 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 $7.4 million and $10.1 million in net revenue from product sales for the three and nine months ended September 30, 2020, respectively. In addition, we had approximately $0 and $232,000 of grant revenues for the three and nine months ended September 30, 2020, respectively, compared to no grant revenue for the three and nine months ended September 30, 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 ongoing development programs for ITI-214 for Parkinson's disease and for the treatment of heart failure. Our other projects are still in the preclinical stages, and will require extensive funding not only to complete preclinical testing, but to commence and complete clinical trials. Expenditures that we incur on these projects will be subject to availability of funding in addition to the funding required for the advancement of lumateperone. Any failure or delay in the advancement of lumateperone could require us to re-allocate resources from our other projects to the advancement of lumateperone, which could have a material adverse impact on the advancement of these other projects and on our results of operations. Our operating expenses are comprised of (i) costs of product sales; (ii) research and development expenses; (iii) general and administrative expenses 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, share-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 September 30, 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 and nine months ended September 30, 2020. The Company's reported cost of product sales as a percentage of product sales, net was 7.5% or approximately $0.6 million for the three months ended September 30, 2020 and was 7.4% or approximately $0.8 million for the nine months ended September 30, 2020.

We will expect to continue to have this favorable impact on cost of product sales and related product gross margins 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 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 selling, general and administrative costs will increase from prior periods primarily due to costs associated with building and maintaining infrastructure and promotional activities to support the commercial sales of CAPLYTA, which will include hiring additional personnel and increasing technological capabilities. 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 782,237 shares of our common stock in the nine months ended September 30, 2020. We also granted time based restricted stock units, or RSUs, for 950,449 shares of our common stock in 2019 and time based RSUs for 1,003,006 shares of our common stock in the nine months ended September 30, 2020. We will recognize expense associated with these RSUs and options over three years in research and development expenses, selling, general and administrative expenses, and inventoriable manufacturing expenses. In the first quarter of 2017, we also granted performance based RSUs, which vest based on the achievement of certain milestones that include (i) the submission of an NDA with the FDA, (ii) the approval of the NDA by the FDA, or the Milestone RSUs, and (iii) the achievement of certain comparative shareholder returns against our peers, or the TSR RSUs. The Milestone RSUs were valued at the closing price on March 8, 2017. The RSUs related to the NDA submission were amortized through December 31, 2018 based on the probable vesting date. The NDA submission milestone was achieved in the third quarter of 2018. The Milestone RSUs related to the NDA submission vested on December 31, 2018. The 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 of our common stock 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 share-based awards in the future, which with our growing employee base will increase our share-based compensation expense in future periods. The following table sets forth our revenues, operating expenses, interest income and income tax expense for the three and nine month periods ended September 30, 2020 and 2019 (in thousands):

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2020	2019	2020	2019
	(Unaudited)		(Unaudited)	
Revenues				
Product sales, net	**$ 7,368**	$ —	**$ 10,127**	$ —
Grant revenue	**—**	—	**232**	—
Total revenues, net	**7,368**	—	**10,359**	—
Expenses				
Cost of product sales	**556**	—	**754**	—
Research and development	**10,275**	21,340	**51,484**	70,059
Selling, general and administrative	**52,474**	15,036	**128,015**	42,184
Total costs and expenses	**63,305**	36,376	**180,253**	112,243
Loss from operations	**(55,937)**	(36,376)	**(169,894)**	(112,243)
Interest income	**753**	1,514	**3,591**	5,106
Income tax expense	**—**	—	**(3)**	(2)
Net loss	**$(55,184)**	$(34,862)	**$(166,306)**	$(107,139)

Comparison of Three and Nine Month Periods Ended September 30, 2020 and September 30, 2019

Total revenues, net

Total revenues, net for the three and nine months ended September 30, 2020 were approximately $7.4 million and $10.4 million, respectively, compared to $0 for the comparable periods in 2019. Net product sales were approximately $7.4 million and $10.1 million for the three and nine months ended September 30, 2020, respectively, 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 and nine months ended September 30, 2019. In addition, revenue from a government grant was approximately $0 and $232,000 for the three and nine months ended September 30, 2020, respectively.

Cost of Product Sales

Cost of product sales was approximately $0.6 million for the three months ended September 30, 2020. Cost of product sales consisted primarily of product royalty fees, overhead and minimal direct costs. Product sold during the three months ended September 30, 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 September 30, 2020. No similar cost of product sales was recognized during the three months ended September 30, 2019.

Cost of product sales was approximately $0.8 million for the nine months ended September 30, 2020. Cost of product sales consisted primarily of product royalty fees, overhead and minimal direct costs. Product sold during the nine months ended September 30, 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 nine months ended September 30, 2020. No similar cost of product sales was recognized during the nine months ended September 30, 2019.

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.

Research and Development Expenses

The following tables set forth our research and development expenses for the three and nine month periods ended September 30, 2020 and 2019 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	**2020**	2019
External costs	**2,815**	14,372	**29,897**	48,302
Internal costs	**7,460**	6,968	**21,587**	21,757
Total research and development expenses	**$ 10,275**	$ 21,340	**$ 51,484**	$ 70,059

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	**2020**	2019
Lumateperone costs	**4,360**	10,515	**30,402**	32,282
Manufacturing costs	**160**	3,061	**3,455**	14,920
Share-based compensation	**2,748**	2,024	**7,789**	6,785
Other projects and overhead	**3,007**	5,740	**9,838**	16,072
Total research and development expenses	**$ 10,275**	$ 21,340	**$ 51,484**	$ 70,059

Research and development expenses decreased to $10.3 million for the three month period ended September 30, 2020 as compared to $21.3 million for the three month period ended September 30, 2019, representing a decrease of approximately 52%. This decrease is due primarily to a decrease of approximately $6.2 million of lumateperone clinical and non-clinical costs and a decrease of approximately $2.9 million in research manufacturing costs, and a decrease of $2.7 million for other projects and overhead. These decreases are offset by an increase of approximately $0.7 million of share-based compensation expense. Manufacturing costs decreased because production of lumateperone prior to FDA approval was expensed and current production is now being capitalized in addition to less clinical trial manufacturing in 2020. Internal costs increased by approximately $0.5 million for the period due primarily to share-based compensation costs. The majority of the research and development expense incurred for the three and nine month periods ended September 30, 2020 and 2019 related to lumateperone.

Research and development expenses decreased to $51.5 million for the nine month period ended September 30, 2020 as compared to $70.1 million for the nine month period ended September 30, 2019, representing a decrease of approximately 27%. This decrease is due primarily to a decrease of approximately $11.5 million in manufacturing expense, a decrease of approximately $1.9 million of lumateperone clinical and non-clinical expenses and a decrease of approximately $6.2 million relating to other projects and overhead. This decrease is offset by an increase of approximately $1.0 million of share-based compensation expense. Internal costs decreased by approximately $0.2 million for the period due to lower bonus accrual, stock compensation expense, travel and other operating costs.

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 for the treatment for schizophrenia in adults.

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 September 30, 2020 were $52.5 million as compared to $15.0 million in the three-month period ended September 30, 2019 which represents an increase of 249%. Below is a breakout of these expenses into selling and general administrative costs for the periods.

General and administrative expenses were $14.2 million in the three month period ended September 30, 2020 as compared to $8.6 million for the same period in 2019, an increase of 65%. This increase is due to increases in information technology costs of $2.4 million, professional fees of $1.4 million, stock compensation expense of $1.4 million, labor and related expenses of $0.4 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 September 30, 2020 and 2019 constituted approximately 53% and 66%, respectively, of our general and administrative costs.

Selling costs were $38.3 million for the three month period ended September 30, 2020 as compared to pre-commercialization costs of $6.4 million in the same period in 2019, or an increase of 498%. This increase is primarily due to increases in sales related labor costs of $15.4 million and commercialization and marketing costs of $15.2 million. Salaries, bonuses and related benefit costs for our sales and marketing functions for the three months ended September 30, 2020 and 2019 constituted approximately 43% and 14%, respectively, of our selling costs.

Selling, general and administrative costs for the nine month period ended September 30, 2020 were $128.0 million as compared to $42.2 million in the nine month period ended September 30, 2019, which represents an increase of 203%.

General and administrative expenses for the nine months ended September 30, 2020 were $40.5 million in 2020 as compared to $22.8 million for the same period in 2019, an increase of 78%. This increase is due to increases in professional and consulting fees of $4.5 million, labor and related expenses of $2.6 million, information technology services of $5.5 million, stock compensation expense of $3.5 million, and the remainder consisting of insurance, lease expense, and other administrative expenses. Salaries, bonuses and related benefit costs for our general and administrative functions for the nine months ended September 30, 2020 and 2019 constituted approximately 52% and 64%, respectively, of our general and administrative costs.

Selling costs were $87.5 million for the nine month period ended September 30, 2020 as compared to pre-commercialization costs of $19.4 million in the same period in 2019, or an increase of 351%. This increase is primarily due to an increase in sales related labor costs of $40.3 million and commercialization costs of $25.5 million. Salaries, bonuses and related benefit costs for our sales and marketing functions for the nine months ended September 30, 2020 and 2019 constituted approximately 50% and 16%, respectively, of our selling costs.

We expect selling, general and administrative costs to increase moderately in the fourth quarter of 2020 as compared to the third quarter of 2020. We are expanding post approval marketing, including increased efforts to educate physicians due to the limitations related to the COVID-19 virus pandemic and market access efforts as well as our administrative infrastructure.

Liquidity and Capital Resources

Through September 30, 2020, we provided funds for our operations by obtaining a total of approximately $1.6 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. In the nine months ended September 30, 2020, we have collected $5.1 million from product sales, which we believe will increase going forward. 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.

In June 2020, we sold 230,000 shares of common stock under our at-the-market equity program generating $5.6 million in net proceeds which was received in July 2020. In the third quarter of 2020, we sold an additional 512,791 shares of common stock utilizing our at-the-market program and received $12.3 million of net proceeds.

In September 2020 we completed a public offering of common stock in which we sold 12,666,667 shares of common stock at a public offering price of $30.00 per share for aggregate gross proceeds of $380.0 million. After deducting underwriting discounts, commissions and offering expenses, the net proceeds to the Company were approximately $357.8 million.

As of September 30, 2020, we had a total of approximately $723.3 million in cash and cash equivalents, available-for-sale investment securities and restricted cash, and approximately $38.0 million of short-term liabilities consisting entirely of liabilities from operations, including approximately $5.3 million of short-term lease obligations. In the nine months ended September 30, 2020, we spent approximately $170.7 million in cash for operations and equipment including $3.6 million of interest income and $5.1 million of collected product sales, resulting in net cash used in operations of $161.8 million. 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 fourth quarter of 2020, we expect to spend up to $85 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 our

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 trial of lumateperone in bipolar disorder as a monotherapy and to file for approval with the FDA for this indication. We also plan to fund additional clinical trials of lumateperone for the treatment of depressive disorders and other CNS 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 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. In the nine months ended September 30, 2020, we spent approximately $170.7 million in cash for operations and equipment, including $3.6 million of interest income and $5.1 million of collected product sales, resulting in net cash used in operations of $161.8 million. 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 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 could 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 the quarter ended June 30, 2020, we sold 230,000 shares of common stock under our “at-the-market” equity program which resulted in our receiving net proceeds of $5.6 million in July 2020. In the quarter ended September 30, 2020, we issued an additional 512,791 shares of common stock under our “at-the-market” equity program and received approximately $12.3 million of net proceeds. On September 10, 2020, we terminated the “at-the-market” equity program agreement with SVB Leerink LLC.

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.

In addition, following the closing of our September 2020 underwritten public offering of common stock, we have a limited number of authorized shares of common stock available for future issuance that are not already issued or reserved for issuance. We have 100.0 million authorized shares of common stock. As of September 30, 2020, we had 80.1 million shares of common stock

outstanding, 7.7 million shares of common stock issuable upon the exercise of outstanding stock options or the vesting of outstanding restricted stock units, and 7.2 million shares of common stock reserved for future issuance under our equity compensation plans. As a result, as of September 30, 2020, we had approximately 5.0 million authorized shares of common stock available for issuance. We will remain limited by the number of additional shares available for future capital raising transactions or strategic transactions unless we obtain stockholder approval to amend our restated certificate of incorporation to increase the number of authorized shares of common stock. This may cause a delay in our future capital raising, collaboration, partnership or other strategic transactions, and may have a material adverse effect on our business and financial condition.

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 condensed 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 and nine months ended September 30, 2020. With the launch of product sales during the first quarter of 2020, the accounting policy for revenue recognition which includes the reserves for variable consideration, 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 U.S. 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 duration and severity of the COVID-19 pandemic and its impact on our business; 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 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 September 30, 2020, we had cash, cash equivalents and marketable securities of approximately $723.3 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. We recognized an unrealized gain of approximately $0.6 million for the nine months ended September 30, 2020, compared to an unrealized gain of approximately $0.1 million 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 Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act) 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 September 30, 2020, we did implement new internal control procedures to support the new accounting and reporting processes associated with adopting the guidance. 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 September 30, 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. 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 elected to cease in-person interactions with physicians and customers entirely for some period of time in the interest of employee and community safety. Even though certain of our sales force and medical organization have begun to have personal interactions with physicians and customers, we may have to cease such personal interactions depending on the COVID-19 situation. In addition, the COVID-19 situation has resulted in a decrease in the number of patient visits to healthcare providers. As a result of the COVID-19 pandemic, 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 pandemic or other pandemics. Some factors from the COVID-19 pandemic that have or 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.

In response to the COVID-19 pandemic, on March 10, 2020, the FDA announced its intention to temporarily postpone most inspections of foreign manufacturing facilities and products. On March 18, 2020, the FDA announced its intention to temporarily postpone routine surveillance inspections of domestic manufacturing facilities and provided guidance regarding the conduct of clinical trials, which has since been further updated. As of June 23, 2020, the FDA noted it was continuing to ensure timely reviews of applications for medical products during the COVID-19 pandemic in line with its user fee performance goals and conducting mission critical domestic and foreign inspections to ensure compliance of manufacturing facilities with FDA quality standards. As of July 2020, utilizing a rating system to assist in determining when and where it is safest to conduct such inspections based on data about the virus' trajectory in a given state and locality and the rules and guidelines that are put in place by state and local governments, FDA is either continuing to, on a case-by-case basis, conduct only mission critical inspections, or, where possible to do so safely, resuming prioritized domestic inspections, which generally include pre-approval inspections. Foreign pre-approval inspections that are not deemed mission-critical remain postponed, while those deemed mission-critical will be considered for inspection on a case-by-case basis. FDA will use similar data to inform resumption of prioritized operations abroad as it becomes feasible and advisable to do so. The FDA may not be able to maintain this pace and delays or setbacks are possible in the future. Should FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel, FDA has stated that it generally intends to issue a complete response letter. Further, if there is inadequate information to make a determination on the acceptability of a facility, FDA may defer action on the application until an inspection can be completed. Additionally, regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

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

We have a limited number of authorized shares of common stock available for issuance, which may impair our ability to issue additional shares for future capital raising transactions or strategic transactions unless we obtain stockholder approval to amend our certificate of incorporation to increase the number of authorized shares of common stock.

Following the closing of our September 2020 underwritten public offering of common stock, we have a limited number of authorized shares of common stock available for future issuance that are not already issued or reserved for issuance. We have 100.0 million authorized shares of common stock. As of September 30, 2020, we had 80.1 million shares of common stock outstanding, 7.7 million shares of common stock issuable upon the exercise of outstanding stock options or the vesting of outstanding restricted stock units, and 7.2 million shares of common stock reserved for future issuance under our equity compensation plans. As a result, as of September 30, 2020, we had approximately 5.0 million authorized shares of common stock available for issuance. We will remain limited by the number of additional shares available for future capital raising transactions or strategic transactions unless we obtain stockholder approval to amend our restated certificate of incorporation to increase the number of authorized shares of common stock. This may cause a delay in our future capital raising, collaboration, partnership or other strategic transactions, and may have a material adverse effect on our business and financial condition.

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 September 30, 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*	Master Services Agreement, effective as of January 10, 2017, by and between ITI Limited and Lonza Ltd.	X			
31.1	Certification of the Registrant's Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X			
31.2	Certification of the Registrant's Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X			
32	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X			
101	The following materials from the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2020, formatted in Inline XBRL (eXtensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets as of September 30, 2020 (unaudited) and December 31, 2019 (audited), (ii) Condensed Consolidated Statements of Operations (unaudited) for the three and nine months ended September 30, 2020 and 2019, (iii) Condensed Consolidated Statements of Comprehensive Loss (unaudited) for the three and nine months ended September 30, 2020 and 2019, (iv) Condensed Consolidated Statements of Stockholders' Equity (unaudited) for the three and nine months ended September 30, 2020 and 2019, (v) Condensed Consolidated Statements of Cash Flows (unaudited) for the nine months ended September 30, 2020 and 2019, and (vi) Notes to Condensed Consolidated Financial Statements (unaudited).	X			
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).	X			

* Certain confidential portions of this Exhibit were omitted by means of marking such portions with brackets ("[***]") because the identified confidential portions (i) are not material and (ii) would be competitively harmful if publicly disclosed.

SIGNATURES

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

INTRA-CELLULAR THERAPIES, INC.

Date: November 9, 2020

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

Date: November 9, 2020

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

Exhibit 10.1

[Pursuant to Item 601(b)(10) of Regulation S-K, certain confidential portions of this exhibit have been omitted by means of marking such portions with asterisks as the identified confidential portions (i) are not material and (ii) would be competitively harmful if publicly disclosed.]

Master Services Agreement

Manufacture of ITI-007

CONFIDENTIAL

Manufacturing Services Agreement

(the "Agreement")

by and between

Lonza Ltd
Münchensteinerstrasse 38
CH-4002 Basel
Switzerland

- hereinafter "Lonza" -

and

ITI Limited
2 Church Street, Hamilton HM 11, Bermuda

- hereinafter "Customer" -

Effective as of January 10, 2017 (the "Effective Date")

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Recitals

WHEREAS, Customer is engaged in the development and research of certain products and requires assistance in the development and manufacture of product;

WHEREAS, Lonza and its Affiliates have expertise in the evaluation, development and manufacture of products;

WHEREAS, Customer wishes to engage Lonza for Services relating to the development and manufacture of the Product as described in this Agreement; and

WHEREAS, Lonza, or its Affiliate, is prepared to perform such Services for Customer on the terms and subject to the conditions set out herein.

NOW, THEREFORE, in consideration of the mutual promises contained herein, and for other good and valuable consideration, the parties intending to be legally bound, agree as follows:

1 Definitions and Interpretation

"Affiliate"	means any company, partnership or other entity which directly or indirectly Controls, is Controlled by or is under common Control with the relevant Party. "Control" means the ownership of more than fifty percent (50%) of the issued share capital or the legal power to direct or cause the direction of the general management and policies of the relevant Party.
"Agreement"	means this agreement incorporating all Appendices, as amended from time to time by written agreement of the Parties.
"Applicable Laws"	means all relevant U.S. and European Union federal, state and local laws, statutes, rules, and regulations which are applicable to a Party's activities hereunder, including, without limitation, the applicable regulations and guidelines of any Governmental Authority and all applicable cGMP together with amendments thereto.
"Approval"	means the first marketing approval by the FDA or EMA of Product from the Facility for commercial supply.
"Background Intellectual Property"	means any Intellectual Property either (i) owned or controlled by a Party prior to the Effective Date or (ii) developed or acquired by a Party independently from the performance of the Services hereunder during the Term of this Agreement.
"Batch"	means the Product derived from a single run of the Manufacturing Process.
"Batch Price"	means the Price of each Batch.
"Campaign"	means a series of no less than three (3) cGMP Batches manufactured consecutively.
"Cancellation Fee"	has the meaning given in Clause 6.6.

“Capital Equipment”	means those certain pieces of equipment described in the Project Plan used to produce the Product that are purchased by Customer or for which Customer reimburses Lonza, including, without limitation, the related documentation regarding the design, validation, operation, calibration and maintenance of such equipment.
“Certificate of Analysis”	means a document prepared by Lonza for each Batch that lists each of the tests performed by Lonza or approved External Laboratories, the Specifications for each test and the test results.
“Certificate of Compliance”	means a document prepared by Lonza: (i) listing the manufacturing date, unique Batch number, and concentration of Product in such Batch, (ii) certifying that such Batch was manufactured in accordance with the Master Batch Record and cGMP, if applicable.
“cGMP”	means those laws and regulations applicable in the U.S. and Europe, relating to the manufacture of medicinal products for human use, including, without limitation, current good manufacturing practices as specified in the ICH guidelines, including without limitation, ICH Q7A “ICH Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients”, US Federal Food Drug and Cosmetic Act at 21CFR (Chapters 210, 211, 600 and 610) and the Guide to Good Manufacturing Practices for Medicinal Products as promulgated under European Directive 91/356/EEC. For the avoidance of doubt, Lonza’s operational quality standards are defined in internal cGMP policy documents.
“cGMP Batches”	means any Batches which are required under the Project Plan to be manufactured in accordance with cGMP.
“Change”	means any change to the Services, pricing or Scope of Work incorporated into a written amendment to the Agreement in accordance with clause 16.2 or effected in accordance with the Quality Agreement.
“Commencement Date”	means the date of commencement of manufacturing activities for a Batch hereunder.
“Competitor”	means an entity that derived greater than twenty-five (25) percent of its revenues from providing contract manufacturing services to third parties in the last completed fiscal year prior to the date of the proposed assignment.
“Confidential Information”	means Customer Information and Lonza Information, as the context requires.
“Customer Information”	means all technical and other information not known to Lonza or in the public domain relating to the Manufacturing Process and the Product, from time to time supplied by the Customer to Lonza, including any materials supplied by Customer to Lonza in accordance with the Project Plan.

"Customer Materials"	means any Raw Materials, components of Product, or other materials of any nature provided by Customer.
"EMA"	means the European Medicines Agency, or any successor agency thereto.
"Engineering Batches"	means a Batch that is intended to demonstrate the transfer of the Manufacturing Process to the Facility.
"External Laboratories"	means any Third Party instructed by Lonza, with Customer's prior consent, to conduct any of the activities required to complete the Services.
"Facility"	means Lonza's manufacturing facilities in [***] or such other Lonza facility as may be agreed upon by the Parties.
"FDA"	means the United States Food and Drug Administration, or any successor agency thereto.
"Governmental Authority"	means any Regulatory Authority and any national, multi-national, regional, state or local regulatory agency, department, bureau, or other governmental entity in the U.S. or European Union.
"Intellectual Property"	means (i) inventions (whether or not patentable), patents, trade secrets, copyrights, trademarks, trade names and domain names, rights in designs, rights in computer software, database rights, rights in confidential information (including know-how) and any other intellectual property rights, in each case whether registered or unregistered, (ii) all applications (or rights to apply) for, and renewals or extensions of, any of the rights described in the foregoing clause (i) and (iii) and all rights and applications that are similar or equivalent to the rights and application described in the foregoing clauses (i) and (ii), which exist now, or which come to exist in the future, in any part of the world.
"Lonza Information"	means all information that is proprietary to Lonza or any Affiliate of Lonza and that is maintained in confidence by Lonza or any Affiliate of Lonza and that is disclosed by Lonza or any Affiliate of Lonza to Customer under or in connection with this Agreement, including without limitation, any and all Lonza know-how and trade secrets.
"Manufacturing Process"	means the production process provided by Customer for the manufacture of Product, as such process may be improved or modified from time to time by agreement of the Parties in writing.
"Master Batch Record"	means the document, proposed by Lonza and approved by Customer, which defines the manufacturing methods, test methods and other procedures, directions and controls associated with the manufacture and testing of Product, and which may be amended from time to time by agreement of the Parties in writing.
"New Customer Intellectual Property"	has the meaning given in Clause 10.2.

“New General Application Intellectual Property”	has the meaning given in Clause 10.3.
“Party”	means each of Lonza and Customer and, together, the “Parties”.
“Price”	means the price for the Services and Products as set out in Appendix A.
“Process Validation Batch”	means a Batch that is produced with the intent to show reproducibility of the Manufacturing Process and is required to complete process validation studies.
“Product”	means the proprietary molecule identified by Customer as ITI-007, to be manufactured by Lonza for Customer using the Manufacturing Process as specified in the Project Plan.
“Project Plan”	means the plan(s) describing the Services to be performed by Lonza under this Agreement, including any update and amendment of the Project Plan to which the Parties may agree from time to time in writing. The initial Project Plan is attached hereto as Appendix A.
“Quality Agreement”	means the written quality agreement, to be entered into by the Parties in accordance with Section 4.1 of this Agreement, setting out the responsibilities of each of the Parties in relation to Product quality as required for compliance with cGMP, and which shall be consistent with this Agreement and Applicable Laws (including meeting the requirements of the FDA’s then-current Guidance for Industry regarding “Contract Manufacturing Arrangements for Drugs: Quality Agreements” and the ICH guidance regarding “Q10 Pharmaceutical Quality Systems”).
“Raw Materials”	means all ingredients, solvents and other components of the Product required to perform the Manufacturing Process or Services set forth in the bill of materials detailing the same (but excluding any consumables). “Regulatory Authority” means the FDA, EMA and any other similar regulatory authorities as may be agreed upon in writing by the Parties.
“Regulatory Approval”	means any approval (including any supplements, amendments, pre- and post-marketing approvals, and pricing and reimbursement approvals, and including the Approval), licenses, registrations or any other authorizations required by a Regulatory Authority necessary for the manufacture, distribution, sale or use of the Product.
“Release”	has the meaning given in Clause 7.1.
“Services”	means all or any part of the services to be performed by Lonza under this Agreement (including, without limitation, process and analytical method transfer; process development; process optimization; validation; clinical and commercial manufacturing; and quality control and quality assurance activities), particulars of which are set out in a Project Plan.

"Specifications"	means the mutually agreed upon specifications, including test procedures and acceptance criteria, of the Product as specified in Appendix B, which may be amended from time to time in accordance with this Agreement.
"Term"	has the meaning given in Clause 14.1.
"Third Party"	means any party other than Customer, Lonza and their respective Affiliates.

In this Agreement references to the Parties are to the Parties to this Agreement, headings are used for convenience only and do not affect its interpretation, references to a statutory provision include references to the statutory provision as modified or re-enacted or both from time to time and to any subordinate legislation made under the statutory provision, references to the singular include the plural and vice versa, and references to the word "including" are to be construed without limitation.

2 Performance of Services

2.1 Performance of Services. Subject to Clause 2.3, Lonza shall itself and through its Affiliates, diligently carry out the Services as provided in the Project Plan and in accordance with this Agreement and use commercially reasonable efforts to perform the Services without any material defect and according to the estimated timelines as set forth in the Project Plan. Lonza shall retain appropriately qualified and trained personnel with the requisite knowledge and experience to perform the Services in accordance with this Agreement. Lonza may not subcontract or delegate any of its rights or obligations under this Agreement to perform the Services without Customer's prior written consent not to be unreasonably withheld or delayed; provided, that any approved subcontractors and approved External Laboratories shall be subject to the same obligations and other provisions contained in this Agreement or any applicable Project Plan, including the obligation to maintain Customer Information in confidence under terms no less stringent than as set forth herein. Except as otherwise agreed to by the Parties or as otherwise agreed to under the Quality Agreement, Lonza shall be liable and responsible for the compliance by such subcontractors and External Laboratories with the applicable provisions of this Agreement.

2.2 Technology Transfer. The Parties expressly agree that they shall work together to transfer the Manufacturing Process to the Facility, including implementing the technology transfer plan set forth in Project Plan. Customer shall fully support such technology transfer as reasonably requested by Lonza.

2.3 Engineering Batches. Lonza shall manufacture Engineering Batches in accordance with the Project Plan. Customer shall have the right to make whatever further use of the non-cGMP Engineering Batches as it shall determine, provided that Customer pays for such Batches, such use is not for human use and does not violate any Applicable Laws. Lonza makes no warranty that Engineering Batches will meet cGMP or the Specifications. If Lonza determines that an Engineering Batch does meet cGMP and the Specifications, it will release such Engineering Batch as a cGMP Batch. Regardless of whether any Engineering Batch meets cGMP or the Specifications, Customer shall pay to Lonza the Price for such Engineering Batch in accordance with the terms of this Agreement.

2.4 cGMP Batches. Lonza will, in accordance with the terms of this Agreement and the Quality Agreement, manufacture at the Facility and Release to Customer, cGMP Batches that comply with the Manufacturing Process, cGMP and the Specifications and this Agreement, and each released Batch will be accompanied by a Certificate of Analysis; provided, however, that cGMP manufacture shall not commence until at least one (1) successful Engineering Batch has been manufactured in compliance with cGMP and Specifications. Prior to commencement of cGMP manufacturing, Lonza shall review the process assumptions. In the event that there is a material difference in the process assumptions as compared with the process results demonstrated during the manufacture

of Engineering Batches, the Parties shall meet to discuss in good faith a revision to the Batch Price to reflect such difference.

2.5 Process Validation Batches. Lonza shall manufacture and deliver Process Validation Batches as mutually agreed by Parties sufficient to document the operability and reproducibility of the Manufacturing Process and permit the Parties to complete and file the necessary regulatory documents.

2.5.1 Prior to commencement of Process Validation Batches, Lonza and Customer shall agree a process validation plan identifying the validation requirements of the Manufacturing Process. All process validation activities are excluded from the Price of Process Validation Batches shall be approved by the Customer in advance and shall be paid for by the Customer at the Price set out in the applicable Project Plan.

2.5.2 Any regulatory support activities (including pre-Approval inspection) required and agreed to by Customer to support the Approval of the Product from the Facility shall be performed and supported by Lonza as reasonably requested by Customer. All such regulatory support activities are excluded from the Price of Process Validation Batches, shall be approved by the Customer in advance, and shall be paid for by the Customer at the Price set out in the applicable Project Plan.

2.6 Supply of Customer Information and Customer Materials. Customer shall supply to Lonza all Customer Information and Customer Materials and other information or materials that may be reasonably required by Lonza to perform the Services. Lonza shall not be responsible for any delays arising out of Customer's failure to provide to Lonza such Customer Information, Customer Materials, or other information or materials reasonably required to perform the Services. Customer shall be responsible for all additional costs and expenses arising out of such delay, including, if applicable, any idle Facility capacity costs.

2.7 Raw Materials. Lonza shall procure all required Raw Materials as well as consumables other than those Raw Materials that are Customer Materials. Customer shall be responsible for payment for all consumables and Raw Materials ordered or irrevocably committed to be procured by Lonza hereunder where the Parties agree that such Raw Materials are included in the Price as identified in the Project Plan. Upon cancellation of any Batch or termination of the Agreement, all unused Raw Materials shall be paid for by Customer within thirty (30) days of invoice and at Customer's option will either be (a) held by Lonza for future use for the production of Product, (b) delivered to Customer, or (c) disposed of by Lonza. Lonza may not use any Raw Materials or Customer Materials for any purpose other than to perform Services in accordance with this Agreement.

3 Project Management / Steering Committee

3.1 Project Plans. With respect to a new project to be governed by this Agreement, a new Project Plan shall be added by agreement in a writing signed by the Parties and appended to Appendix A. Each Project Plan shall include a description of the Services to be provided, the Product to be manufactured, Specifications, a schedule for completion of the Project Plan, pricing details, and such other information as is necessary for relevant Services. In the event of a conflict between the terms of a Project Plan and this Agreement, the terms of this Agreement will govern, except to the extent that the applicable Project Plan expressly and specifically states an intent to supersede this Agreement on a specific matter.

3.2 Project Management. With respect to each Project Plan, each Party will appoint a project manager who will be the person responsible for overseeing the Project Plan on behalf of the respective Party.

3.3 Steering Committee. Each Party shall name a mutually agreed upon equal number of representatives for the Steering Committee, which shall meet twice per calendar year, or as

otherwise mutually agreed by the Parties. In the event that a Steering Committee dispute cannot be resolved, such dispute shall be escalated to a senior executive of each of Customer and Lonza.

The primary function of the Steering Committee is to ensure the ongoing communication between the Parties and to discuss and resolve any issues arising under this Agreement. In addition to the primary function described above, the Steering Committee shall take on the following responsibilities:

3.3.1 discuss and seek resolution of issues around management of the Services;

3.3.2 agree and monitor deadlines and milestones for the Services; and

3.3.3 discuss and recommend any changes to the Services (although such changes will not take effect until they have been incorporated into a written amendment to the Project Plan which has been signed by the Parties).

The Steering Committee may not waive or modify the terms of this Agreement, or take any action that would bind a Party without its prior written consent.

3.4 Person in Plant. Customer shall be permitted to have, at no additional cost, one (1) employee at the Facility as reasonably requested by Customer, at any time during the Manufacturing Process for the purpose of observing, reporting on, and consulting as to the performance of the Services. Such employee shall be subject to and agree to abide by confidentiality obligations to Third Parties and Lonza's customary practices and operating procedures regarding persons in plant, and such employee agrees to comply with all instructions of Lonza's employees at the Facility.

4 Quality

4.1 Responsibility for quality assurance and quality control of Product shall be allocated between Customer and Lonza as set forth in the Quality Agreement and in Lonza standard operating procedures. If there is a conflict between the terms and conditions of this Agreement and the Quality Agreement, the terms and conditions of this Agreement shall prevail. If the Quality Agreement is not in place at the Effective Date, Lonza and Customer commit to enter into the Quality Agreement in a timely manner, but in no event later than the commencement of cGMP manufacturing. Provisions regarding inspections by Regulatory Authorities and audits shall be set out in the Quality Agreement.

5 Insurance

5.1 Each Party shall, during the Term and [***] after delivery of the last Product manufactured or Services provided under this Agreement, obtain and maintain at its own cost and expense from a qualified insurance company, comprehensive general liability insurance including, but not limited to product liability coverage in the amount of at least [***] per claim in the case of a Lonza insurance policy and [***] in the case of a Customer insurance policy. Each Party shall provide the respective other Party with a certificate of such insurance upon reasonable request.

6 Forecasting, Ordering and Cancellation

6.1 Forecasting and Ordering. No later than [***], Customer shall supply Lonza with a written forecast showing Customer's good faith estimated quarterly requirements for Batches for the following [***] (the "Forecast"). No later than [***] following Lonza's receipt of a Forecast, Lonza shall provide written notice to Customer with an estimated production schedule showing the estimated Commencement Date and delivery date of each Batch; provided that if the Forecast for any [***] exceeds the capacity reserved for such [***] in Section 6.4 of this Agreement or agreed between the Parties in accordance with Section 6.9 of this Agreement (the "Reserved Capacity"), Lonza

shall notify Customer within [***] of receipt of the Forecast of its ability (as of the date of receipt of the Forecast) to manufacture the number of Batches forecasted in excess of the Reserved Capacity. The [***] of any Forecast shall be binding ("Binding Forecast"). Except as otherwise provided in Section 6.4 below, binding purchase orders ("Purchase Orders") for the [***] shall be submitted by Customer on the basis of the Binding Forecast within [***] of submission of the Forecast. No Forecast shall amend any previous Binding Forecast, and all Purchase Orders shall be for an amount not less than [***].

6.2 Order Confirmation. Lonza shall confirm the delivery date(s) and quantity of Product to be delivered as set out in each Purchase Order within [***] days of receipt from Customer of the relevant Purchase Order. Upon confirmation, each Purchase Order will be regarded by the Parties as a binding commitment by Lonza to manufacture and to deliver to Customer the relevant quantity of Product according to the requirements set out in such Purchase Order. Lonza shall confirm and accept each Purchase Order that is consistent with the corresponding Forecast. Any delivery date set forth in Lonza's written confirmation of a purchase order shall be an estimated delivery date only. All ordered Batches shall be scheduled in a single Campaign in each calendar year unless otherwise agreed by Lonza. Any additional or inconsistent terms or conditions of any Customer purchase order, acknowledgement, invoice, or similar standardized form given or received pursuant to this Agreement shall have no effect and such terms and conditions are hereby rejected.

6.3 Rescheduling. Lonza shall have the right to reschedule a Commencement Date of any Batch or Campaign upon reasonable prior written notice to Customer, provided that the rescheduled Commencement Date is no earlier or no later than [***] from the Commencement Date originally estimated at the time of Lonza's acceptance of the binding purchase order. If the Customer requests to change the Commencement Date, Lonza will make all reasonable attempts to accommodate the request; provided, however, in the event that this change would impact other projects scheduled for occupancy in the designated suite or suites, manufacture of the Customer's Batch or Campaign may be delayed until an adequate time period is available in the Facility schedule, and any such change requested by Customer may result in a rescheduling fee, all of which shall be confirmed by their Parties in writing. Any delay requested by Customer of more than [***] shall be considered a cancellation pursuant to Section 6.6.

6.4 Dedicated Supply: Lonza will reserve capacity for Customer, sufficient for the manufacture of approximately (i) [***] for [***], until [***], at which time the commitment for [***] capacity becomes binding; (ii) [***] for [***]; and (iii) [***] for [***]. Customer may cancel this reservation in writing by [***], only if Approval is not received, on or before end [***] without penalty. For [***], the Reserved Capacity becomes binding [***] prior to the estimated Commencement Date of the campaign.

6.5 Product Quantities. Quantities of Product arising from a Campaign up to a maximum of [***] above or below the Purchase Order will be invoiced according to the [***] price as outlined in the Project Plan. In case of additional surplus quantities or quantities below [***] of the target quantity the Parties will negotiate in good faith a reasonable price. The Purchase Order shall be fulfilled if at least [***] of the target quantity is delivered.

6.6 Cancellation of a Binding Purchase Order. Customer may cancel a binding purchase order upon written notice to Lonza, subject to the payment of a cancellation fee as calculated below (the "Cancellation Fee"):

6.6.1 In the event that Customer provides written notice of cancellation to Lonza [***] prior to the Commencement Date of one or more Batches, then [***] of the Batch Price of each such Batch cancelled is payable; or

6.6.2 In the event Customer provides written notice of cancellation more than [***] prior to the Commencement Date of a Batch, then [***] Cancellation Fee is payable.

6.7 Payment of Cancellation Fee. Any Cancellation Fee shall be payable within [***] following the written notice of cancellation associated with the cancelled Batch. Any Cancellation Fee shall include all costs associated with the cancelled Batch, including any Raw Materials.

6.8 Replacement Project. Notwithstanding the foregoing, Lonza will use commercially reasonable efforts to secure a new project (but excluding any project then under contract with Lonza) for the cGMP manufacturing space, and for the same dates and duration that would have been occupied by Customer, and then, in such case, the Cancellation Fee for each Batch cancelled that is replaced by a Batch of the new project shall be reduced by an amount equal to [***] of the production fees associated with such replacement Batch.

6.9 Commercial Supply Negotiations: Prior to [***], Customer and Lonza will enter good faith negotiations to develop and finalize an operating model that can support projected commercial supply of Product starting in [***].

7 Delivery and Acceptance

7.1 Delivery. All Product shall be delivered FCA (as defined by Incoterms® 2010) the Facility. Lonza shall deliver to Customer the Certificate of Analysis, the Certificate of Compliance and such other documentation as is reasonably required to meet all applicable regulatory requirements of the Governmental Authorities not later than the date of delivery of Batches to the common carrier chosen by Customer (the "Release"). With respect to any Customer Materials, title and risk of loss shall remain with the Customer and shall not transfer to Lonza. With respect to Product, title and risk of loss shall transfer to Customer upon Release in accordance with this provision.

7.2 Storage. Customer shall arrange for shipment and take delivery of such Batch from the Facility, at Customer's expense, within [***] after Release or pay applicable storage costs. Lonza shall provide storage on a bill and hold basis for such Batch(es) at no charge for up to [***]; provided that any additional storage beyond [***] will be subject to availability and, if available, will be charged to Customer and will be subject to a separate agreement. In addition to Section 8.2, Customer shall be responsible for all value added tax (VAT) and any other applicable taxes, levies, import, duties and fees of whatever nature imposed as a result of any storage. Notwithstanding anything to the contrary contained in this Agreement, in no event shall Lonza be required to store any Batch for more than [***] after Release. Within [***] following a written request from Lonza, Customer shall provide Lonza with a letter in form satisfactory to Lonza confirming the bill and hold status of each stored Batch.

7.3 Acceptance/Rejection of Product.

7.3.1 Promptly following Release of Batches, Customer shall inspect such Batches and shall have the right to test such Batches to determine compliance with the Specifications. Customer shall notify Lonza in writing of any rejection of a Batch based on any claim that it fails to meet Specifications within [***] of Release, after which time all unrejected Batches shall be deemed accepted. Customer shall inform Lonza in writing in case of concealed or latent defects (i.e. not discovered by routine quality control means), promptly upon discovery of such defects but no later than [***] after delivery of the Product.

7.3.2 In the event that Lonza believes that a Batch has been incorrectly rejected, Lonza may require that Customer provide to it Batch samples for testing. Lonza may retain and test the samples of such Batch. In the event of a discrepancy between Customer's and Lonza's test results such that Lonza's test results fall within relevant Specifications, or there exists a dispute between the Parties over the extent to which such failure is attributable to a given Party, the Parties shall cause an independent laboratory promptly to review records, test data and perform comparative tests and analyses on samples of the Product that allegedly fails to conform to Specifications. Such independent laboratory shall be mutually agreed upon by the Parties. The independent laboratory's results shall be in writing and shall be

final and binding save for manifest error. Unless otherwise agreed to by the Parties in writing, the costs associated with such testing and review shall be borne by the Party against whom the independent laboratory rules.

7.3.3 For Engineering Batches, Lonza shall, at its own expense, reprocess any Engineering Batch or, if reprocessing is not possible, replace any Engineering Batch that failed to conform with the Specifications (a "Failed Engineering Batch"). Following completion of Engineering Batches, before proceeding to Process Validation Batches, the Parties shall agree, in writing, that the Process is validation ready. Following such agreement to proceed with Process Validation Batches, Lonza shall, at its own expense, reprocess any Batch or, if reprocessing is not possible, replace any Batch that failed to conform with the Specifications (a "Failed Batch"). Such reprocessing or replacement shall be made as promptly as practicable, in light of available manufacturing capacity. Where possible, any replacement Batch shall be manufactured with the next scheduled cGMP Batch or Campaign. Customer acknowledges and agrees that its sole remedy with respect to a Failed Engineering Batch or a Failed Batch is as set forth in this Clause 7.3.3, and in furtherance thereof, Customer hereby waives all other remedies at law or in equity regarding the foregoing claims. Lonza shall be responsible for the cost of Raw Materials or Customer Materials consumed in any Failed Batch. Customer shall be responsible for the cost of Raw Materials or Customer Materials consumed in any Failed Engineering Batch; provided, however that in the event that it is determined (by the Parties or an independent laboratory) that a Failed Engineering Batch was solely due to Lonza's material breach of its obligations hereunder, gross negligence or operator error, then Lonza shall be responsible for the cost of Raw Materials or Customer Materials consumed in such Failed Engineering Batch. Lonza shall promptly destroy each Failed Engineering Batch or Failed Batch at its cost and expense, if reprocessing is not possible.

8 Price and Payment

8.1 Pricing for the Services provided by Lonza are set out in, and based on the assumptions and information set out in, the applicable Project Plan. In the event of changes to the Services based on Customer's request, the Parties shall discuss and agree upon any additional costs.

8.2 Unless otherwise indicated in writing by Lonza, all Prices and charges are exclusive of value added tax (VAT) and of any other applicable taxes, levies, import, duties and fees of whatever nature imposed by or under the authority of any government or public authority and all such charges applicable to the Services shall be paid by Customer (other than taxes based on Lonza's income).

8.3 Lonza shall issue invoices to Customer for [***] of the Price for Products or Services upon the confirmation of a Purchase Order for the applicable Batch or Campaign, [***] of the Price for Products or Services upon commencement of the manufacturing of Products or Services, and [***] upon Release of applicable Batches or completion of applicable Services, unless otherwise stated in the Project Plan. To the extent not included in the Price, charges for Raw Materials for each Batch shall be invoiced upon the Release of each Batch, provided, that any Raw Materials required to be ordered more than [***] in advance shall be invoiced [***] at the time of order by Lonza and [***] upon Release of the Batch. All undisputed invoices are payable within [***] of date of invoice. Payment shall be made without deduction, deferment, set-off, lien or counterclaim.

8.4 If in default of payment of any undisputed invoice on the due date, interest shall accrue on any amount overdue at the lesser of (i) rate of [***] per month above the London Interbank Offered Rate (LIBOR) or (ii) [***]; and Lonza shall, at its sole discretion, and without prejudice to any other of its accrued rights, be entitled upon [***] notice to suspend the provision of the Services and or delivery of Product until all overdue amounts have been paid in full including interest for late payments.

8.5 Price adjustments.

8.5.1 Not more than once per calendar year, Lonza may adjust the Price in accordance with the European Union Manufacturing Producer Prices Index (or any successor index) increase for the previous calendar year. The new Price reflecting such Batch Price adjustment shall be effective for any Batch for which the Commencement Date is on or after the date of Lonza's notice to Customer of the Price adjustment.

8.5.2 In addition to the above, the Price may be changed by Lonza, upon reasonable prior written notice to Customer (providing reasonable detail and documentation in support thereof), to reflect (i) an increase in variable costs (such as energy or Raw Materials) by more than [***] (based on the initial Price or any previously amended Price), or for a process adjustment or assumption changes, and (ii) any material change in an environmental, safety or regulatory standard that substantially impacts Lonza's cost and ability to perform the Services.

8.5.3 The Prices outlined in the Project Plan are based on the currency exchange rate of the [***] to the United States Dollars (USD) at the Effective Date. Lonza shall bear the risk of any increase or decrease of the [***]/USD exchange rate up to [***] from the base currency exchange rate. If the [***]/USD exchange rate is more than [***] the base currency exchange rate at the date on which the Prices become due for payment, then the Prices will be adjusted to compensate all exchange rate differences higher than [***]. The currency adjustments to be made, if any, shall be based on the market rate of exchange as published by Bloomberg.

9 Capital Equipment

9.1 Any Capital Equipment required for the performance of the Services shall be acquired on terms to be agreed by the Parties prior to commencement of the relevant Services.

10 Intellectual Property

10.1 Except as expressly otherwise provided herein, neither Party will, as a result of this Agreement, acquire any right, title, or interest in any Background Intellectual Property of the other Party, including any improvements made thereto during the Services under this Agreement.

10.2 Subject to Clause 10.3, Customer shall own all right, title, and interest in and to any and all Intellectual Property that Lonza and its Affiliates, the External Laboratories or other contractors or agents of Lonza develops, conceives, invents, first reduces to practice or makes, solely or jointly with Customer or others, that is a direct derivative of or improvement to Customer Information or Customer Background Intellectual Property, or that cannot be practiced without use of Customer Information or Customer Background Intellectual Property (collectively, the "New Customer Intellectual Property"). For avoidance of doubt, "New Customer Intellectual Property" shall include any material, processes or other items that embody, or that are claimed or covered by, any of the foregoing Intellectual Property, but excluding any New General Application Intellectual Property.

10.3 Notwithstanding Clause 10.2, and subject to the license granted in Clause 10.5, Lonza shall own all right, title and interest in Intellectual Property that Lonza and its Affiliates, the External Laboratories or other contractors or agents of Lonza, solely or with each other (and without Customer), develops, conceives, invents, or first reduces to practice or makes in the course of performance of the Services that is generally applicable to the development or manufacture of chemical or biological products or product components ("New General Application Intellectual Property"). For avoidance of doubt, "New General Application Intellectual Property" shall include any material, processes or other items that embody, or that are claimed or covered by, any of the foregoing Intellectual Property.

10.4 Lonza hereby assigns to Customer all of its right, title and interest in any New Customer Intellectual Property. Lonza shall execute, and shall require its personnel as well as its Affiliates, External Laboratories or other contractors or agents and their personnel involved in the performance of the Services to execute, any documents reasonably required to confirm Customer's ownership of the New Customer Intellectual Property, and any documents required to apply for, maintain and enforce any patent or other right in the New Customer Intellectual Property.

10.5 Subject to the terms and conditions set forth herein (including the payment of the Price as required above), Lonza hereby grants to Customer a non-exclusive, world-wide, fully paid-up, irrevocable, transferable license, including the right to grant sublicenses, under the New General Application Intellectual Property, to use, sell and import the Product manufactured under this Agreement.

10.6 Customer hereby grants Lonza the non-exclusive right to use the Customer Information, Customer Background Intellectual Property and New Customer Intellectual Property during the Term solely for the purpose of fulfilling its obligations under this Agreement and in accordance with the terms of this Agreement.

10.7 Customer will have the right to transfer the Manufacturing Process to itself and any Third Party for the manufacture of that Product (but no other product); provided, however, to the extent such technology transfer includes Lonza Confidential Information, Lonza Background Intellectual Property or New General Application Intellectual Property, such technology transfer shall be subject to (i) approval by Lonza in writing; (ii) a reasonable royalty and licensing fee; and (iii) terms to be agreed upon by the Parties. Lonza shall provide reasonably necessary documents to complete such technology transfer and Customer shall reimburse Lonza for any costs (based on a full-time employee rate for such support) and expenses.

11 Warranties

11.1 Lonza warrants, represents and covenants to Customer that:

11.1.1 the Services shall be performed in accordance with all Applicable Laws;

11.1.2 except with respect to any development services and Engineering Batches, the manufacture of Product shall be performed in accordance with cGMP and will meet the Specifications at the date of delivery;

11.1.3 To its knowledge, any Intellectual Property provided and used by Lonza and its Affiliates in performance of Services which relate to developing, formulation, manufacturing, filling, processing, packaging, analyzing or testing the Product shall not infringe, violate or misappropriate any third party Intellectual Property rights, and this warranty shall not apply to the extent such infringement, violation or misappropriation of any third Party Intellectual Property is based upon, in part or whole, Client's written instructions, Specifications or use of Client Materials.

11.1.4 Lonza is not debarred, and has not been convicted of a crime which could lead to debarment, under 21 U.S.C. §335(a) or (b) ("the Debarment Act"), and Lonza will not in the performance of its obligations under this Agreement use the services of any person debarred or suspended under the Debarment Act. If Lonza becomes debarred or receives notice of action with respect to its debarment, Lonza shall promptly notify Customer;

11.1.5 no transactions or dealings under this Agreement shall be conducted with or for an individual or entity that is designated as the target of any sanctions, restrictions or embargoes administered by the United Nations, European Union, United Kingdom or the United States of America;

11.1.6 it or its Affiliate holds all necessary permits, registrations, approvals, consents and licenses to enable it to perform the Services at the Facility; and

11.1.7 it has the necessary corporate authorizations to enter into and perform this Agreement.

11.2 Customer warrants that:

11.3 To its knowledge, Customer has all the rights to Customer Information and Customer Background Intellectual Property necessary to permit Lonza to perform the Services without infringing the Intellectual Property rights of any Third Party and the use of Customer Information and Customer Background Intellectual Property in the performance of the Services shall not infringe any Third Party Intellectual Property rights;

11.4 Customer will promptly notify Lonza in writing if it receives or is notified of a formal written claim from a Third Party that Customer Information and Customer Intellectual Property or that the use by Lonza thereof for the provision of the Services infringes any Intellectual Property or other rights of any Third Party; and

11.5 Customer has the necessary corporate authorizations to enter into this Agreement.

11.6 DISCLAIMER: THE WARRANTIES EXPRESSLY SET FORTH IN THIS AGREEMENT ARE IN LIEU OF ALL OTHER WARRANTIES, AND ALL OTHER WARRANTIES, BOTH EXPRESS AND IMPLIED, ARE EXPRESSLY DISCLAIMED, INCLUDING WITHOUT LIMITATION ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

12 Indemnification and Liability

12.1 Indemnification by Lonza. Lonza shall indemnify the Customer, its Affiliates, and their respective officers, employees and agents ("Customer Indemnitees") for any loss, damage, costs and expenses (including reasonable attorney fees) that Customer Indemnitees may suffer as a result of any Third Party claim arising directly out of (i) any material breach of the warranties given by Lonza in Clause 11.1 above or (ii) any claims alleging that the Services (excluding use by Lonza of Customer Information and Customer Background Intellectual Property) infringe any Intellectual Property rights of a Third Party except, in each case, to the extent that such claims resulted from the negligence, intentional misconduct or breach of this Agreement by any Customer Indemnitees.

12.2 Indemnification by Customer. Customer shall indemnify Lonza, its Affiliates, and their respective officers, employees and agents ("Lonza Indemnitees") from and against any loss, damage, costs and expenses (including reasonable attorney fees) that Lonza Indemnitees may suffer as a result of any Third Party claim arising directly out of (i) any material breach of the warranties given by Customer in Clause 11.2 above; or (ii) any claims alleging that Lonza's use of Customer Information or Customer Background Intellectual Property in accordance with this Agreement infringes any Intellectual Property rights of third parties; or (iii) the use, sale, or distribution of any Product, including any claims of product liability but excluding claims covered by Lonza's indemnification obligation in Section 12.2(ii); except, in each case, to the extent that such claims resulted from the negligence, intentional misconduct or breach of this Agreement by any Lonza Indemnitees.

12.3 Indemnification Procedure. If the Party to be indemnified intends to claim indemnification under this Clause 12, it shall promptly notify the indemnifying Party in writing of such claim. The indemnitor shall have the right to control the defense and settlement thereof; provided, however, that any indemnitee shall have the right to retain its own counsel at its own expense. The indemnitee, its employees and agents, shall reasonably cooperate with the indemnitor in the investigation of any liability covered by this Clause 12, and shall not consent to any settlement or judgment of such claim, nor make any admission, without the indemnifying Party's prior written consent. The failure to deliver prompt written notice to the indemnitor of any claim, to the extent prejudicial to its ability to defend such claim, shall relieve the indemnitor of any obligation to the indemnitee under this Clause 12.

12.4 DISCLAIMER OF CONSEQUENTIAL DAMAGES. IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR INCIDENTAL, INDIRECT, SPECIAL, PUNITIVE OR CONSEQUENTIAL DAMAGES, LOST PROFITS OR LOST REVENUES ARISING FROM OR RELATED TO THIS AGREEMENT, EXCEPT TO THE EXTENT RESULTING FROM FRAUD, GROSS NEGLIGENCE OR INTENTIONAL MISCONDUCT.

12.5 [***]

13 Confidentiality

13.1 A Party receiving Confidential Information (the "Receiving Party") agrees to strictly keep secret any and all Confidential Information received during the Term from or on behalf of the other Party (the "Disclosing Party") using at least the same level of measures as it uses to protect its own Confidential Information, but in any case at least commercially reasonable and customary efforts. Confidential Information shall include information disclosed in any form including but not limited to in writing, orally, graphically or in electronic or other form to the Receiving Party, observed by the Receiving Party or its employees, agents, consultants, or representatives, or otherwise learned by the Receiving Party under this Agreement, which the Receiving Party knows or reasonably should know is confidential or proprietary.

13.2 Notwithstanding the foregoing, Receiving Party may disclose to any courts and/or other authorities Confidential Information of the Disclosing Party which is or will be required pursuant to applicable governmental or administrative or public law, rule, regulation or order. In such case the Party that received the Confidential Information will, to the extent legally permitted, inform the other Party promptly in writing and cooperate with the Disclosing Party in seeking to minimize the extent of Confidential Information which is required to be disclosed to the courts and/or authorities.

13.3 The obligation to maintain confidentiality under this Agreement does not apply to Confidential Information, which:

13.3.1 at the time of disclosure was publicly available; or

13.3.2 is or becomes publicly available other than as a result of a breach of this Agreement by the Receiving Party; or

13.3.3 as the Receiving Party can establish by competent proof, was rightfully in its possession at the time of disclosure by the Disclosing Party and had not been received from or on behalf of Disclosing Party; or

13.3.4 is supplied to a Party by a Third Party which was not in breach of an obligation of confidentiality to Disclosing Party or any other party; or

13.3.5 is developed by the Receiving Party independently from and without use of the Disclosing Party's Confidential Information, as evidenced by the Receiving Party's contemporaneous written records.

13.4 The Receiving Party will use the Disclosing Party's Confidential Information only for the purposes of this Agreement and will not make any use of the Confidential Information for its own separate benefit or the benefit of any Third Party including, without limitation, with respect to research or product development or any reverse engineering or similar testing. The Receiving Party agrees to return or destroy promptly (and certify such destruction) on Disclosing Party's request all written or tangible Confidential Information of the Disclosing Party, except that one copy of such Confidential Information may be kept by the Receiving Party in its confidential files for record keeping purposes only.

13.5 Each Party will restrict the disclosure of Confidential Information to such officers, employees, consultants and representatives of itself and its Affiliates who have been informed of the confidential nature of the Confidential Information and who have a need to know such Confidential Information for the purpose of this Agreement. Prior to disclosure to such persons, the Receiving Party shall bind its and its Affiliates' officers, employees, consultants and representatives to confidentiality and non-use obligations no less stringent than those set forth herein. The Receiving Party shall notify the Disclosing Party as promptly as practicable of any unauthorized use or disclosure of its Confidential Information.

13.6 The Receiving Party shall at any time be fully liable for any and all breaches of the confidentiality obligations in this Clause 13 by any of its Affiliates or the employees, consultants and representatives of itself or its Affiliates.

13.7 Each Party hereto expressly agrees that any breach or threatened breach of the undertakings of confidentiality provided under this Clause 13 by a Party may cause irreparable harm to the other Party and that money damages may not provide a sufficient remedy to the non-breaching Party for any breach or threatened breach. In the event of any breach and/or threatened breach, then, in addition to all other remedies available at law or in equity, the non-breaching Party shall be entitled to seek injunctive relief and any other relief deemed appropriate by the non-breaching Party, without posting a bond.

14 Term and Termination

14.1 Term. This Agreement shall commence on the Effective Date and shall end on the seventh (7th) anniversary of the Effective Date, or the fifth (5th) anniversary of Approval, whichever is longer, unless terminated earlier as provided herein or extended by mutual written consent of the Parties (the "Term"). Notwithstanding the foregoing, each Project Plan may have separate term and termination provisions so long as the term of any Project Plan does not extend beyond the Term.

14.2 Termination. This Agreement may be terminated as follows:

14.2.1 by either Party for any reason upon twenty-four (24) months prior written notice to the other Party;

14.2.2 by either Party if the other Party breaches a material provision of this Agreement or a Project Plan and fails to cure such breach to the reasonable satisfaction of the non-breaching Party within [***] for non-payment) following written notification of such breach from the non-breaching party to the breaching party; provided, however, that such [***] period shall be extended as agreed by the Parties if the identified breach is incapable of cure within [***] and if the breaching Party provides a plan and timeline to cure the breach, promptly commences efforts to cure the breach and diligently prosecutes such cure (it being understood that this extended period shall be unavailable for any breach regarding non-payment), in which case such Party shall have an additional [***] to cure the breach;

14.2.3 Termination for NDA Rejection. Customer may terminate this Agreement if Customer receives notice that the New Drug Application for Product has been rejected, suspended indefinitely or terminated by the FDA. Customer must provide [***] written notice of termination in advance of the date of termination. For the avoidance of doubt, in the event of termination by Customer, Customer shall remain liable for all fees actually incurred by Lonza, including, but not limited to, work conducted prior to the effective date of termination (including all un-cancellable labor commitments, non-cancellable Third Party fees, and all work in process including all professional services rendered through the effective date of

termination), for any charges for materials that have already been purchased for the project and for any wind- down costs agreed by the Parties to be performed by Lonza.

14.2.4 by either Party, immediately, if the other Party becomes insolvent, is dissolved or liquidated, makes a general assignment for the benefit of its creditors, or files or has filed against it, a petition in bankruptcy that is not dismissed within 90 days or has a receiver appointed for a substantial part of its assets; or

14.2.5 by either Party pursuant to Clause 15.

14.3 Consequences of Termination. In the event of termination hereunder, Lonza shall be compensated for (i) Services rendered up to the date of termination, including in respect of any Product in-process; (ii) all costs incurred through the date of termination, including Raw Materials costs for Raw Materials used or purchased for use in accordance with the Project Plan; (iii) all unreimbursed Capital Equipment and related decommissioning charges incurred pursuant to Clause 9; (iv) all amounts due under Clause 6.4, without proration of the final calendar year and (v) any applicable Cancellation Fees. In the case of termination by Lonza for Customer's material breach, Cancellation Fees shall be calculated as of the effective date of termination.

14.4 Survival. The rights and obligations of each Party which by their nature survive the termination or expiration of this Agreement shall survive the termination or expiration of this Agreement, including Clauses 1, 10-13 and 16 (to the extent relevant).

15 Force Majeure

15.1 If Lonza or its Affiliate or permitted contractor, as applicable, is prevented or delayed in the performance of any of its obligations under the Agreement by Force Majeure and gives written notice thereof to Customer specifying the matters constituting Force Majeure together with such evidence as Lonza reasonably can give and specifying the period for which it is estimated that such prevention or delay will continue, Lonza shall be excused from the performance or the punctual performance of such obligations as the case may be from the date of such notice for so long as such cause of prevention or delay shall continue. Provided that, if such Force Majeure persists for a period of [***] or more, Customer may terminate this Agreement by delivering written notice to Lonza.

15.2 "Force Majeure" means any reason or cause beyond Lonza's reasonable control and that is not foreseeable nor due to Lonza's negligence and affecting the performance by Lonza of its obligations under the Agreement, which may include, but is not limited to, any cause arising from or attributable to acts of God, strike, lockouts, labor troubles, restrictive governmental orders or decrees, riots, insurrection, war, terrorists acts, or the inability of Lonza to obtain any required raw material, energy source, equipment, labour or transportation.

16 Miscellaneous

16.1 Severability. If any provision hereof is or becomes at any time illegal, invalid or unenforceable in any respect, neither the legality, validity nor enforceability of the remaining provisions hereof shall in any way be affected or impaired thereby. The Parties hereto undertake to substitute any illegal, invalid or unenforceable provision by a provision which is as far as possible commercially equivalent considering the legal interests and the Purpose.

16.2 Amendments/Assignment. Modifications and/or amendments of this Agreement must be in writing and signed by the Parties. Lonza shall be entitled to instruct one or more of its Affiliates to perform any of Lonza's obligations contained in this Agreement, but Lonza shall remain fully responsible in respect of those obligations, and its Affiliates' actions and omissions shall be deemed made by Lonza. Subject thereto, neither Party may assign its interest under this Agreement without the prior

written consent of the other Party, such consent not to be unreasonably withheld, conditioned or delayed, provided, however that (a) Lonza may assign this Agreement to any Affiliate of Lonza or (b) either Party may assign this Agreement to any third party in connection with the sale or transfer (by whatever method) of all or substantially all of the assets of the business related to this Agreement; provided, however, that Customer shall not assign this Agreement to a Competitor of Lonza, and (c) Lonza shall be entitled to sell, assign and/or transfer its payment receivables resulting from this Agreement without the consent of the Customer. For purposes of this Clause 16.2, the terms "assign" and "assignment" shall include, without limitation (i) the sale of fifty percent (50%) or more of the outstanding stock of such Party to an Affiliate of such Party or an unrelated entity or natural person, (ii) the sale or transfer or other assignment of all or substantially all of the assets of the Party or the line of business or Product to which this Agreement relates, and (iii) a merger, consolidation, acquisition or other form of business combination. Any purported assignment without a required consent shall be void. No assignment shall relieve any Party of responsibility for the performance of any obligation that accrued prior to the effective date of such assignment. This Agreement shall be binding upon the Parties' successors and permitted assigns.

16.3 Notice. All notices must be written and sent to the address of the Party first set forth above. All notices must be given (a) by personal delivery, with receipt acknowledged, (b) by facsimile followed by hard copy delivered by the methods under (c) or (d), (c) by prepaid certified or registered mail, return receipt requested, or (d) by prepaid recognized next business day delivery service. Notices will be effective upon receipt or at a later date stated in the notice.

16.4 Governing Law/Jurisdiction. This Agreement is governed in all respects by the laws of New York, USA, without regard to its conflicts of laws principles. The Parties agree to submit to the jurisdiction of the courts of New York, USA.

16.5 Entire Agreement. This Agreement and the Project Plan and Quality Agreement, together with the Appendices referenced and incorporated herein, constitute the entire agreement between the Parties as to the subject matter hereof and supersedes all prior and contemporaneous agreements with respect to the subject matter hereof. This Agreement may be executed in any number of counterparts, each of which shall be deemed to be an original, and all of which together shall constitute one and the same document. Each Party acknowledges that an original signature or a copy thereof transmitted by facsimile or by .pdf shall constitute an original signature for purposes of this Agreement.

16.6 Waiver. Failure by a Party to insist upon strict compliance with any term of this Agreement in any one or more instances will not be deemed to be a waiver of its rights to insist upon such strict compliance with respect to any subsequent failure.

16.7 Further Assurances. The Parties shall execute, acknowledge and deliver such further instruments and to take all such other incidental acts as may be reasonably necessary or appropriate to carry out the purpose and intent of this Agreement.

16.8 No Third Party Beneficiaries. This Agreement shall not confer any rights or remedies upon any person or entity other than the Parties and their respective successors and permitted assigns.

16.9 Publicity. Neither Party will make any press release or other public disclosure regarding this Agreement or the transactions contemplated hereby without the other Party's express prior written consent, except as required under Applicable Laws, by any governmental agency or by the rules of any stock exchange on which the securities of the disclosing party are listed, in which case the party required to make the press release or public disclosure shall use commercially reasonable efforts to obtain the approval of the other party as to the form, nature and extent of the press release or public disclosure prior to issuing the press release or making the public disclosure. In addition, neither Party shall use the other Party's name in a manner that could be construed as an endorsement of the other Party's product or service, including any scientific conclusion as to safety or efficacy.

IN WITNESS WHEREOF, each of the Parties hereto has caused this Manufacturing Services Agreement to be executed by its duly authorized representative effective as of the Effective Date.

LONZA LTD

By: /s/ Cordula Altekrüger
Name: Cordula Altekrüger
Title: Senior Legal Counsel

By: /s/ Bart A.M. van Aarnhem
Name: Bart A.M. van Aarnhem
Title: Senior Legal Counsel

ITI Limited

By: /s/ Michael Halstead
Name: Michael Halstead
Title: SVP, General Counsel

By: /s/ Sharon Mates
Name: Sharon Mates
Title: CEO

APPENDIX A

Project Plan A -1

[***]

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: November 9, 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: November 9, 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 September 30, 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: November 9, 2020

/s/ Sharon Mates, Ph.D.

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

Dated: November 9, 2020

/s/ Lawrence J. Hineline

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