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, 2021
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 5, 2021, the registrant had 81,463,253 shares of common stock outstanding.

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.

PART I: FINANCIAL INFORMATION

Item 1. FINANCIAL STATEMENTS

Intra-Cellular Therapies, Inc. and Subsidiaries

Condensed Consolidated Balance Sheets

	September 30, 2021 (Unaudited)	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	**$ 106,125,959**	$ 60,045,933
Investment securities, available-for-sale	**371,157,974**	597,402,126
Restricted cash	**1,400,000**	1,400,000
Accounts receivable, net	**16,934,352**	10,764,583
Inventory	**8,166,935**	7,056,385
Prepaid expenses and other current assets	**29,457,445**	14,235,455
Total current assets	**533,242,665**	690,904,482
Property and equipment, net	**1,936,308**	1,998,346
Right of use assets, net	**21,710,677**	24,324,762
Other assets	**86,084**	86,084
Total assets	**$ 556,975,734**	$ 717,313,674
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	**$ 12,030,614**	$ 5,501,825
Accrued and other current liabilities	**16,928,669**	10,902,117
Lease liabilities, short-term	**6,082,054**	5,541,802
Accrued employee benefits	**14,854,226**	14,907,479
Total current liabilities	**49,895,563**	36,853,223
Lease liabilities	**20,323,918**	23,600,347
Total liabilities	**70,219,481**	60,453,570
Stockholders' equity:		
Common stock, $0.0001 par value: 175,000,000 and 100,000,000 shares authorized at September 30, 2021 and December 31, 2020, respectively; 81,377,406 and 80,463,089 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	**8,138**	8,046
Additional paid-in capital	**1,622,149,674**	1,593,475,506
Accumulated deficit	**(1,135,495,761)**	(937,104,032)
Accumulated comprehensive income	**94,202**	480,584
Total stockholders' equity	**486,756,253**	656,860,104
Total liabilities and stockholders' equity	**$ 556,975,734**	$ 717,313,674

See accompanying notes to these condensed consolidated financial statements.

Intra-Cellular Therapies, Inc. and Subsidiaries

Condensed Consolidated Statements of Operations (Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	**2021**	2020
Revenues				
Product sales, net	**$ 21,606,163**	$ 7,368,594	**$ 56,191,848**	$ 10,126,999
Grant revenue	**601,038**	—	**1,940,243**	231,710
Total revenues	**22,207,201**	7,368,594	**58,132,091**	10,358,709
Operating expenses:				
Cost of product sales	**2,001,315**	556,107	**5,496,561**	753,957
Research and development	**27,031,825**	10,275,368	**59,386,413**	51,483,551
Selling, general and administrative	**70,497,885**	52,473,573	**192,932,688**	128,015,496
Total operating expenses	**99,531,025**	63,305,048	**257,815,662**	180,253,004
Loss from operations	**(77,323,824)**	(55,936,454)	**(199,683,571)**	(169,894,295)
Interest income	**392,695**	752,829	**1,297,473**	3,591,091
Loss before provision for income taxes	**(76,931,129)**	(55,183,625)	**(198,386,098)**	(166,303,204)
Income tax (expense) benefit	**23,125**	—	**(5,631)**	(3,281)
Net loss	**$ (76,908,004)**	$ (55,183,625)	**$(198,391,729)**	$(166,306,485)
Net loss per common share:				
Basic & Diluted	**$ (0.95)**	$ (0.79)	**$ (2.44)**	$ (2.48)
Weighted average number of common shares:				
Basic & Diluted	**81,354,724**	69,530,039	**81,178,482**	67,030,991

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,	
	2021	2020	**2021**	2020
Net loss	**$ (76,908,004)**	$ (55,183,625)	**$(198,391,729)**	$(166,306,485)
Other comprehensive loss:				
Unrealized (loss) gain on investment securities	**(81,916)**	(399,361)	**(386,382)**	640,421
Comprehensive loss	**$ (76,989,920)**	$ (55,582,986)	**$ (198,778,111)**	$(165,666,064)

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, 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 issued 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

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Comprehensive (Loss) Income	Total Stockholders' Equity
	Shares	Amount				
Balance at June 30, 2021	**81,311,878**	**$8,132**	**$1,611,989,381**	**$(1,058,587,757)**	**$ 176,118**	**$ 553,585,874**
Exercise of stock options and issuances of restricted stock	**64,489**	**6**	**591,290**	**—**	**—**	**591,296**
Stock issued for services	**1,039**	**—**	**38,734**	**—**	**—**	**38,734**
Share-based compensation	**—**	**—**	**9,530,269**	**—**	**—**	**9,530,269**
Net loss	**—**	**—**	**—**	**(76,908,004)**	**—**	**(76,908,004)**
Other comprehensive loss	**—**	**—**	**—**	**—**	**(81,916)**	**(81,916)**
Balance at September 30, 2021	**81,377,406**	**$8,138**	**$1,622,149,674**	**$(1,135,495,761)**	**$ 94,202**	**$ 486,756,253**

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Comprehensive (Loss) Income	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2020	**80,463,089**	**$8,046**	**$1,593,475,506**	**$ (937,104,032)**	**$ 480,584**	**$ 656,860,104**
Exercise of stock options and issuances of restricted stock	**910,428**	**92**	**3,604,559**	**—**	**—**	**3,604,651**
Stock issued for services	**3,889**	**—**	**144,199**	**—**	**—**	**144,199**
Share-based compensation	**—**	**—**	**24,925,410**	**—**	**—**	**24,925,410**
Net loss	**—**	**—**	**—**	**(198,391,729)**	**—**	**(198,391,729)**
Other comprehensive loss	**—**	**—**	**—**	**—**	**(386,382)**	**(386,382)**
Balance at September 30, 2021	**81,377,406**	**$8,138**	**$1,622,149,674**	**$(1,135,495,761)**	**$ 94,202**	**$ 486,756,253**

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,	
	2021	2020
Cash flows used in operating activities		
Net loss	**$(198,391,729)**	$(166,306,485)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	**386,534**	402,146
Share-based compensation	**24,925,410**	19,352,150
Stock issued for services	**144,199**	160,583
Amortization of premiums and discounts on investment securities, net	**(3,301,051)**	(177,374)
Changes in operating assets and liabilities:		
Accounts receivable, net	**(6,169,769)**	(7,480,604)
Inventory	**(1,110,550)**	(2,947,138)
Prepaid expenses and other assets	**(15,221,990)**	(4,776,989)
Long term deferred tax asset, net	**—**	264,609
Accounts payable	**6,528,789**	1,144,124
Accrued liabilities and other	**5,973,299**	(1,419,249)
Lease liabilities, net	**(122,092)**	(45,899)
Net cash used in operating activities	**(186,358,950)**	(161,830,126)
Cash flows provided by (used in) investing activities		
Purchases of investments	**(155,193,808)**	(488,524,539)
Maturities of investments	**384,352,629**	184,757,160
Purchases of property and equipment	**(324,496)**	(191,958)
Net cash provided by (used in) investing activities	**228,834,325**	(303,959,337)
Cash flows provided by financing activities		
Proceeds from exercise of stock options	**3,604,651**	7,829,584
Proceeds of public offering, net	**—**	652,712,011
Net cash provided by financing activities	**3,604,651**	660,541,595
Net increase in cash, cash equivalents, and restricted cash	**46,080,026**	194,752,132
Cash, cash equivalents, and restricted cash at beginning of period	**61,445,933**	107,636,849
Cash, cash equivalents, and restricted cash at end of period	**$ 107,525,959**	$ 302,388,981
Non-cash investing and financing activities		
Right of use assets under operating leases	**$ 8,917,935**	$ 7,750,959

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,	
	2021	2020
Cash and cash equivalents	**$106,125,959**	$300,988,981
Restricted cash	**1,400,000**	1,400,000
Total cash, cash equivalents and restricted cash	**$107,525,959**	$302,388,981

See accompanying notes to these condensed consolidated financial statements.

Intra-Cellular Therapies, Inc.

Notes to Condensed Consolidated Financial Statements (Unaudited)

September 30, 2021

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 and major depressive disorder.

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 or convertible 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 much 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 included up to $75 million of common stock that the Company could 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. During the year ended December 31, 2020, the Company 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 ("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 primarily for the treatment of neurological and psychiatric disorders.

Recent Accounting Pronouncements

Management does not believe that any recently issued, but not yet effective, accounting pronouncements, if currently adopted, would have a material effect on the Company's financial statements.

Use of Estimates

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

Cash and Cash Equivalents

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

Investment Securities

Investment securities consisted of the following (in thousands):

	September 30, 2021			
	Amortized Cost	Unrealized Gains	Unrealized (Losses)	Estimated Fair Value
		(Unaudited)		
U.S. Government Agency Securities	$101,673	$ 1	$ (8)	$101,666
Certificates of Deposit	25,500	—	—	25,500
Commercial Paper	66,454	5	(6)	66,453
Corporate Notes/Bonds	177,437	141	(39)	177,539
	$371,064	$ 147	$ (53)	$371,158

	December 31, 2020			
	Amortized Cost	Unrealized Gains	Unrealized (Losses)	Estimated Fair Value
U.S. Government Agency Securities	$259,304	$ 3	$ (31)	$259,276
Certificates of Deposit	10,500	—	—	10,500
Commercial Paper	124,368	23	(21)	124,370
Corporate Notes/Bonds	202,749	624	(117)	203,256
	$596,921	$ 650	$ (169)	$597,402

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, 2021 and December 31, 2020, the Company held $54.9 million and $188.5 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, 2021 was $165.3 million, which consisted of $46.5 million from U.S. government agency securities, $40.0 million of commercial paper, and $78.8 million of corporate notes/bonds. The aggregate amount of unrealized losses as of September 30, 2021 was approximately $53.5 thousand, which consisted of $7.9 thousand from U.S. government agency securities, $6.2 thousand from commercial paper, and $39.4 thousand from corporate notes/bonds. The $165.3 million aggregate fair value of investments with unrealized losses as of September 30, 2021 has been held in a continuous unrealized loss position for less than 12 months. As of December 31, 2020, the aggregate related fair value of investments with unrealized losses was $372.3 million and the aggregate amount of unrealized losses was approximately $169 thousand. The $372.3 million aggregate fair value of investments with unrealized losses as of December 31, 2020 had been held in a continuous unrealized loss position for less than 12 months.

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. The Company does not intend to sell these securities, nor is it more likely than not that the Company will be required to sell them prior to the end of their contractual terms. Furthermore, the Company does not believe that these securities expose the Company to undue market risk or counterparty credit risk.

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, 2021 or December 31, 2020. The carrying value of cash held in money market funds of approximately $88.2 million as of September 30, 2021 and $27.9 million as of December 31, 2020 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 cash held in commercial paper of approximately $7.0 million as of September 30, 2021 is included in cash and cash equivalents.

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

	September 30, 2021	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	$ 88,250	$ 88,250	$ —	$ —
U.S. Government Agency Securities	101,666	—	101,666	—
Certificates of Deposit	25,500	—	25,500	—
Commercial Paper	73,452	—	73,452	—
Corporate Notes/Bonds	177,539	—	177,539	—
	$ 466,407	$ 88,250	$ 378,157	$ —

	December 31, 2020	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	$ 27,917	$ 27,917	$ —	$ —
U.S. Government Agency Securities	259,276	—	259,276	—
Certificates of Deposit	10,500	—	10,500	—
Commercial Paper	124,370	—	124,370	—
Corporate Notes/Bonds	203,256	—	203,256	—
	$ 625,319	$ 27,917	$ 597,402	$ —

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, right of use asset, net, 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, 2021 and December 31, 2020. 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 presents 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. The Company reserves against accounts receivable for estimated losses that may arise from a customer's inability to pay and any amounts determined to be uncollectible are written off against the reserve when it is probable that the receivable will not be collected. The reserve amount for estimated collectability losses was not significant as of September 30, 2021 and December 31, 2020.

We are also subject to credit risk from our accounts receivable related to our product sales. We monitor our exposure within accounts receivable and record a credit loss reserve against uncollectible accounts receivable as necessary. We extend credit primarily to pharmaceutical wholesale distributors. Customer creditworthiness is monitored and collateral is not required. Historically, we have not experienced credit losses on our accounts receivable and as of September 30, 2021 and December 31, 2020, our credit loss reserve on receivables was not material.

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-month period ended September 30, 2021, all of the Company's accounts receivable, net arose from product sales in the United States and all customers have standard payment terms which generally require payment within 60 days. For the nine-month period ended September 30, 2021, 96% of sales were generated from three major industry wholesalers which accounted for approximately 40%, 29%, and 27% of product sales, respectively. As of September 30, 2021, the Company believes that such customers are of high credit quality. The percentage of the total net product sales by individual customers has not significantly changed since inception.

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. Inventories consist of raw materials (active pharmaceutical ingredients ("API"), drug product, and packaged product in saleable condition). The consumption of raw materials during production is classified as work in process until saleable. Once it is determined to be in saleable condition, inventory is classified as finished goods. 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 when identified in the manufacturing process, 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 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 on 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-month periods ended September 30, 2021 and 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 United States, 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 the Company's best estimates that take into consideration a range of possible outcomes which are considered more likely 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, and forecasted customer buying and payment patterns. The Company's estimates regarding the payer mix for CAPLYTA are based on historical industry information regarding the payer mix for comparable pharmaceutical products and product portfolios, in particular, information related to similar products in their initial launch stages and through the use of historical information experienced in CAPLYTA's launch period.

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 it was probable that a significant reversal of revenue would not occur in a future period for the estimates detailed below as of September 30, 2021 and 2020, and, therefore, the transaction price was not reduced further during the three and nine-month periods ended September 30, 2021 and 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 product sales, net within the condensed consolidated statements of operations for the three and nine-month periods ended September 30, 2021 and 2020, as well as a reduction to accounts receivable, 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 expired product 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 purchase the product directly 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 receivable, 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-month periods ended September 30, 2021 and 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 applies the claims for vouchers for product that is in the distribution channel 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 condensed 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 of inventory and therefore, no inventory costs were incurred. Therefore, at December 31, 2019, no inventory costs had been capitalized. The cost of product sales in the three and nine-month periods ended September 30, 2021 and 2020, are lower than incurred due to the 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 condensed consolidated balance sheets 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 condensed consolidated statement of operations 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.

Advertising Expense

In connection with the FDA approval of CAPLYTA in 2019, the Company began to incur advertising costs in connection with the subsequent commercial launch of CAPLYTA in 2020. Advertising costs are expensed when services are rendered. Advertising expense for the three and nine months ended September 30, 2021 was $23.2 million and $57.4 million, respectively, as compared to $13.2 million and $18.6 million, respectively, for the three and nine months ended September 30, 2020, related to the Company's marketed product, CAPLYTA.

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, 2021 and 2020 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, and 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 year ended December 31, 2020. The Company did reclassify its deferred tax asset related to the AMT tax credit carryforward of approximately $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.

On March 11, 2021, the American Rescue Plan Act of 2021 ("ARPA 2021") was signed into law. ARPA 2021 included various income and payroll tax provisions. The Company has analyzed the tax provisions of ARPA 2021 and determined they have no significant financial impact to the Company's condensed consolidated financial statements.

Comprehensive Loss

All components of comprehensive loss, including net loss, are reported in the financial statements in the period in which they are incurred. Comprehensive 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 loss for each period.

Share-Based Compensation

Share-based payments for stock options 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 condensed consolidated statements of operations for the three and nine months ended September 30, 2021 and 2020 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. Beginning in the fourth quarter of 2019, expected volatility rates have been 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 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 (the "2020 Milestone RSUs") 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.

In the first quarter of 2021, the Company granted performance-based RSUs for 64,518 shares of common stock, which vest based on the achievement of certain milestones that include (i) certain operational milestones (the "2021 Milestone RSUs", and collectively with the 2020 Milestone RSUs, the "Milestone RSUs") and (ii) the achievement of certain comparative shareholder returns against the Company's peers (the "2021 TSR RSUs," and collectively with the 2020 TSR RSUs, the "TSR RSUs"). The 2021 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.

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, 2021, 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, 2021 and 2020:

	Three and Nine Months Ended September 30,	
	2021	2020
Stock options	5,952,252	5,964,135
RSUs	1,601,273	1,702,538
TSR RSUs	68,598	43,022

3. Inventory

Inventory consists of the following:

	September 30, 2021	December 31, 2020
Raw materials	$ 2,182,261	$2,483,801
Work in process	**3,444,013**	1,781,101
Finished goods	**2,540,661**	2,791,483
	$ 8,166,935	$7,056,385

Inventory acquired prior to receipt of the FDA approval on December 20, 2019 for CAPLYTA was expensed as research and development expense as incurred.

4. Property and Equipment

Property and equipment consist of the following:

	September 30, 2021	December 31, 2020
Computer equipment	**$ 408,751**	$ 243,532
Furniture and fixtures	**423,097**	423,097
Scientific equipment	**4,287,228**	4,127,951
Leasehold improvements	**1,240,315**	1,240,315
	6,359,391	6,034,895
Less accumulated depreciation	**(4,423,083)**	(4,036,549)
	$ 1,936,308	$ 1,998,346

Depreciation expense for the three and nine months ended September 30, 2021 was $133,945 and $386,534, respectively, as compared to $121,044 and $402,146 for the three and nine months ended September 30, 2020, respectively.

5. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities as of September 30, 2021 and December 31, 2020 consisted of the following:

	September 30, 2021	December 31, 2020
Accrued expenses	$ 12,144,235	$ 7,896,942
Medicaid rebates	3,226,394	1,998,953
Other revenue related accruals	1,558,040	1,006,222
Total accrued expenses and other current liabilities	$ 16,928,669	$ 10,902,117

6. Right of Use Assets and Lease Liabilities

Real Estate Leases

In 2014, the Company entered into a long-term lease with a related party which, as amended, provided for a lease of useable laboratory and office space located in New York, New York. A member of the Company's board of directors is the Executive Chairman of the parent company to the landlord under this lease. Concurrent with this lease, the Company entered into a license agreement to occupy certain vivarium related space in the same facility for the same term and rent escalation provisions as the lease. This license has the primary characteristics of a lease and is characterized as a lease in accordance with ASU 2016-02 for accounting purposes. In September 2018, the Company further amended the lease to obtain an 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. The Company has no other significant leases. In addition, no identified leases require allocations between lease and non-lease components.

In adopting ASU 2016-02 as of January 1, 2019, the Company elected the package of practical expedients, which permit 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 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, 2021	$ 871,321
Year ending December 31, 2022	3,491,166
Year ending December 31, 2023	3,566,466
Year ending December 31, 2024	3,675,196
Year ending December 31, 2025	3,787,248
Thereafter	13,839,791
Total	29,231,188
Less: Present value discount	(8,505,190)
Total Lease liability	20,725,998
Less: Current portion	(3,322,657)
Long-term lease liabilities	$17,403,341

Lease expense for the three and nine months ended September 30, 2021 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, 2020.

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 was approximately $5.7 million and $7.3 million, respectively, as of September 30, 2021 and December 31, 2020. The vehicle leases entered into since March 2020 represent non-cash transactions. The total operating lease cost for the three and nine months ended September 30, 2021 was $583,142 and $1.8 million, respectively. The operating cash outflows related to vehicle fleet operating lease obligations for the nine months ended September 30, 2021 and 2020 were $1.8 million and $585,490, respectively.

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, 2021 and December 31, 2020:

Lease Assets and Liabilities – Fleet	Classification	September 30, 2021	December 31, 2020
Assets			
Right of use assets, net	Operating lease right of use assets	$ 5,679,974	$ 7,295,515
		$ 5,679,974	$ 7,295,515
Liabilities			
Current			
Lease liabilities, short-term	Operating lease liabilities	$ 2,759,397	$ 2,257,262
Non-Current			
Lease liabilities	Non-current operating lease liabilities	2,920,577	5,038,253
Total lease liabilities		$ 5,679,974	$ 7,295,515
Weighted average remaining lease term		1.3 years	2.0 years
Weighted average discount rate		1.71%	1.74%

The following table presents the maturity of the Company’s fleet lease liability as of September 30, 2021:

Time Period	
Three months ending December 31, 2021	$ 596,241
Year ending December 31, 2022	3,480,355
Year ending December 31, 2023	1,691,462
Thereafter	—
Total	5,768,058
Less: Present value discount	(88,084)
Total operating lease liabilities	5,679,974
Less: Current portion	(2,759,397)
Long-term lease liabilities	$ 2,920,577

Right of use assets and lease liabilities for all operating leases were approximately $21.7 million and $26.4 million, respectively, as of September 30, 2021.

7. Commitments and Contingencies

License and Royalty Commitments

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. The Company expensed approximately $1.1 million and $2.8 million, respectively, for the three and nine-month periods ended September 30, 2021, in cost of product sales to satisfy its obligation under the BMS agreement, in comparison to $0.4 million and $0.5 million, respectively, for the three and nine-month periods ended September 30, 2020.

Research and Other Commitments

As of September 30, 2021, the Company has committed to purchasing production campaigns for various raw materials and API from each of its supply vendors – Siegfried Evionnaz SA ("Siegfried") and Lonza Ltd. ("Lonza"). The campaigns are expected to be received into inventory during 2022. The Company has a total commitment of $32.1 million related to these agreements. As of September 30, 2021, the Company had paid a deposit of $5.2 million and $4.3 million for the Siegfried and Lonza campaigns, respectively, which is recorded within prepaid expenses and other current assets. Over the course of the vendors' manufacturing period, the Company will remit payments to each vendor based on the payment plan within the executed agreements.

8. 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, 2020, the total number of shares reserved under all equity plans was 17,787,390 and the Company had 7,459,117 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. The Company does not intend to issue any additional equity awards under the 2019 Inducement Plan.

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, 2021 and 2020, was comprised of the following:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Inventoriable costs	**$ 413,103**	$ 345,460	**$ 1,212,943**	$ 996,802
Research and development	**2,769,561**	2,402,865	**7,153,803**	6,792,498
General and administrative	**6,347,605**	4,152,394	**16,558,664**	11,562,850
Total share-based compensation expense	**$ 9,530,269**	$ 6,900,719	**$ 24,925,410**	$ 19,352,150

The following table describes the weighted-average assumptions used for calculating the value of options granted during the nine months ended September 30, 2021 and 2020:

	2021	2020
Dividend yield	**0%**	0%
Expected volatility	**94.5%-94.9%**	91.6%-92.7%
Weighted-average risk-free interest rate	**0.86%**	1.31%
Expected term (in years)	**5.9**	6.0

Information regarding stock option awards under the 2019 Inducement Plan, including with respect to grants to employees as of September 30, 2021, and changes during the three-month period then ended, are summarized as follows:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Contractual Life
Outstanding at December 31, 2020	39,728	$ 17.18	9.2 years
Options granted in 2021	—	—	
Options exercised in 2021	(4,347)	19.98	9.2 years
Outstanding at September 30, 2021	35,381	$ 16.83	9.2 years
Vested and expected to vest at September 30, 2021	35,381	$ 16.83	
Exercisable at September 30, 2021	4,658	$ 19.70	9.2 years

Information regarding RSU awards under the 2019 Inducement Plan during the three-month period ended September 30, 2021 are summarized as follows:

	Number of Shares	Weighted-Average Grant Date Fair Value Per Share	Weighted-Average Contractual Life
Outstanding at December 31, 2020	251,867	$ 16.03	2.2 years
Time based RSUs vested in 2021	(82,355)	$ 16.03	2.0 years
Time based RSUs cancelled in 2021	(16,023)	$ 15.81	2.0 years
Outstanding at September 30, 2021	153,489	$ 16.05	2.0 years
Vested and expected to vest at September 30, 2021	153,489	$ 16.05	
Exercisable at September 30, 2021	—	$ —	

As of September 30, 2021, the Company granted options and time based RSUs totaling 314,138 shares under the 2019 Inducement Plan. These grants were made in the first quarter of 2020 and the Company does not intend to grant 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, 2021, 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, 2020	5,477,894	$ 18.43	6.6 years
Options granted 2021	670,250	$ 30.39	9.5 years
Options exercised 2021	(202,124)	$ 17.28	6.2 years
Options canceled or expired 2021	(29,149)	$ 18.66	8.0 years
Outstanding at September 30, 2021	5,916,871	$ 20.70	6.2 years
Vested and expected to vest at September 30, 2021	5,916,871	$ 20.70	
Exercisable at September 30, 2021	4,212,172	$ 18.66	5.3 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, 2021 are summarized as follows:

	Number of Shares	Weighted-Average Grant Date Fair Value Per Share	Weighted-Average Contractual Life
Outstanding at December 31, 2020	1,311,877	$ 18.77	1.7 years
Time based RSUs granted in 2021	710,318	$ 35.69	2.4 years
Time based RSUs vested in 2021	(614,838)	$ 16.58	1.0 years
Time based RSUs cancelled in 2021	(28,171)	$ 29.90	2.0 years
Outstanding at September 30, 2021	1,379,186	$ 27.80	1.7 years

Information related to the Company's Milestone RSUs and TSR RSUs during the nine-month period ended September 30, 2021 are summarized as follows:

	Number of Shares	Weighted-Average Grant Date Fair Value Per Share	Weighted-Average Contractual Life
Outstanding at December 31, 2020	72,678	$ 28.25	2.1 years
Milestone RSUs and TSR RSUs granted in 2021	64,518	$ 44.04	2.4 years
Milestone RSUs and TSR RSUs vested in 2021	—	$ —	0.0 years
Outstanding at September 30, 2021	137,196	$ 35.67	5.2 years

The weighted average estimated fair value per share of the 2020 TSR RSUs granted was $32.56, and the 2021 TSR RSUs granted was $51.18, which were derived from Monte Carlo simulations. Significant assumptions utilized in estimating the value of the 2020 awards granted include an expected dividend yield of 0%, a risk-free rate of 1.4%, and expected volatility of 91.3%. Significant assumptions utilized in estimating the value of the 2021 awards granted include an expected dividend yield of 0%, a risk-free rate of 0.2%, and expected volatility of 95.8%. The 2020 TSR RSUs granted 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 after December 31, 2022 but before February 18, 2023, provided the grantee remained in the service of the Company on the settlement date. Similarly, the 2021 TSR RSUs granted 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 after December 31, 2023 but before February 23, 2024, 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 returns, expressed as a percentile ranking of the Company's total shareholder return as compared to the Company's peer group. 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 the settlement date by the average share value of the Company's common stock over the 30 trading days beginning on January 1, 2020 and 2021, accordingly, 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 and 2020, respectively.

The Company recognized non-cash share-based compensation expense related to time based RSUs for the three and nine months ended September 30, 2021 of approximately $4.4 million and $12.3 million, respectively, as compared to $3.2 million and $8.9 million, respectively, for the three and nine months ended September 30, 2020. Total expense for all RSUs, including the time based and performance based RSUs, was $4.3 million and $12.6 million, respectively, for the three and nine months ended September 30, 2021, as compared to $3.4 million and $9.2 million, respectively, for the three and nine months ended September 30, 2020. As of September 30, 2021, there was approximately $29.5 million of unrecognized compensation costs related to unvested time based RSUs. As of September 30, 2021, there was $2.1 million and $1.3 million of unrecognized compensation costs related to unvested Milestone RSUs and TSR RSUs, respectively.

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

You should read the following in conjunction with our unaudited condensed consolidated financial statements and the related notes thereto that appear elsewhere in this Quarterly Report on Form 10-Q and the audited consolidated financial statements and notes thereto and under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K filed on February 25, 2021. In addition to historical information, the following discussion and analysis includes forward-looking information that involves risks, uncertainties and assumptions. Our actual results and the timing of events could differ materially from those anticipated by these forward-looking statements as a result of many factors, including those discussed under "Risk Factors" in our Annual Report on Form 10-K filed on February 25, 2021, 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 employ a national salesforce. 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 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, or MDD. We expect to complete Study 403 in the second half of 2022 and following completion we intend to discuss the results with the FDA to determine whether Study 403, as amended, will provide supportive data for 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 United States, 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.

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. In February 2021, we submitted supplemental new drug applications, or sNDAs, 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. In May 2021, we announced that the FDA had accepted the sNDAs for review and assigned a Prescription Drug User Fee Act (PDUFA) target action date of December 17, 2021 for these applications. In support of the potential commercial launch of lumateperone for the treatment of bipolar depression upon approval, we have substantially completed the expansion of our sales force from approximately 240 sales representatives to approximately 320 sales representatives.

We are also pursuing clinical development of lumateperone for the treatment of additional CNS diseases and disorders. At a dose of 42 mg, lumateperone has been shown effective in treating the symptoms associated with schizophrenia, and we believe lumateperone may represent a potential treatment for mood disorders including MDD, post-traumatic stress disorder and intermittent explosive disorder. Patient enrollment in Study 501 and Study 502, our global Phase 3 clinical trials evaluating lumateperone 42 mg as an adjunctive therapy to antidepressants for the treatment of MDD has commenced. We expect to file an sNDA with the FDA for approval of lumateperone as an adjunctive therapy to antidepressants for the treatment of MDD in 2024. We have also initiated a Phase 3 study evaluating lumateperone for the prevention of relapse in patients with schizophrenia. The study is being conducted in five phases consisting of a screening phase, a 6-week, open-label run-in phase during which all patients will receive 42 mg of lumateperone per day, a 12-week, open-label stabilization phase during which all patients will receive 42 mg of lumateperone per day; a double-blind treatment phase 26 weeks in duration during which patients receive either 42 mg of lumateperone per day or placebo (1:1 ratio) and a 2-week safety follow-up phase. This study is being conducted in accordance with our post approval marketing commitment to the FDA in connection with the approval of CAPLTYA for the treatment of schizophrenia as is typical for antipsychotics.

Within the lumateperone portfolio, we are also developing a long-acting injectable formulation to provide more treatment options to patients suffering from mental illness. We have completed the preclinical development of a long-acting injectable formulation and in December 2020 we initiated a Phase 1 single ascending dose study of lumateperone LAI, a formulation of lumateperone designed to be administered subcutaneously and to maintain therapeutic levels of lumateperone for at least one month. This study will evaluate the pharmacokinetics, safety and tolerability of lumateperone LAI in patients with stable symptoms of schizophrenia. We anticipate we will complete this study in the second half of 2021. Results from this study will inform the dosing strategy for future studies. We are evaluating several additional formulations of the lumateperone LAI with treatment durations of one month and longer. 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 are developing ITI-1284-ODT-SL for the treatment of behavioral disturbances in patients with dementia, the treatment of dementia-related psychosis and for the treatment of certain depressive disorders, in the elderly. ITI-1284-ODT-SL is a deuterated form of lumateperone, a new molecular entity formulated as an oral disintegrating tablet for sublingual administration. ITI-1284-ODT-SL is formulated as an oral solid dosage form that dissolves almost instantly when placed under the tongue, allowing for ease of use in the elderly and may be particularly beneficial for patients who have difficulty swallowing conventional tablets. Phase 1 single and multiple ascending dose studies in healthy volunteers and healthy elderly volunteers (> than 65 years of age) evaluated the safety, tolerability and pharmacokinetics of ITI-1284-ODT-SL. In these studies, there were no reported serious adverse events in either age group. In the elderly cohort, reported adverse events were infrequent with the most common adverse event being transient dry mouth (mild). Based on these results, we have initiated our program evaluating ITI-1284-ODT-SL for the treatment of agitation in patients with probable Alzheimer’s disease. Clinical conduct in this program is expected to commence early in 2022. Additional studies in dementia-related psychosis, and certain depressive disorders in the elderly are planned for the first half of 2022.

We have another 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 aberrant immune system activation in 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, cancers and other non-CNS disorders. ITI-214 is our lead compound in this program. 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. We have initiated our Phase 2 clinical program with ITI-214 for Parkinson’s disease and expect to commence patient enrollment in the first half of 2022. 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.

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. ITI-333 is a novel compound that uniquely combines activity as an antagonist at serotonin 5-HT2A receptors and a partial agonist at μ-opioid receptors. These combined actions support the potential utility of ITI-333 in the treatment of opioid use disorder and associated comorbidities (e.g., depression, anxiety, sleep disorders) without opioid-like safety and tolerability concerns. In December 2020, we initiated a Phase 1 single ascending dose study evaluating the safety, tolerability and pharmacokinetics of ITI-333 in healthy volunteers and we anticipate topline results from this study will be available in the fourth quarter of 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 commercialization of our product and 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.

COVID-19

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 FDA 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 continue to conduct many 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 United States, 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 CAPLYTA and to produce our product candidates in quantities we require, which may impair the commercialization and our research and development activities.

We conduct 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, patient enrollment, 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, in March 2020, the FDA announced its intention to temporarily postpone most inspections of foreign manufacturing facilities and products, as well as routine surveillance inspections of domestic manufacturing facilities, and it also provided guidance regarding the conduct of clinical trials, which has been further updated several times since that time. In mid-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. The FDA subsequently publicized its development and use of an internal rating system called the COVID-19 Advisory Rating system, to assist in determining when and where it is safest to conduct such inspections based on data about the virus's trajectory in a given country, state and locality and the rules and guidelines that are put in place by foreign, state and local governments. As of October 2021, 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 ("PAIs"). Foreign PAIs 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 other prioritized operations abroad as it becomes feasible and advisable to do so.

During the global response to the COVID-19 pandemic, moreover, there have been strategic redeployments of government resources to priority projects, including FDA and EMA resources and staff, which could have an impact on the timeline for review and approval of new marketing applications. Over the course of 2020 and to date in 2021, FDA's new drug review programs continued to

meet key performance goals related to working with applicants and approving NDAs and NDA supplements, although the agency has also stated that the uncertainty of the COVID-19 situation may make it difficult to sustain that level of performance indefinitely. The FDA may not be able to maintain its normal pace with respect to new drug applications and delays or setbacks are possible in the future. The FDA has told industry that it intends to be as transparent as possible about its workload and performance metrics as the situation evolves, and also that it intends to communicate proactively with applicants during the review cycle regarding the need for a pre-approval inspection and whether such PAI is considered "mission-critical."

Should FDA determine that a PAI is necessary for approval of an NDA or NDA supplement and such an inspection cannot be completed during the review cycle due to restrictions on travel or other safety protocols, 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. Such decisions will be based on the totality of the information available to the FDA, including considerations of whether it can obtain existing inspection reports from trusted foreign regulatory partners through mutual recognition and confidentiality agreements and/or secure additional records from the applicant, the manufacturing facility, or other inspected entities. Accordingly, FDA has encouraged applicants to effectively communicate with all their facilities and sites to ensure timely responses to any inquiries from FDA for information needed to support its assessment of pending drug applications. FDA has also stated that it is using all available tools and sources of information to support regulatory decisions on NDAs such as the historical compliance status of a manufacturing facility and other risk-benefit considerations pertaining to the proposed new drug product and its manufacturing process and facilities. In addition, whether or not FDA considers a facility inspection to be "mission-critical" involves several factors related to the public health benefits of the proposed new drug product, including but not limited to whether the candidate has been granted breakthrough therapy designation and whether the candidate is intended to treat or prevent a serious disease or medical condition for which there is no other appropriate substitute. Regulatory authorities outside the United States, including but not limited to the EMA, may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic.

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.

Results of Operations

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

Revenues

Total revenues for the three and nine months ended September 30, 2021 were approximately $22.2 million and $58.1 million, respectively, as compared to $7.4 million and $10.4 million, respectively, for the three and nine month periods ended September 30, 2020. Net revenues from product sales consist of sales of CAPLYTA, which was approved by the FDA in December 2019. We initiated the commercial launch of CAPLYTA in late March 2020. We generated approximately $21.6 million and $56.2 million, respectively, in net revenue from product sales for the three and nine months ended September 30, 2021 as compared to approximately $7.4 million and $10.1 million, respectively, for the three and nine months ended September 30, 2020. In addition, we had $0.6 million and $1.9 million, respectively, of grant revenues for the three and nine months ended September 30, 2021 as compared to $0 and $232 thousand, respectively, of grant revenue for the three and nine months ended September 30, 2020. We have received and may continue to receive grants from U.S. government agencies and foundations.

The revenues that we may generate in the next several years may not 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 trials of lumateperone, together with our anticipated clinical development programs for depressive disorders, ITI-214 and ITI-1284, 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. 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, and we have initiated a Phase 1 single ascending dose study evaluating the safety, tolerability and pharmacokinetics of ITI-333 in healthy volunteers. We are also developing ITI-1284 for the treatment of behavioral disturbances in patients with dementia, the treatment of dementia-related psychosis and for the treatment of certain depressive disorders, in the elderly. Our other projects are still in the preclinical stages, and will require extensive funding not only to complete preclinical testing, but also 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) selling expenses; and (iv) general and administrative 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.

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.

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.

Product sold through September 30, 2021 consisted of raw materials that were previously charged to research and development expense prior to FDA approval of CAPLYTA. Because we previously expensed raw materials, the cost of drug product sold was lower than it would have been, which had a positive impact on our cost of product sales and related product gross margins for the three and nine months ended September 30, 2021 and 2020. Our reported cost of product sales as a percentage of product sales, net was 9.3% or approximately $2.0 million and 9.8% or approximately $5.5 million, respectively, for the three and nine months ended September 30, 2021, as compared to 7.5% or approximately $0.6 million and 7.4% or approximately $0.8 million, respectively, for the three and nine months ended September 30, 2020. This increase in the percentages of cost of product sales is due primarily to a higher proportion of previously expensed product costs incurred prior to drug approval associated with product sold in the prior year.

We 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 purchased after the FDA approval. We are currently unable to estimate when all previously expensed inventory costs will be recognized.

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, and 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 moderately over the next several quarters as we expand our marketing and promotional activities including advertising expenses and preparing for potential FDA approval of lumateperone for the treatment of bipolar depression. In September 2018, we amended our corporate headquarters lease to acquire 15,534 square feet of additional office space. We granted options to purchase

800,200 shares of our common stock in 2020 and granted options to purchase an additional 511,932 shares of our common stock in March 2021. We also granted time based restricted stock units, or RSUs, for 1,007,402 shares of our common stock in 2020 and time based RSUs for 702,830 shares of our common stock in March 2021. We also granted 162,377 options and 6,999 RSUs to board members and new hires in June 2021. 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.

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, 2021 and 2020 (in thousands):

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2021	2020	2021	2020
	(Unaudited)		(Unaudited)	
Revenues				
Product sales, net	**$ 21,606**	$ 7,368	**$ 56,192**	$ 10,127
Grant revenue	**601**	—	**1,940**	232
Total revenues, net	**22,207**	7,368	**58,132**	10,359
Expenses				
Cost of product sales	**2,001**	556	**5,497**	754
Research and development	**27,032**	10,275	**59,386**	51,484
Selling, general and administrative	**70,498**	52,474	**192,933**	128,015
Total costs and expenses	**99,531**	63,305	**257,816**	180,253
Loss from operations	**(77,324)**	(55,937)	**(199,684)**	(169,894)
Interest income	**393**	753	**1,298**	3,591
Income tax expense (benefit)	**23**	—	**(6)**	(3)
Net loss	**$(76,908)**	$(55,184)	**$(198,392)**	$(166,306)

Comparison of Three and Nine-Month Periods Ended September 30, 2021 and September 30, 2020

Total Revenues, Net

Revenues for the three and nine months ended September 30, 2021 were approximately $22.2 million and $58.1 million, respectively, compared to $7.4 million and $10.4 million, respectively for the three and nine months ended September 30, 2020. Net product sales were approximately $21.6 million and $56.2 million, respectively, for the three and nine months ended September 30, 2021 as compared to approximately $7.4 million and $10.1 million, respectively for the three and nine months ended September 30, 2020. Net product sales were comprised of sales of CAPYLTA, which was approved by the FDA on December 20, 2019 and became available to wholesalers in March 2020. The increase in net product sales was due to the initial launch occurring in the three months ended March 30, 2020 and the increase in prescriptions since that period. In addition, revenue from a government grant was approximately $0.6 million and $1.9 million, respectively, for the three and nine months ended September 30, 2021 as compared to $0 and $232 thousand, respectively, for the three and nine months ended September 30, 2020. The increase in grant revenue relates to the increased activity within the applicable studies during the same periods.

Cost of Product Sales

Cost of product sales was approximately $2.0 million and $5.5 million, respectively, for the three and nine months ended September 30, 2021, compared to $0.6 million and $0.8 million, respectively, for the three and 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 produced and charged to research and development expense prior to FDA approval of CAPLYTA. Because the cost of drug product was charged as an expense prior to 2020, this had a positive impact on our cost of product sales and related product gross margins in 2020. In 2021, the product sold during the three and nine months ended September 30, 2021 also consisted of drug product costs and production costs that were incurred and previously charged to research and development expense prior to FDA approval of CAPLYTA. The increase in the cost of product sales in the three and nine months ended September 30, 2021 compared to the three and nine months ended September 30, 2020 is due primarily to the increase in the volume of product sales.

We will continue to have a 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 fully manufactured after the FDA approval. We are currently unable to estimate when all previously expensed inventory costs will be recognized.

Research and Development Expenses

The following tables set forth our research and development expenses for the three and nine-month periods ended September 30, 2021 and 2020 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	**2021**	2020
External costs	**17,679**	2,815	**33,554**	29,897
Internal costs	**9,353**	7,460	**25,832**	21,587
Total research and development expenses	**$ 27,032**	$ 10,275	**$ 59,386**	$ 51,484
Lumateperone costs	**14,750**	4,360	**32,032**	30,402
Manufacturing costs	**1,926**	160	**3,891**	3,455
Stock based compensation	**3,183**	2,748	**8,367**	7,789
Other projects and overhead	**7,173**	3,007	**15,096**	9,838
Total research and development expenses	**$ 27,032**	$ 10,275	**$ 59,386**	$ 51,484

Research and development expenses increased to $27.0 million for the three-month period ended September 30, 2021 as compared to $10.3 million for the three-month period ended September 30, 2020, representing an increase of approximately 163%. This increase is due primarily to an increase of approximately $8.7 million for lumateperone clinical trial costs, and an increase of $4.2 million for other projects and overhead, including the ITI-1284, ITI-214, and ITI-333 programs, among others. In addition, the remaining increase is attributable to an increase in lumateperone non-clinical trial and manufacturing costs. Internal costs increased by approximately $1.9 million for the period due primarily to labor related costs.

Research and development expenses increased to $59.4 million for the nine-month period ended September 30, 2021 as compared to $51.5 million for the nine-month period ended September 30, 2020, representing an increase of approximately 15%. This increase is due primarily to an increase of approximately $5.3 million for other projects and overhead, including the ITI-1284, ITI-214, and ITI-333 programs, among others, and $1.6 million for lumateperone clinical trial and other costs. Internal costs increased by approximately $4.2 million for the period due primarily to labor related costs.

As the development of lumateperone progresses, we anticipate research and development costs for lumateperone programs to increase moderately due primarily to conducting ongoing and planned Phase 3 and other clinical trials relating to our lumateperone programs in the next several years. 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 drug product in anticipation of possible additional FDA approvals of lumateperone for indications beyond schizophrenia.

We currently have several projects, in addition to lumateperone, that are in the research and development stages. 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 table above 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, 2020, 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, 2021 were $70.5 million as compared to $52.5 million in the three-month period ended September 30, 2020, which represents an increase of 34%, which was due to an increase in selling costs and an increase in general and administrative expenses as discussed below.

Selling costs were $52.6 million for the three-month period ended September 30, 2021 as compared to selling costs of $38.3 million in the same period in 2020, which represents an increase of 37%. This increase is primarily due to increases in commercialization, marketing and advertising expenses totaling $12.5 million, approximately $941 thousand in travel and other costs, and sales related labor costs of approximately $694 thousand. Salaries, bonuses and related benefit costs for our sales and marketing functions for the three months ended September 30, 2021 and 2020 constituted approximately 32% and 43%, respectively, of our selling costs.

General and administrative expenses were $17.9 million in the three-month period ended September 30, 2021 as compared to $14.2 million for the same period in 2020, an increase of 27%. This increase is due to increases in stock-based compensation of $2.2 million, labor related costs of approximately $659 thousand, patent related expenses of approximately $353 thousand, and the remainder for insurance, professional fees, and other expenses. Salaries, bonuses and related benefit costs for our general and administrative functions for the three months ended September 30, 2021 and 2020 constituted approximately 57% and 53%, respectively of our general and administrative costs.

Selling, general and administrative costs for the nine-month period ended September 30, 2021 were $192.9 million as compared to $128.0 million in the nine-month period ended September 30, 2020, which represents an increase of 51%, which was due to an increase in selling, marketing, and advertising expenses and an increase in general and administrative expenses as discussed below.

Selling costs were $143.0 million for the nine-month period ended September 30, 2021 as compared to $87.5 million in the same period in 2020, or an increase of 63%. This increase is primarily due to an increase in commercialization costs of $45.5 million, sales related labor costs of approximately $7.0 million and approximately $2.8 million in travel and other sales related expenses. Salaries, bonuses and related benefit costs for our sales and marketing functions for the nine months ended September 30, 2021 and 2020 constituted approximately 35% and 50%, respectively, of our selling costs.

General and administrative expenses for the nine months ended September 30, 2021 were $50.0 million as compared to $40.5 million for the same period in 2020, an increase of 23%. This increase is due to increases in stock compensation expense of $5.0 million, labor and bonus expense of $2.1 million, professional fees of $1.4 million, and the remainder for 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, 2021 and 2020 constituted approximately 56% and 52%, respectively of our general and administrative costs.

We expect selling, general and administrative costs to increase moderately over the next several quarters as we increase advertising costs, expand other marketing efforts, and prepare for the potential commercial launch of CAPLYTA for the treatment bipolar depression.

Liquidity and Capital Resources

Through September 30, 2021, 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 in prior periods, grants from government agencies and foundations and payments received under a terminated license and collaboration agreement. Through September 30, 2021, we have collected approximately $77.0 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 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, 2021, we had a total of approximately $478.7 million in cash and cash equivalents, available-for-sale investment securities and restricted cash, and approximately $49.9 million of short-term liabilities consisting entirely of liabilities from operations, including approximately $6.1 million of short-term lease obligations. In the nine months ended September 30, 2021, we spent approximately $248.1 million in cash for operations and equipment. During this period, we collected $60.1 million of product sales and $1.3 million of interest income, resulting in net cash used of $186.7 million. The use of cash was primarily for selling and marketing costs in connection with our commercialization 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 and in preparation for the potential approval of CAPLYTA for the treatment of bipolar depression; 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.

In the fourth quarter of 2021, we expect to spend up to $100 million primarily related to the marketing and commercialization of CAPLYTA, increasing inventory and sample levels of CAPLYTA, advancing lumateperone related programs 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-1284, 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.

Subject to the levels of product sales we achieve, we may 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 and prepare for the potential approval and initial launch of CAPLYTA for the treatment of bipolar depression. We also plan to fund additional clinical trials of lumateperone for the treatment of depressive disorders and other CNS disorders; clinical development of our ITI-007 long acting injectable; additional clinical trials of lumateperone and ITI-1284; continued advancement 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. While we have several research and development programs in progress, 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 for additional indications and our other product candidates, as well as commercialization efforts, we expect the amount of cash to be used to fund operations to increase considerably 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 included 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.

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 historically not been adversely impacted by problems in the credit markets, 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. 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.

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, 2020 and Note 2 to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q. There have been no material changes to our critical accounting policies during the nine months ended September 30, 2021.

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 Part II, Item 7, in our Annual Report on Form 10-K for the year ended December 31, 2020 filed on February 25, 2021.

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, 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, management, or sales and marketing 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 and uncertainties include, but are not limited to, the following: whether the preclinical and clinical results of the lumateperone studies will meet the regulatory requirements for approval by the FDA for the proposed indications; whether the sNDAs for lumateperone will be approved by the FDA and whether the FDA will complete its review within its target timelines, including its target action date; whether the FDA will require additional information, whether we will be able to provide in a timely manner any additional information that the FDA requests, and whether such additional information will be satisfactory to the FDA; 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 payors; 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 or in clinical trials for other indications; 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, commercialization, manufacturing or supply of our product and 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, 2021, we had cash, cash equivalents, marketable securities, and restricted cash of approximately $478.7 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 $0.3 million for the nine months ended September 30, 2021, compared to an unrealized gain of approximately $0.4 million for the year ended of December 31, 2020. 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*. There were no changes in our internal control over financial reporting identified in connection with the evaluation of such internal control that occurred during the three months ended September 30, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II: OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS

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

Item 1A. RISK FACTORS

There have been no material changes to the risk factors discussed in Item 1A. Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2020, filed with the Securities and Exchange Commission on February 25, 2021.

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, 2021.

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
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, 2021, formatted in Inline XBRL (eXtensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets as of September 30, 2021 (unaudited) and December 31, 2020 (audited), (ii) Condensed Consolidated Statements of Operations (unaudited) for the three and nine months ended September 30, 2021 and 2020, (iii) Condensed Consolidated Statements of Comprehensive Loss (unaudited) for the three and nine months ended September 30, 2021 and 2020, (iv) Condensed Consolidated Statements of Stockholders' Equity (unaudited) for the three and nine months ended September 30, 2021 and 2020, (v) Condensed Consolidated Statements of Cash Flows (unaudited) for the three and nine months ended September 30, 2021 and 2020, 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			

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, 2021

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

Date: November 9, 2021

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

Exhibit 31.1

CERTIFICATIONS UNDER SECTION 302

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

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

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

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

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

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

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

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

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

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

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

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

Date: November 9, 2021

/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, 2021

/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, 2021 (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, 2021

/s/ Sharon Mates, Ph.D.

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

Dated: November 9, 2021

/s/ Lawrence J. Hineline

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