




REFINITIV

DELTA REPORT

10-Q

ITCI - INTRA-CELLULAR THERAPIES,
10-Q - MARCH 31, 2024 COMPARED TO 10-Q - SEPTEMBER 30, 2023

The following comparison report has been automatically generated

TOTAL DELTAS	1172
 CHANGES	147
 DELETIONS	324
 ADDITIONS	701

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, 2023** **March 31, 2024**

or

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

For the transition period from _____ to _____

Commission File Number: 001-36274

INTRA-CELLULAR THERAPIES, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation or organization)

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

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

10016
(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	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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 **October 31, 2023** **May 3, 2024**, the registrant had **96,238,126** **105,574,855** shares of common stock outstanding.

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Intra-Cellular Therapies, Inc.

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

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PART I: FINANCIAL INFORMATION

Item 1. FINANCIAL STATEMENTS

Intra-Cellular Therapies, Inc. and Subsidiary

Condensed Consolidated Balance Sheets (in thousands except share and per share amounts)

	September 30, 2023	December 31, 2022
	(Unaudited)	
	March 31, 2024	March 31, 2024
	(unaudited)	December 31, 2023
Assets		
Assets		

Assets	Assets		
Current assets:	Current assets:		
Current assets:			
Current assets:			
Cash and cash equivalents			
Cash and cash equivalents			
Cash and cash equivalents	Cash and cash equivalents	\$ 99,402	\$ 148,615
Investment securities, available-for-sale	Investment securities, available-for-sale	393,619	443,290
Restricted cash	Restricted cash	1,750	1,750
Accounts receivable, net	Accounts receivable, net	102,670	75,189
Inventory	Inventory	42,986	23,920
Prepaid expenses and other current assets	Prepaid expenses and other current assets	61,998	45,193
Total current assets	Total current assets	702,425	737,957
Property and equipment, net	Property and equipment, net	1,789	1,913
Right of use assets, net	Right of use assets, net	13,364	14,824
Inventory, non-current			
Other assets	Other assets	86	86
Total assets	Total assets	\$ 717,664	\$ 754,780
Liabilities and stockholders' equity	Liabilities and stockholders' equity		
Current liabilities:	Current liabilities:		
Current liabilities:			
Current liabilities:			
Accounts payable			
Accounts payable			
Accounts payable	Accounts payable	\$ 10,613	\$ 10,395
Accrued and other current liabilities	Accrued and other current liabilities	27,829	19,657
Accrued customer programs	Accrued customer programs	35,618	25,621

Accrued employee benefits	Accrued employee benefits	25,448	22,996
Operating lease liabilities	Operating lease liabilities	3,584	4,567
Total current liabilities	Total current liabilities	103,092	83,236
Operating lease liabilities, non-current	Operating lease liabilities, non-current	13,891	15,474
Total liabilities	Total liabilities	116,983	98,710
Stockholders' equity:	Stockholders' equity:		
Common stock, \$0.0001 par value: 175,000,000 shares authorized at September 30, 2023 and December 31, 2022; 96,225,617 and 94,829,794 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively		10	9
Common stock, \$0.0001 par value: 175,000,000 shares authorized at March 31, 2024 and December 31, 2023, respectively; 97,477,818 and 96,379,811 shares issued and outstanding at March 31, 2024 and December 31, 2023, respectively			
Common stock, \$0.0001 par value: 175,000,000 shares authorized at March 31, 2024 and December 31, 2023, respectively; 97,477,818 and 96,379,811 shares issued and outstanding at March 31, 2024 and December 31, 2023, respectively			
Common stock, \$0.0001 par value: 175,000,000 shares authorized at March 31, 2024 and December 31, 2023, respectively; 97,477,818 and 96,379,811 shares issued and outstanding at March 31, 2024 and December 31, 2023, respectively			
Additional paid-in capital	Additional paid-in capital	2,190,587	2,137,737
Accumulated deficit	Accumulated deficit	(1,588,581)	(1,477,486)
Accumulated comprehensive loss	Accumulated comprehensive loss	(1,335)	(4,190)

Accumulated comprehensive (loss) income			
Total stockholders' equity	Total stockholders' equity	600,681	656,070
Total liabilities and stockholders' equity	Total liabilities and stockholders' equity	\$ 717,664	\$ 754,780

See accompanying notes to these condensed consolidated financial statements.

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Intra-Cellular Therapies, Inc. and Subsidiary

Condensed Consolidated Statements of Operations (in thousands except share and per share amounts) (Unaudited)

		Three Months Ended September 30,		Nine Months Ended September 30,	
		2023	2022	2023	2022
		Three Months Ended March 31,			
		Three Months Ended March 31,			
		Three Months Ended March 31,			
		2024			
		2024			
		2024			
Revenues					
Revenues					
Revenues	Revenues				
Product sales, net	Product sales, net	\$ 125,810	\$ 71,870	\$ 330,669	\$ 161,699
Product sales, net					
Product sales, net					
Grant revenue					
Grant revenue					
Grant revenue	Grant revenue	363	—	1,602	746
Total revenues, net	Total revenues, net	126,173	71,870	332,271	162,445
Total revenues, net					
Total revenues, net					
Operating expenses:					
Operating expenses:					
Operating expenses:	Operating expenses:				
Cost of product sales	Cost of product sales	9,129	5,850	23,043	13,655
Cost of product sales					
Cost of product sales					
Selling, general and administrative					
Selling, general and administrative					
Selling, general and administrative	Selling, general and administrative	105,207	88,375	305,144	264,151

Research and development	Research and development	41,550	33,274	129,368	100,853
Research and development	Research and development				
Total operating expenses	Total operating expenses				
Total operating expenses	Total operating expenses				
Total operating expenses	Total operating expenses	155,886	127,499	457,555	378,659
Loss from operations	Loss from operations	(29,713)	(55,629)	(125,284)	(216,214)
Loss from operations	Loss from operations				
Loss from operations	Loss from operations				
Interest income	Interest income				
Interest income	Interest income				
Interest income	Interest income	5,498	2,122	14,377	3,990
Loss before provision for income taxes	Loss before provision for income taxes	(24,215)	(53,507)	(110,907)	(212,224)
Loss before provision for income taxes	Loss before provision for income taxes				
Loss before provision for income taxes	Loss before provision for income taxes				
Income tax expense	Income tax expense				
Income tax expense	Income tax expense				
Income tax expense	Income tax expense	(43)	(1)	(188)	(6)
Net loss	Net loss	\$ (24,258)	\$ (53,508)	\$ (111,095)	\$ (212,230)
Net loss	Net loss				
Net loss	Net loss				
Net loss per common share:	Net loss per common share:				
Net loss per common share:	Net loss per common share:				
Net loss per common share:	Net loss per common share:				
Basic & Diluted	Basic & Diluted	\$ (0.25)	\$ (0.57)	\$ (1.16)	\$ (2.26)
Basic & Diluted	Basic & Diluted				
Basic & Diluted	Basic & Diluted				
Weighted average number of common shares:	Weighted average number of common shares:				
Weighted average number of common shares:	Weighted average number of common shares:				
Weighted average number of common shares:	Weighted average number of common shares:				
Weighted average number of common shares:	Weighted average number of common shares:				
Weighted average number of common shares:	Weighted average number of common shares:				
Weighted average number of common shares:	Weighted average number of common shares:				
Basic & Diluted	Basic & Diluted	96,143,083	94,516,794	95,745,641	93,809,124
Basic & Diluted	Basic & Diluted				
Basic & Diluted	Basic & Diluted				

See accompanying notes to these condensed consolidated financial statements.

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Intra-Cellular Therapies, Inc. and Subsidiary

Condensed Consolidated Statements of Comprehensive Loss (in thousands) (Unaudited)

		Three Months Ended September 30,		Nine Months Ended September 30,	
		2023	2022	2023	2022
Three Months Ended March 31,					
Three Months Ended March 31,					
Three Months Ended March 31,					
2024					
2024					
2024					
Net loss	Net loss	\$ (24,258)	\$ (53,508)	\$ (111,095)	\$ (212,230)
Other comprehensive gain (loss):					
Unrealized gain (loss) on investment securities					
		933	(694)	2,855	(5,132)
Net loss					
Net loss					
Other comprehensive (loss) gain:					
Other comprehensive (loss) gain:					
Other comprehensive (loss) gain:					
Unrealized (loss) gain on investment securities					
Unrealized (loss) gain on investment securities					
Unrealized (loss) gain on investment securities					
Comprehensive loss	Comprehensive loss	\$ (23,325)	\$ (54,202)	\$ (108,240)	\$ (217,362)
Comprehensive loss					
Comprehensive loss					

See accompanying notes to these condensed consolidated financial statements.

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Intra-Cellular Therapies, Inc. and Subsidiary

Condensed Consolidated Statements of Stockholders' Equity (in thousands except share and per share amounts) (Unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Comprehensive (Loss) Income	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2021	81,886,965	\$ 8	\$1,639,476	\$(1,221,230)	\$ (364)	\$ 417,890
Common shares issued January 7, 2022	10,952,381	1	433,724	—	—	433,725
	Common Stock				Common Stock	
	Shares				Paid-in Capital	
					Accumulated Deficit	
					Accumulated Comprehensive (Loss) Income	
					Total Stockholders' Equity	
Balance at December 31, 2022						
Balance at December 31, 2022						
Balance at December 31, 2022						

Exercise of stock options and issuances of restricted stock	Exercise of stock options and issuances of restricted stock	1,180,696	—	8,089	—	—	8,089
Stock issued for services	Stock issued for services	383	—	24	—	—	24
Share-based compensation	Share-based compensation	—	—	8,105	—	—	8,105
Net loss	Net loss	—	—	—	(72,119)	—	(72,119)
Other comprehensive loss		—	—	—	—	(2,964)	(2,964)
Balance at March 31, 2022		94,020,425	\$ 9	\$2,089,418	\$(1,293,349)	\$ (3,328)	\$ 792,750
Exercise of stock options and issuances of restricted stock		346,411	—	5,504	—	—	5,504
Stock issued for services		397	—	22	—	—	22
Share-based compensation		—	—	11,998	—	—	11,998
Net loss		—	—	—	(86,603)	—	(86,603)
Other comprehensive loss		—	—	—	—	(1,474)	(1,474)
Balance at June 30, 2022		94,367,233	9	2,106,942	(1,379,952)	(4,802)	722,197
Exercise of stock options and issuances of restricted stock		333,954	—	5,654	—	—	5,654
Stock issued for services		475	—	22	—	—	22
Share-based compensation		—	—	11,751	—	—	11,751
Net loss		—	—	—	(53,508)	—	(53,508)
Other comprehensive loss		—	—	—	—	(694)	(694)
Balance at September 30, 2022		94,701,662	\$ 9	\$2,124,369	\$(1,433,460)	\$ (5,496)	\$ 685,422
Other comprehensive gain							
Balance at March 31, 2023							

Balance at December 31, 2022 **94,829,794 \$ 9 \$2,137,737 \$(1,477,486) \$(4,190) \$656,070**

		Common Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Comprehensive (Loss) Income	Total Stockholders' Equity
		Shares							
Balance at December 31, 2023									
Balance at December 31, 2023									
Balance at December 31, 2023									
Exercise of stock options and issuances of restricted stock	Exercise of stock options and issuances of restricted stock	849,827	1	3,639	—	—	—	—	3,640
Stock issued for services	Stock issued for services	408	—	22	—	—	—	—	22
Share-based compensation	Share-based compensation	—	—	10,439	—	—	—	—	10,439

Net loss	Net loss	—	—	—	(44,053)	—	(44,053)
Other comprehensive gain		—	—	—	—	1,492	1,492
Balance at March 31, 2023		95,680,029	\$10	\$2,151,837	\$(1,521,539)	\$(2,698)	\$627,610
Exercise of stock options and issuances of restricted stock		402,994	—	8,585	—	—	8,585
Stock issued for services		364	—	23	—	—	23
Share-based compensation		—	—	13,226	—	—	13,226
Net loss		—	—	—	(42,784)	—	(42,784)
Other comprehensive gain		—	—	—	—	430	430
Balance at June 30, 2023		96,083,387	\$10	\$2,173,671	\$(1,564,323)	\$(2,268)	\$607,090
Exercise of stock options and issuances of restricted stock		141,780	—	2,581	—	—	2,581
Stock issued for services		450	—	24	—	—	24
Share-based compensation		—	—	14,311	—	—	14,311
Net loss		—	—	—	(24,258)	—	(24,258)
Other comprehensive gain		—	—	—	—	933	933
Balance at September 30, 2023		96,225,617	\$10	\$2,190,587	\$(1,588,581)	\$(1,335)	\$600,681
Other comprehensive loss							
Balance at March 31, 2024							

See accompanying notes to these condensed consolidated financial statements.

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Intra-Cellular Therapies, Inc. and Subsidiary

Condensed Consolidated Statements of Cash Flows (in thousands) (Unaudited)

		Nine Months Ended September 30,			
		2023	2022		
		Three Months Ended March 31,		Three Months Ended March 31,	
		2024		2024	2023
Cash flows used in operating activities	Cash flows used in operating activities				
Net loss	Net loss	\$(111,095)	\$(212,230)		
Net loss					
Net loss					
Adjustments to reconcile net loss to net cash used in operating activities:	Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation	Depreciation				
Depreciation					
Depreciation	Depreciation	392	513		

Share-based compensation	Share-based compensation	37,976	31,854
Stock issued for services	Stock issued for services	69	68
Amortization of premiums and accretion of discounts on investment securities, net	Amortization of premiums and accretion of discounts on investment securities, net	(5,861)	(717)
Changes in operating assets and liabilities:	Changes in operating assets and liabilities:		
Accounts receivable, net			
Accounts receivable, net			
Accounts receivable, net	Accounts receivable, net	(27,481)	(41,382)
Inventory	Inventory	(19,066)	(15,649)
Prepaid expenses and other assets	Prepaid expenses and other assets	(16,805)	(18,686)
Accounts payable	Accounts payable	218	5,528
Accrued and other current liabilities	Accrued and other current liabilities	8,172	3,777
Accrued customer programs	Accrued customer programs	9,997	13,982
Accrued employee benefits	Accrued employee benefits	2,452	253
Operating lease liabilities, net	Operating lease liabilities, net	(1,106)	1,696
Net cash used in operating activities	Net cash used in operating activities	(122,138)	(230,993)
Cash flows provided by (used in) investing activities	Cash flows provided by (used in) investing activities		
Purchases of investments	Purchases of investments	(310,805)	(643,707)
Purchases of investments			
Purchases of investments			
Maturities of investments	Maturities of investments	369,192	465,877

Purchases of property and equipment		(268)	(806)
Net cash provided by (used in) investing activities	Net cash provided by (used in) investing activities	58,119	(178,636)
Cash flows provided by financing activities	Cash flows provided by financing activities		
Proceeds of public offering, net		—	433,725
Proceeds from exercise of stock options			
Proceeds from exercise of stock options			
Proceeds from exercise of stock options	Proceeds from exercise of stock options	14,806	19,247
Net cash provided by financing activities	Net cash provided by financing activities	14,806	452,972
Net (decrease) increase in cash, cash equivalents, and restricted cash	Net (decrease) increase in cash, cash equivalents, and restricted cash	(49,213)	43,343
Cash, cash equivalents, and restricted cash at beginning of period	Cash, cash equivalents, and restricted cash at beginning of period	150,365	93,765
Cash, cash equivalents, and restricted cash at end of period	Cash, cash equivalents, and restricted cash at end of period	\$ 101,152	\$ 137,108
Non-cash investing and financing activities			
Right of use assets under operating leases		\$ —	\$ 5,375

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,	
		2023	2022
		March 31,	
		2024	2023
Cash and cash equivalents	Cash and cash equivalents	\$ 99,402	\$135,358
Restricted cash	Restricted cash	1,750	1,750

Total cash, cash equivalents and restricted cash	Total cash, cash equivalents and restricted cash		
		\$101,152	\$137,108

See accompanying notes to these condensed consolidated financial statements.

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Intra-Cellular Therapies, Inc.

Notes to Condensed Consolidated Financial Statements (Unaudited)

September 30, 2023 March 31, 2024

1. Organization

Intra-Cellular Therapies, Inc. (the "Company"), through its wholly-owned operating subsidiary, ITI, Inc. ("ITI"), 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 psychiatric and neurological disorders by targeting intracellular signaling mechanisms within the central nervous system ("CNS"). disorders. In December 2019, CAPLYTA® (lumateperone) was approved by the U.S. Food and Drug Administration ("FDA") for the treatment of schizophrenia in adults (42mg/ (42 mg/day) and the Company initiated the commercial launch of CAPLYTA in March 2020. In December 2021, CAPLYTA was approved by the FDA for the treatment of bipolar depression in adults (42mg/ (42 mg/day). The and the Company initiated the commercial launch of CAPLYTA for the treatment of bipolar depression in December 2021. depression. Additionally, in April 2022, the FDA approved two additional dosage strengths of CAPLYTA, 10.5 mg and 21 mg capsules, to provide dosage recommendations for patients concomitantly taking strong or moderate CYP3A4 inhibitors, and 21 mg capsules for patients with moderate or severe hepatic impairment (Child-Pugh class B or C). The commercial launch of these special population doses occurred in August 2022. 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 for the treatment of bipolar depression in adults, and "lumateperone" refers to, where applicable, CAPLYTA as well as lumateperone for the treatment of indications beyond schizophrenia and bipolar depression. Lumateperone is

In April 2024, the Company completed a public offering of common stock in Phase 3 clinical development as which the Company sold 7,876,713 shares of common stock at a novel treatment public offering price of \$73.00 per share for major depressive disorder.

aggregate gross proceeds of \$575.0 million. After deducting underwriting discounts, commissions and offering expenses, the net proceeds to the Company were approximately \$543.0 million. In order to further its commercial activities and research projects and support its collaborations, the Company may 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 working capital expenditures needs 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 products, product candidates and technology and, to a much lesser extent, grant funding.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying condensed consolidated financial statements of Intra-Cellular Therapies, Inc. and its wholly owned subsidiary 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. United States GAAP set forth in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB"). All intercompany accounts and transactions have been eliminated in consolidation. The Company currently operates in one operating segment. Operating segments are defined as components of an enterprise about which separate discrete information is available for the chief operating decision maker, or decision making group, in deciding how to allocate resources and assessing performance. The Company views its operations and manages its business in one segment, which is discovering, developing and commercializing drugs primarily for the treatment of in psychiatric and neurological and psychiatric disorders.

Recent Accounting Pronouncements

Management has evaluated all accounting pronouncements. In November 2023, the FASB issued through ASU 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures, requiring public entities to disclose information about their reportable segments' significant expenses and other segment items on an interim and annual basis. Public entities with a single reportable segment are also required to apply the date of disclosure requirements. The

standard is effective for annual reporting periods beginning after December 15, 2023, and for interim reporting periods beginning January 1, 2025, with early adoption permitted. The Company is currently evaluating the condensed potential impact that this new standard will have on our consolidated financial statements and does not believe that any recently issued, but not yet effective, pronouncements, if currently adopted, would have a material effect on the Company's financial statements, related disclosures.

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Use of Estimates

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

Significant Accounting Policies

The accounting policies used by the Company in its presentation of interim financial results are consistent with those presented in Note 2 to the consolidated financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2022 December 31, 2023.

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 equivalents and investments held at financial institutions. As For the three-month period ended March 31, 2024, 98% of September 30, 2023, the majority of the Company's accounts receivable, net arose from product sales in the United States. For the nine-month period ended September 30, 2023, 97% of sales were generated from three major wholesalers accounting industry wholesalers.

Three individual customers accounted for approximately 36% 37%, 32% 26%, and 35% as well as 37%, 31%, and 29% of product sales. The percentage of sales for the total net product sales by individual customers has not significantly changed since inception. All customers have standard payment terms which generally require payment within 60 days. three-month periods ended March 31, 2024 and 2023, respectively. As of September 30, 2023 March 31, 2024, the Company continues to believe that such customers are of high credit quality.

Cash equivalents are held with major financial institutions in the United States. Certificates of deposit, cash and cash equivalents held with banks may exceed the amount of insurance provided on such deposits. Generally, these deposits may be redeemed upon demand and, therefore, bear minimal risk.

3. Investment Securities

Investment securities consisted of the following (in thousands):

		September 30, 2023			
		Amortized	Unrealized	Unrealized	Estimated
		Cost	Gains	(Losses)	Fair Value
		March 31, 2024			
		Amortized	Unrealized	Unrealized	Estimated
		Cost	Gains	(Losses)	Fair Value
U.S. Government Agency Securities	U.S. Government Agency Securities	\$191,726	\$ 4	\$ (692)	\$191,038
FDIC Certificates of Deposit	FDIC Certificates of Deposit	5,131	—	(40)	5,091
Certificates of Deposit	Certificates of Deposit	60,000	—	—	60,000
Commercial Paper	Commercial Paper	81,594	—	(150)	81,444
Corporate Notes/Bonds	Corporate Notes/Bonds	76,503	—	(457)	76,046

		\$414,954	\$	4	\$(1,339)	\$413,619
		\$				
		December 31, 2022				
		Amortized	Unrealized	Unrealized	Estimated	
		Cost	Gains	(Losses)	Fair	
					Value	
		December 31, 2023				
		Amortized				Estimated
		Cost				Fair
						Value
U.S. Government Agency Securities	U.S. Government Agency Securities	\$188,465	\$	14	\$(1,729)	\$186,750
FDIC Certificates of Deposit	FDIC Certificates of Deposit	4,155		3	(72)	4,086
Certificates of Deposit	Certificates of Deposit	7,500		—	—	7,500
Commercial Paper	Commercial Paper	100,711		3	(269)	100,445
Corporate Notes/Bonds	Corporate Notes/Bonds	189,588		1	(2,141)	187,448
		\$490,419	\$	21	\$(4,211)	\$486,229
		\$				

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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, 2023** **March 31, 2024** and **December 31, 2022** **December 31, 2023**, the Company held **\$41.2 million** **\$93.0 million** and **\$71.5 million** **\$77.8 million**, respectively, of available-for-sale investment securities with contractual maturity dates more than one year and less than two years, with the remainder of the available-for-sale investment securities having contractual maturity dates less than one year.

Unrealized losses as of September 30, 2023 approximate less than 1% of the estimated fair value of investments. The aggregate related fair value of investments with unrealized losses as of **September 30, 2023** **March 31, 2024** was **\$340.9 million** **\$253.5 million**, which consisted of **\$183.4 million** **\$81.3 million** from U.S. government agency securities, **\$5.1 million** **\$3.4 million** of certificates of deposit, **\$81.4 million** **\$56.2 million** of commercial paper, and **\$71.0 million** **\$112.6 million** of corporate notes/bonds. **\$58.9 million** **\$37.8 million** of the aggregate fair value of investments with unrealized losses as of **September 30, 2023** **March 31, 2024** has been held in a continuous unrealized loss position for over 12 months, with the remaining **\$282.0 million** **\$215.7 million** held in a continuous unrealized loss position for less than 12 months. As of **December 31, 2022** **December 31, 2023**, the aggregate related fair value of investments with unrealized losses was **\$438.3 million** **\$165.2 million**. **\$49.1 million** **\$70.1 million** of the aggregate fair value of investments with unrealized losses as of **December 31, 2022** **December 31, 2023** had been held in a continuous unrealized loss position for over 12 months, with the remaining **\$389.2 million** **\$95.1 million** 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.

The Company applies the fair value method under ASC Topic 820, *Fair Value Measurements and Disclosures*. 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 has had no assets or liabilities that were measured using prices with significant unobservable inputs (Level 3 assets and liabilities) as of September 30, 2023, March 31, 2024 and December 31, 2022. The carrying value of cash held in money market funds of \$4.4 million \$31.2 million as of September 30, 2023, March 31, 2024 and \$12.2 million \$10.7 million as of December 31, 2022, December 31, 2023 is included in cash and cash equivalents on the condensed consolidated balance sheets and approximates market value based on quoted market prices or Level 1 inputs. The carrying value of cash held in certificates of deposit of \$20.0 million \$60.0 million as of September 30, 2023, March 31, 2024 is included in cash and cash equivalents. The carrying value of cash held in commercial paper of \$14.9 million, U.S. government agency securities of \$20.5 million \$2.5 million and certificates of deposit of \$7.5 million \$60.0 million as of December 31, 2022, December 31, 2023 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):

[illegible]

Certificates of Deposit	Certificates of Deposit	60,000	—	60,000	—
Commercial Paper	Commercial Paper	81,444	—	81,444	—
Corporate Notes/Bonds	Corporate Notes/Bonds	76,046	—	76,046	—
		<u>\$418,039</u>	<u>\$4,420</u>	<u>\$413,619</u>	<u>\$ —</u>
		<u>\$</u>			

Fair Value Measurements at Reporting Date Using					
Quoted Prices in Active Markets for Significant Other Significant					
December 31, 2022					
Identical Assets (Level 1)					
Observable Inputs (Level 2)					
Unobservable Inputs (Level 3)					

Fair Value Measurements at Reporting Date Using				Fair Value Measurements at Reporting Date Using		
December 31, 2023				December 31, 2023		
				Quoted Prices in Active Markets for Identical Assets (Level 1)		
				Significant Other Observable Inputs (Level 2)		
				Significant Unobservable Inputs (Level 3)		

Money Market Funds	Money Market Funds	\$ 12,203	\$12,203	\$ —	\$ —
U.S. Government Agency Securities	U.S. Government Agency Securities	186,750	—	186,750	—
FDIC Certificates of Deposit	FDIC Certificates of Deposit	4,086	—	4,086	—
Certificates of Deposit	Certificates of Deposit	7,500	—	7,500	—
Commercial Paper	Commercial Paper	100,445	—	100,445	—
Corporate Notes/Bonds	Corporate Notes/Bonds	187,448	—	187,448	—
		<u>\$498,432</u>	<u>\$12,203</u>	<u>\$486,229</u>	<u>\$ —</u>
		<u>\$</u>			

5. Inventory

Inventory consists of the following (in thousands):

September 30, 2023	December 31, 2022

	March 31, 2024	March 31, 2024	December 31, 2023
Raw materials	Raw materials	\$33,173	\$17,227
Work in process	Work in process	4,773	2,594
Finished goods	Finished goods	5,040	4,099
		<u>\$42,986</u>	<u>\$23,920</u>
Total			
Less: Current portion			
Total inventory, non-current			

The raw materials As of March 31, 2024 and December 31, 2023, the Company has recorded \$7.8 million and \$7.7 million, respectively, in inventory on the condensed consolidated balance includes the active pharmaceutical ingredients (API) sheets which is subject to supplemental regulatory procedures but believes it is probable that it has future economic benefit.

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6. Prepaid and any related intermediate compounds. This supply exceeds 12 months of forecasted sales Other Assets

Prepaid expenses and other needs. assets consist of the following (in thousands):

	March 31, 2024	December 31, 2023
Prepaid operating expenses, non-clinical	\$ 28,312	\$ 19,465
Production campaign deposits	23,781	15,127
Clinical trial advances	17,076	11,630
Prefunded customer programs	4,567	3,514
Total	<u>73,736</u>	<u>49,736</u>
Less: Current portion	<u>(66,048)</u>	<u>(42,443)</u>
Total other assets	<u>\$ 7,688</u>	<u>\$ 7,293</u>

6.7. Right of Use Assets and Lease Liabilities

In 2014, the Company entered into a long-term lease with a related party, which, as amended, provided for a lease of 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. lease in accordance with ASC Topic 842, Leases, 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.

The Company has also entered into an agreement (the "Vehicle Lease") with a company (the "Lessor") to obtain acquire motor vehicles for certain employees. The Vehicle Lease provides for individual vehicle leases, for the vehicles, which at each lease commencement was determined to qualify for operating lease treatment. 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 12 months. Leases which the Company determined to have a lease term of 12 months or less will be treated as short-term in accordance with the accounting policy election and are not recognized on the balance sheet. Each 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 \$1.75 million

letter of credit that the Lessor may draw upon in the event the Company defaults on the Vehicle Lease, which has been recorded as restricted cash on the condensed consolidated balance sheets.

The Company has no other significant leases. In addition, no identified leases require allocations between lease and non-lease components.

The following tables present the lease balances within the condensed consolidated balance sheets, weighted average remaining lease term, and the weighted average discount rates related to leases as of September 30, 2023, March 31, 2024 and December 31, 2022, December 31, 2023:

	March 31, 2024	December 31, 2023
Other information		
Weighted average remaining lease term	5.0 years	5.3 years
Weighted average discount rate	9.07 %	9.07 %

The following table presents the lease cost for the three-month periods ended March 31, 2024 and operating cash outflows as of September 30, 2023 and December 31, 2022, 2023 (in thousands, except years and percentages) thousands):

	September 30, 2023	December 31, 2022
Other information		
Weighted average remaining lease term	5.6 years	5.9 years
Weighted average discount rate	9.07 %	8.76 %

		Nine Months Ended September 30,			
		2023	2022		
		Three Months Ended March 31,			
		2024		2024	Three Months Ended March 31, 2023
Lease cost	Lease cost				
Operating lease cost					
Operating lease cost					
Operating lease cost	Operating lease cost	\$2,921	\$4,139	\$941	\$1,085
Variable lease cost	Variable lease cost	1,130	1,218	411	404
Short-term lease cost	Short-term lease cost	1,757	—	536	672
		\$5,808	\$5,357		
	\$			\$1,888	\$2,161

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Maturity analysis under the lease agreements is as follows (in thousands):

Three Nine months ending December 31, 2023 December 31, 2024	\$	930 2,850
Year ending December 31, 2024		3,792
Year ending December 31, 2025		3,907
Year ending December 31, 2026		3,974
Year ending December 31, 2027		4,022
Year ending December 31, 2028		4,144
Thereafter		5,915 1,771
Total		22,540 20,668
Less: Present value discount		(5,065) (4,292)
Total operating lease liability		17,475 16,376
Less: Current portion		(3,584) (3,639)
Operating lease liabilities, non-current	\$	13,891 12,737

7.8. 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") (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 has made payments of \$10.75 million \$10.8 million to BMS related to milestones achieved to date for lumateperone. 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 ten 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.

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Purchase Commitments

The Company enters into certain other long-term commitments for goods and services that are outstanding for periods greater than one year. The Company recently amended certain has manufacturing service agreements committing the Company to certain minimum annual purchase commitments for which the Company anticipates making payments within the years 2025 through 2029. As of September 30, 2023 March 31, 2024, the Company has committed to purchasing production campaigns for various raw materials including active pharmaceutical ingredients (API) and its intermediates from each of its supply vendors. The current campaigns are expected to be received into inventory during 2023 and 2024, through 2027. The Company has paid deposits of \$19.4 million \$23.8 million and \$21.6 million \$15.1 million as of September 30, 2023 March 31, 2024 and December 31, 2022 December 31, 2023, respectively, for related to these campaigns. Of the various campaigns, which are \$23.8 million balance as of March 31, 2024, \$16.2 million is recorded within prepaid expenses and other current assets. assets as the campaigns are expected to be received within one year of the balance sheet date and \$7.6 million is recorded within other assets on the condensed consolidated balance sheet as the campaigns are expected to be received after March 31, 2025. Of the \$15.1 million balance as of December 31, 2023, \$7.9 million is recorded within prepaid expenses and other current assets and \$7.2 million is recorded within other assets on the condensed consolidated balance sheet. 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.

8.9. Share-Based Compensation

Total share-based compensation expense related to all of the Company's share-based awards, including stock options and restricted stock units (RSUs), granted to employees and directors recognized during the nine-month three-month periods ended September 30, 2023 March 31, 2024 and 2022, 2023, was comprised of the

following (in thousands):

		Nine Months Ended September 30,	
		2023	2022
Three Months Ended March 31,			
		2024	2023
Inventoriable costs	Inventoriable costs	\$ 1,186	\$ 1,307
Selling, general and administrative	Selling, general and administrative	25,269	19,293
Research and development	Research and development	11,521	11,254
Total share-based compensation expense	Total share-based compensation expense	\$ 37,976	\$31,854

Information regarding the stock options activity, including with respect to grants to employees and directors under the Amended and Restated 2018 Equity Incentive Plan (the Amended 2018 Plan) and 2019 Inducement Award Plan (the 2019 Inducement Plan) as of September 30, 2023 March 31, 2024, and changes during the nine-month three-month period then ended, are summarized as follows:

	Number of Shares	Weighted- Average Exercise Price	Weighted- Average Contractual Life
Outstanding at December 31, 2022	4,785,972	\$ 26.27	5.8 years
Options granted 2023	284,212		
Options exercised 2023	(645,977)		
Options canceled or expired 2023	(38,652)		
Outstanding at September 30, 2023	4,385,555	\$ 27.96	
Vested and expected to vest at September 30, 2023	4,385,555	\$ 27.96	
Exercisable at September 30, 2023	3,605,710	\$ 23.37	

	Number of Shares	Weighted- Average Exercise Price	Weighted- Average Contractual Life
Outstanding at December 31, 2023	4,239,982	\$ 28.22	5.2 years
Options granted 2024	—		
Options exercised 2024	(461,857)		
Options canceled or expired 2024	(5,020)		
Outstanding at March 31, 2024	3,773,105	\$ 28.99	5.2 years
Vested and expected to vest at March 31, 2024	3,773,105	\$ 28.99	
Exercisable at March 31, 2024	3,379,986	\$ 26.29	4.9 years

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The fair value of the time-based RSUs is based on the closing price of the Company's common stock on the date of grant. Information regarding the time-based RSU activity, including with respect to grants to employees under the Amended 2018 Plan and 2019 Inducement Plan, and changes during the nine-month three-month period ended September 30, 2023 March 31, 2024 is summarized as follows:

	Number of Shares	Weighted-Average Grant Date Fair Value Per Share	Weighted- Average Contractual Life
Outstanding at December 31, 2022	1,274,664	\$ 42.76	0.8 years
Time-based RSUs granted in 2023	1,090,927		
Time-based RSUs vested in 2023	(657,775)		
Time-based RSUs cancelled in 2023	(60,148)		
Outstanding at September 30, 2023	1,647,668	\$ 48.90	

	Number of Shares	Weighted-Average Grant Date Fair Value Per Share	Weighted- Average Contractual Life
Outstanding at December 31, 2023	1,645,130	\$ 48.92	1.0 year
Time-based RSUs granted in 2024	980,422		
Time-based RSUs vested in 2024	(697,741)		
Time-based RSUs cancelled in 2024	(12,676)		
Outstanding at March 31, 2024	1,915,135	\$ 59.67	1.6 years

As of September 30, 2023 March 31, 2024, there was \$61.3 million were \$109.6 million of unrecognized compensation costs estimated related to unvested time-based RSUs.

9.10. Loss Per Share

The following share-based awards were excluded in the calculation of diluted net loss per common share because their effect could be anti-dilutive as applied to the loss from operations for the three and nine-month three-month periods ended September 30, 2023 March 31, 2024 and 2022; 2023:

Three and Nine Months Ended September 30, 2023 2022		Three Months Ended March 31, 2024		Three Months Ended March 31, 2023	
Stock options	4,385,555	4,926,117			
Stock options					
Stock options			3,773,105		4,737,963
RSUs	1,755,460	1,495,711	2,139,637		1,829,155

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

You should read the following in conjunction with our unaudited condensed consolidated financial statements and the related notes thereto that appear elsewhere in this Quarterly Report on Form 10-Q and the audited consolidated financial statements and notes thereto and under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K filed on [March 1, 2023](#) [February 22, 2024](#). In addition to historical information, the following discussion and analysis includes forward-looking information that involves risks, uncertainties and assumptions. Our actual results and the timing of events could differ materially from those anticipated by these forward-looking statements as a result of many factors, including those discussed under "Risk Factors" in our Annual Report on Form 10-K filed on [March 1, 2023](#) [February 22, 2024](#), 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 psychiatric](#) and neurological [disorders by targeting intracellular signaling mechanisms within the central nervous system, or CNS disorders](#). In December 2019, CAPLYTA® (lumateperone) was approved by the U.S. Food and Drug Administration, or FDA, for the treatment of schizophrenia in adults ([42mg/ \(42 mg/day\)](#)) and we initiated the commercial launch of CAPLYTA in March 2020. In December 2021, CAPLYTA was approved by the FDA for the treatment of bipolar depression in adults ([42mg/ \(42 mg/day\)](#)). We initiated the commercial launch of CAPLYTA for the treatment of bipolar depression in December 2021. Additionally, in April 2022, the FDA approved two additional dosage strengths of CAPLYTA, 10.5 mg and 21 mg capsules, to provide dosage recommendations for patients concomitantly taking strong or moderate CYP3A4 inhibitors, and 21 mg [capsules](#) for patients with moderate or severe hepatic impairment (Child-Pugh class B or C). We initiated the commercial launch of these special population doses in August 2022. As used in this report, "CAPLYTA" refers to lumateperone approved by the FDA for the treatment of schizophrenia in adults and for the treatment of bipolar depression in adults, and "lumateperone" refers to, where applicable, CAPLYTA as well as lumateperone for the treatment of indications beyond schizophrenia and bipolar depression.

Lumateperone is in Phase 3 clinical development as a novel treatment for major depressive disorder, or MDD. [Patient enrollment](#)

In April 2024, we announced positive topline results from our Phase 3 clinical trial, Study 501, evaluating lumateperone 42 mg as an adjunctive therapy to antidepressants for the treatment of MDD. Lumateperone 42 mg given once daily as adjunctive therapy to antidepressants met the primary endpoint in Study 501 by demonstrating a statistically significant and [Study](#) clinically meaningful reduction in the Montgomery Asberg Depression Rating Scale (MADRS) total score compared to placebo at Week 6. In the modified intent-to-treat (mITT) study population, the least squares (LS) mean reduction from baseline for lumateperone 42 mg was 14.7 points, versus 9.8 points for placebo (LS mean difference = -4.9 points; $p < 0.0001$; ES= 0.61). Lumateperone 42 mg also met the key secondary endpoint in the study by demonstrating a statistically significant and clinically meaningful reduction in the Clinical Global Impression Scale for Severity of Illness (CGI-S) score compared to placebo at Week 6 ($p < 0.0001$; ES= 0.67). Statistically significant efficacy was seen at the earliest time point tested (Week 1) and maintained throughout the study in both the primary and the key secondary endpoints. In this study, lumateperone 42 mg robustly improved depressive symptoms as reported by patients as measured by the Quick Inventory of Depressive Symptomatology Self Report (QIDS-SR-16) ($p < 0.0001$). Lumateperone was generally safe and well-tolerated in this study. The most commonly reported adverse events that were observed at a rate greater than or equal to 5% and at least twice the rate of placebo in the total population were dry mouth (10.8%), fatigue (9.5%) and tremor (5.0%). Adverse events were mostly mild to moderate and resolved within a short period of time. These adverse events were similar to those seen in prior studies of lumateperone as a treatment for bipolar depression and schizophrenia.

[Studies 502 and 505](#) are our global Phase 3 clinical trials evaluating lumateperone 42 mg as an adjunctive therapy to antidepressants for the treatment of MDD, MDD. We recently completed clinical conduct in Study 502 and clinical conduct in Study 505 is ongoing. [In addition, we initiated a third global Phase 3 trial, Study 505, also evaluating lumateperone 42 mg as an adjunctive therapy to antidepressants for the treatment of MDD.](#) Study 505 is intended to serve as a potential additional registration trial in support of a supplemental New Drug Application, or sNDA, for approval of lumateperone as an adjunctive therapy to antidepressants for the treatment of MDD, if needed. [This is a common strategy employed](#) We are also conducting an open label roll-over study, Study 503, to assess long-term safety in [mood disorder development programs, this patient population, which we expect to complete in the third quarter of 2024.](#) We expect to announce topline results from Study 501 in the first quarter of 2024 and Study 502 [late](#) in the second quarter of 2024 and, subject to [the such](#) results, [of these studies](#), 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 the second half of 2024.

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In the first quarter of 2020, as part of our lumateperone bipolar depression clinical program, 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 our adjunctive study that was part of our bipolar depression clinical program, 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 MDD. In March 2023, we announced positive topline results from Study 403 as lumateperone [42mg 42 mg](#) given once daily met the primary endpoint in the study by demonstrating a statistically significant and clinically meaningful reduction in the [Montgomery Asberg Depression Rating Scale \(MADRS\) MADRS](#) total score compared to placebo at Week 6 in the combined patient population of MDD with mixed features and bipolar depression with mixed features (5.7 point reduction [v. vs.](#) placebo; $p < 0.0001$; Cohen's d effect size (ES) of 0.64). Robust results were also seen in the individual patient population of MDD with mixed features (5.9 point reduction [v. vs.](#) placebo; $p < 0.0001$; ES= 0.67), and in the individual patient population of bipolar depression with mixed features (5.7 point reduction [v. vs.](#) placebo; $p < 0.0001$; ES= 0.64). Additionally, lumateperone [42mg 42 mg](#) met the key secondary endpoint in the study by demonstrating a statistically significant and clinically meaningful reduction in the clinician's assessment of improvement in the overall severity on the [Global Impression of Severity Scale \(CGI-S\) CGI-S](#) score compared to placebo at Week 6 in the combined patient population of MDD with mixed features and bipolar depression with mixed features ($p < 0.0001$; ES= 0.59) and in the individual patient population of MDD with mixed

features ($p=0.0003$; $ES= 0.57$), as well as the individual patient population of bipolar depression with mixed features p ($p<0.0001$; $ES=0.61$). We expect to discuss the results of Study 403 with the FDA in late 2023 or the first quarter of 2024.

We also have an ongoing study, Study 304, 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 CAPLYTA for the treatment of schizophrenia as is typical for antipsychotics. We expect to complete Study 304 and report topline results in the second half of 2024.

Within the lumateperone portfolio, we have conducted or are also in the process of conducting studies with pediatric patients in schizophrenia, bipolar disorder and irritability associated with autism spectrum disorder. Our lumateperone pediatric program includes a double-blind, placebo-controlled study in bipolar depression and two double-blind, placebo-controlled studies in irritability associated with autism spectrum disorder. Additionally, the program includes an open-label safety study in schizophrenia and bipolar disorder. Patient enrollment is ongoing in the open-label safety study as well as in the double-blind, placebo-controlled study in bipolar depression. In addition, we are developing a long-acting injectable, or LAI, formulation to provide more treatment options to patients suffering from mental illness. We have conducted a Phase 1 single ascending dose study with our initial an LAI formulation. This study evaluated the pharmacokinetics, safety and tolerability of this a lumateperone LAI in patients with stable symptoms of schizophrenia and was generally safe and well-tolerated. We are also evaluating several additional formulations of the a lumateperone LAI with treatment durations of one month and longer. We have completed all non-clinical studies to support the initiation of a Phase 1 study with four additional formulations of our LAI. We expect to commence clinical conduct in this study in the first second half of 2024. Given the encouraging tolerability data efficacy and favorable safety profile to date with oral lumateperone, we believe that an LAI 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 generalized anxiety disorder, psychosis in Alzheimer's disease and agitation in patients with dementia, the treatment of dementia-related psychosis and the treatment of certain depressive disorders in the elderly. Alzheimer's disease. 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 Phase 2 programs evaluating ITI-1284-ODT-SL for the treatment of generalized anxiety disorder, psychosis in Alzheimer's disease and agitation in patients with agitation in Alzheimer's disease. The FDA has informed us that they do not believe the deuterated and undeuterated forms of lumateperone are identical. As a result, the non-clinical data from lumateperone may not be broadly applied to ITI-1284-ODT-SL, and we conducted additional toxicology studies. These studies have been completed and we expect to commence clinical conduct in our Phase 2 studies in the first half of 2024. We are continuing with Phase 1 studies with ITI-1284-ODT-SL, including drug-drug interaction studies.

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We have another major program 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 central nervous system, or 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 immune system regulation, neurodegenerative diseases, cancers and other non-CNS disorders. Lenrispodun (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 lenrispodun for Parkinson's disease and conducted a Phase 1/2 clinical trial of lenrispodun 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 this study, lenrispodun was generally well-tolerated with a favorable safety profile and clinical signs consistent with improvements in motor symptoms and dyskinesias. Our Phase 2 clinical trial of lenrispodun evaluating improvements in motor symptoms, changes in cognition, and inflammatory biomarkers in patients with Parkinson's disease is ongoing. We expect to complete report topline results from this study in the first half of 2025. We also have an active Investigational New Drug application, or IND, to evaluate our newest candidate within the PDE 1 PDE1 inhibitor program, ITI-1020, as a novel cancer immunotherapy. Our Phase 1 program with ITI-1020 in healthy volunteers is ongoing.

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-HT_{2A} 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. We have conducted a Phase 1 single ascending dose study evaluating the safety, tolerability and pharmacokinetics of ITI-333 in healthy volunteers. In this study, ITI-333 achieved plasma exposures at or above those required for efficacy and was generally safe and well-tolerated. We have commenced a neuroimaging study to investigate brain occupancy for receptors that play a role in substance use disorder and also have applicability for pain. The results of this study will support the dose selection for future studies. We also have an ongoing multiple ascending dose study with ITI-333 in healthy volunteers that we expect to complete in 2024. 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 also have assembled the ITI-1500 program focused on the development of novel non-hallucinogenic psychedelics. Compounds in this series interact with serotonergic (5-HT_{2A}) receptors in a management team with significant industry experience to lead unique way, potentially allowing the commercialization development 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 this new drug class in the fields of schizophrenia, bipolar depression mood, anxiety and other CNS disorders.

COVID-19

The COVID-19 pandemic has had widespread, rapidly evolving, neuropsychiatric disorders without the liabilities of known psychedelics including the hallucinogenic potential and unpredictable impacts on global societies, economies, financial markets, and business practices. We continue to closely monitor the evolution and global impact of the COVID-19 pandemic, the identification of new variants of the COVID-19 virus and related developments, and our focus remains on promoting employee health and safety while continuing to advance the commercialization of our products and the research and development of our product candidates. Please refer to our Risk Factors risk for cardiac valvular pathologies. Our lead compound in Part I, Item 1A of our Annual Report on Form 10-K for further discussion of risks related to the COVID-19 pandemic. this program, ITI-1549, is currently being evaluated in IND enabling studies.

Results of Operations

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

Revenues

Net revenues

Revenues are comprised primarily of net product sales of our commercial product, CAPLYTA, in the United States and is supplemented, to a much lesser extent, by grant revenue from government programs. Our net product sales of CAPLYTA represent sales primarily to wholesalers and specialty distributors and reflect certain adjustments deducted from product sales, consist of sales of CAPLYTA, which was approved by the FDA for the treatment of schizophrenia in adults in December 2019 and for the treatment of bipolar depression in adults in December 2021. In addition, in April 2022, the FDA approved two additional dosage strengths of CAPLYTA for certain patients. During the three and nine-month periods ended September 30, 2023, net gross to arrive at product sales, increased net.

Expenses

Our operating expenses are comprised of (i) costs of product sales; (ii) selling expenses; (iii) general and administrative expenses; and (iv) research and development expenses.

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Costs of product sales are comprised of:

- royalty payments on product sales;
- direct costs of formulating, manufacturing and packaging drug product; and
- overhead costs consisting of labor, share-based compensation, shipping, external inventory manufacturing and other miscellaneous operating costs.

Selling expenses are incurred in three major categories:

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

General and administrative expenses are incurred in three major categories:

- salaries, share-based compensation and related benefit costs;
- patent, legal and professional costs; and
- office, facilities and infrastructure overhead.

Research and development costs are comprised of:

- fees paid to approximately \$125.8 million external parties that provide us with contract services, such as pre-clinical testing, manufacturing and \$330.7 million, respectively, from approximately \$71.9 million related testing, clinical trial activities and \$161.7 million for the three license milestone payments; and nine-month periods ended September 30, 2022, respectively.

Expenses: internal recurring costs, such as costs relating to labor and fringe benefits, share-based compensation, materials, supplies, facilities and maintenance.

The process of researching, developing and commercializing drugs for human use is lengthy, unpredictable and subject to many risks. The costs associated with the commercialization of CAPLYTA are substantial and will be incurred prior to our generating sufficient revenue to offset these costs. Costs for the clinical development of lumateperone-related projects, including for the treatment of MDD, consume and, together with our required post-marketing studies and other anticipated clinical development programs, 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 PDE, ITI-1284 and ITI-333 development programs are currently in clinical development. Our other programs are still in the pre-clinical stages and will require extensive funding not only to complete pre-clinical testing, but also to commence and complete clinical trials. Expenditures that we incur in connection with these programs 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 programs to the advancement of lumateperone, which could have a material adverse impact on the advancement of these other programs and on our results of operations.

Our operating expenses are comprised of (i) costs of product sales; (ii) selling expenses; (iii) general and administrative expenses; and (iv) research and development expenses.

Costs of product sales are comprised of:

- royalty payments on product sales;
- direct costs of formulating, manufacturing and packaging drug product; and
- overhead costs consisting of labor, share-based compensation, shipping, outside inventory manufacturing and other miscellaneous operating costs.

Selling expenses are incurred in three major categories:

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

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.

Research and development costs are comprised of:

- fees paid to external parties that provide us with contract services, such as pre-clinical testing, manufacturing and related testing, clinical trial activities and license milestone payments; and
- internal recurring costs, such as costs relating to labor and fringe benefits, materials, supplies, facilities and maintenance.

Product sold through September 30, 2023 March 31, 2024 consisted of active pharmaceutical ingredient (API) and drug product that was previously charged to research and development expenses prior to FDA approval of CAPLYTA and other direct, indirect, and overhead costs required to make final product for sale, CAPLYTA. Because the Company's policy does not allow for the capitalization of pre-approval the cost of drug product that was incurred prior to FDA approval, the cost of drug product sold is lower than it would have been and has a positive impact on our cost of product sales for the three and nine-month three-month periods

ended **September 30, 2023** **March 31, 2024** and **2022, 2023**. We expect to continue to have this favorable impact on cost of product sales and related product gross margins until the cost of our sales of CAPLYTA include drug product that is manufactured entirely after the FDA approval. We expect that this will be the case for the **near-term** **near term** and, as a result, our cost of product sales is less than we anticipate it will be in future periods. In addition, as our net product sales increase in the future and, we exceed certain sales thresholds, the applicable royalty rate for payments we make under our License Agreement with Bristol Myers Squibb (BMS) will increase, which we anticipate will result in an increase to cost of product sales.

We expect that research and development expenses will increase moderately as we proceed with our clinical trials, including increased manufacturing of drug product for clinical trials and pre-clinical development activities. We also expect that our selling, general and administrative costs will increase from prior periods primarily due to costs associated with promotional activities to support the commercial sales of CAPLYTA as well as costs associated with building, **maintaining** and **maintaining** **expanding** infrastructure, which will include hiring additional personnel and increasing technological capabilities. We granted significant share-based awards in **2023 2024** and **2022, 2023**. We expect to continue to grant share-based awards in the future. We expect that our growing employee base will increase our share-based compensation expense in future periods. In addition, inflation has and may continue to affect us by increasing clinical trial and other operational costs. To date, inflation has not had a material impact on our business, but if the global inflationary trends continue, we expect appreciable increases in clinical trial, selling, labor, and other operating costs.

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The following table sets forth our revenues, operating expenses, interest income and income tax expense for the **three and nine-month** **three-month** periods ended **September 30, 2023** **March 31, 2024** and **2022 2023** (in thousands):

		Three Months Ended September 30,		Nine Months Ended September 30,	
		2023	2022	2023	2022
		(Unaudited)		(Unaudited)	
		Three Months Ended September 30,		Three Months Ended September 30,	
		Three Months Ended March 31,		Three Months Ended March 31,	
		Three Months Ended March 31,		Three Months Ended March 31,	
		2024		2024	
		2024		2024	
		2024		2024	
Revenues					
Revenues					
Revenues	Revenues				
Product sales, net	Product sales, net	\$ 125,810	\$ 71,870	\$ 330,669	\$ 161,699
Product sales, net					
Product sales, net					
Grant revenue					
Grant revenue					
Grant revenue	Grant revenue	363	—	1,602	746
Total revenues	Total revenues	126,173	71,870	332,271	162,445
Total revenues					
Total revenues					
Expenses					
Expenses					
Expenses	Expenses				
Cost of product sales	Cost of product sales	9,129	5,850	23,043	13,655
Cost of product sales					

Cost of product sales					
Selling, general and administrative					
Selling, general and administrative					
Selling, general and administrative	Selling, general and administrative	105,207	88,375	305,144	264,151
Research and development	Research and development	41,550	33,274	129,368	100,853
Research and development					
Research and development					
Total operating expenses					
Total operating expenses					
Total operating expenses	Total operating expenses	155,886	127,499	457,555	378,659
Loss from operations	Loss from operations	(29,713)	(55,629)	(125,284)	(216,214)
Loss from operations					
Loss from operations					
Interest income					
Interest income					
Interest income	Interest income	5,498	2,122	14,377	3,990
Income tax expense	Income tax expense	(43)	(1)	(188)	(6)
Income tax expense					
Income tax expense					
Net loss	Net loss	\$ (24,258)	\$ (53,508)	\$ (111,095)	\$ (212,230)
Net loss					
Net loss					

Comparison of Three and Nine-Month Three-Month Periods Ended September 30, 2023 March 31, 2024 and September 30, 2022 March 31, 2023

Product Sales, Net

Net product sales were \$125.8 million and \$330.7 million \$144.8 million for the three and nine-month periods three-month period ended September 30, 2023, respectively, March 31, 2024 compared to \$71.9 million and \$161.7 million \$94.7 million for the three and nine-month periods three-month period ended September 30, 2022 March 31, 2023, respectively, which represents an increase of 53%. Net product sales for the periods presented are comprised of sales of CAPLYTA for the treatment of schizophrenia and bipolar depression.

Cost of Product Sales

Cost of product sales was \$9.1 million and \$23.0 million \$9.9 million for the three and nine-month periods three-month period ended September 30, 2023 March 31, 2024, respectively, compared to \$5.9 million and \$13.7 million \$6.8 million for the three and nine-month periods three-month period ended September 30, 2022 March 31, 2023, respectively, which represents an increase of 47%. Cost of product sales consisted primarily of product royalty fees, and direct costs and overhead, costs. Drug product costs, including certain direct, indirect, and overhead costs, for product all of which increased as a result of the increased sales from commercial launch through September 30, 2023 were previously charged to research and development expenses prior to FDA approval in December 2019 and are not a component of cost of product sales. This minimal cost drug product had a favorable impact on our cost of product sales and related product gross margins for the three and nine-month periods ended September 30, 2023 and 2022.

volume.

We expect our product sales in future quarters will continue to be impacted by lower cost of product sales that excludes the cost of the drug product that was incurred prior to FDA approval until our sales of CAPLYTA include drug product that is manufactured entirely manufactured after the FDA approval. We expect that this will continue to be the case for the near-term and, as a result, our cost of product sales will be less than we anticipate it will be in future periods. We expect cost of product sales will increase in future quarters as minimum sales thresholds are met, resulting in royalty payment increases under the BMS License Agreement.

Selling, General and Administrative Expenses

Selling, general and administrative costs expenses for the three-month period ended September 30, 2023 March 31, 2024 were \$105.2 million \$113.1 million as compared to \$88.4 million \$98.9 million in the three-month period ended September 30, 2022 March 31, 2023, which represents an increase of 19% 14%.

Selling costs were \$80.9 million \$87.7 million for the three-month period ended September 30, 2023 March 31, 2024 as compared to selling costs of \$68.1 million \$76.5 million in the same period in 2022, 2023, which represents an increase of 19% 15%. This increase is primarily due to increases of marketing salaries, benefits and advertising expenses share-based compensation of \$6.8 million, \$6.5 million, sales related labor force costs of \$5.0 million \$3.9 million primarily due to the increase in our sales force expansion that occurred in the first half of 2023, and travel professional fees and other sales related expenses costs of \$1.0 million \$0.8 million. Salaries, bonuses Compensation and related benefit costs for our sales and marketing functions for the three-month periods ended September 30, 2023 March 31, 2024 and 2022 2023 constituted 35% 32% and 34% 33%, respectively, of our selling costs.

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General and administrative expenses were \$24.3 million in \$25.4 million for the three-month period ended September 30, 2023 March 31, 2024 as compared to \$20.3 million for \$22.4 million in the same period in 2022, 2023, which represents an increase of 20% 13%. This increase is due to increases in share-based compensation IT related services of \$2.5 million, \$2.5 million and professional and other administrative expenses fees of \$1.0 million, partially offset by a decrease in insurance and the remainder of the increase relates to information technology related other costs of \$0.5 million. Salaries, bonuses Compensation and related benefit costs for our general and administrative functions for the three-month periods ended September 30, 2023 March 31, 2024 and 2022 2023 constituted 18% and 23% 24%, respectively, of our general and administrative costs.

Selling, general and administrative costs for the nine-month period ended September 30, 2023 were \$305.1 million as compared to \$264.2 million in the nine-month period ended September 30, 2022, which represents an increase of 16%.

Selling costs were \$233.5 million for the nine-month period ended September 30, 2023 as compared to \$205.4 million in the same period in 2022, or an increase of 14%. This increase is primarily due to increases in commercialization costs of \$14.5 million, sales related labor costs of \$11.1 million primarily due to the increase in our sales force and \$2.5 million in travel and other sales related expenses. Salaries, bonuses and related benefit costs for our sales and marketing functions for the nine-month periods ended September 30, 2023 and 2022 constituted approximately 35% of our selling costs.

General and administrative expenses for the nine-months ended September 30, 2023 were \$71.6 million as compared to \$58.7 million for the same period in 2022, an increase of 22%. This increase is due to increases in stock compensation expense of \$6.0 million, labor related expense of \$2.0 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-month periods ended September 30, 2023 and 2022 constituted approximately 22% and 23%, respectively, of our general and administrative costs.

We expect selling, general and administrative costs to increase moderately in 2023 as compared to 2022 due to our sales force expansion and increased marketing, promotional and advertising costs.

Research and Development Expenses

The following tables set forth our research and development expenses for the three and nine-month three-month periods ended September 30, 2023 March 31, 2024 and 2022 2023 (in thousands):

		Three Months Ended September 30,		Nine Months Ended September 30,	
		2023	2022	2023	2022
Three Months Ended March 31,					
Three Months Ended March 31,					
Three Months Ended March 31,					
2024					
2024					
2024					
External service costs					
External service costs					
External service costs	External service costs	\$ 29,123	\$ 22,654	\$ 94,579	\$ 69,801

Internal and other costs	Internal and other costs	12,427	10,620	34,789	31,052
Internal and other costs					
Internal and other costs					
Total research and development expenses	Total research and development expenses	\$ 41,550	\$ 33,274	\$ 129,368	\$ 100,853
Total research and development expenses					
Total research and development expenses					
<div> <div>Three Months Ended September 30,</div> <div>2023</div> <div>2022</div> <div>Nine Months Ended September 30,</div> <div>2023</div> <div>2022</div> </div>					
<div> <div>Three Months Ended March 31,</div> <div>Three Months Ended March 31,</div> <div>Three Months Ended March 31,</div> <div>2024</div> <div>2024</div> <div>2024</div> </div>					
Lumateperone costs					
Lumateperone costs					
Lumateperone costs	Lumateperone costs	\$ 23,149	\$ 16,877	\$ 78,510	\$ 56,487
Non-lumateperone costs	Non-lumateperone costs	9,614	9,017	27,670	23,281
Non-lumateperone costs					
Non-lumateperone costs					
Overhead and other costs					
Overhead and other costs					
Overhead and other costs	Overhead and other costs	8,787	7,380	23,188	21,085
Total research and development expenses	Total research and development expenses	\$ 41,550	\$ 33,274	\$ 129,368	\$ 100,853
Total research and development expenses					
Total research and development expenses					

Research and development expenses increased to \$41.6 million were \$42.8 million for the three-month period ended September 30, 2023 March 31, 2024 as compared to \$33.3 million for \$38.0 million in the three-month same period ended September 30, 2022, representing in 2023, which represents an increase of \$8.3 million, or 25% approximately 13%. This increase is due primarily to an increase increases of \$6.3 million \$3.5 million for lumateperone project costs an increase of \$0.6 million for non-lumateperone projects, and an increase of \$1.4 million \$1.8 million for overhead and other costs, partially offset by a decrease of \$0.5 million for non-lumateperone costs. External service costs increased by \$6.5 million \$2.8 million for the period due to the increased lumateperone and non-lumateperone clinical trials as well as other project costs. Internal and other costs increased by \$1.8 million \$2.0 million for the period due primarily to labor related costs and share-based compensation.

Research As the development of lumateperone and non-lumateperone programs progresses, we anticipate research and development expenses increased to \$129.4 million for the nine-month period ended September 30, 2023 as compared to \$100.9 million for the nine-month period ended September 30, 2022, representing an costs will increase of \$28.5 million, or 28%. This increase is moderately due primarily to increases non-clinical testing and conducting ongoing and planned clinical trials during the next several years. We are also required to complete non-clinical testing to obtain FDA approval and manufacture materials needed for clinical trial use, which includes non-clinical testing of \$22.0 million the drug product, and manufacturing of drug product in anticipation of possible additional FDA approvals of lumateperone for lumateperone project costs, \$4.4 million for non-lumateperone projects, indications beyond schizophrenia and \$2.1 million for overhead and other costs. External service costs increased by \$24.8 million for the period due to the increased lumateperone and non-lumateperone project costs. Internal and other costs increased by \$3.7 million for the period due primarily to labor related costs and share-based compensation. bipolar depression.

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 non-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 titled "Risk Factors" in our Annual Report on Form 10-K for the year ended **December 31, 2022** **December 31, 2023**, as updated by the section titled "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.

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Liquidity and Capital Resources

Since **our** inception, we have incurred significant operating and cash losses from our operations. We have primarily funded our operations to date through proceeds from public and private offerings of our common stock and other securities, and to a far lesser extent, through proceeds from grants from government agencies and foundations. In addition, we began to generate net product revenue in the first quarter of 2020 in conjunction with the commercial launch of CAPLYTA.

As of **September 30, 2023** **March 31, 2024**, our cash and cash equivalents, **available-for-sale** investment securities, and restricted cash totaled **\$494.8 million** **\$477.4 million**. In April 2024, we completed an underwritten public offering of shares of our common stock in which we sold an aggregate of 7,876,713 shares of common stock at a public offering price of \$73.00 per share resulting in net proceeds to us of approximately \$543.0 million, after deducting underwriting discounts and commissions and offering expenses. We invest cash in excess of our immediate requirements **with regard to liquidity and capital preservation** in a variety of interest-bearing instruments, including obligations of U.S. government agencies and money market accounts. **Wherever** **Whenever** possible, we seek to minimize the potential effects of concentration and degrees of risk. Although we maintain cash balances and investments with financial institutions in excess of insured limits, we do not anticipate any losses with respect to such **balances**, **balances because these financial institutions are custodians of our investments**.

During the **nine three** months ended **September 30, 2023** **March 31, 2024**, we used **\$122.1 million** **\$34.1 million** of net cash in operating activities, a decrease from \$60.1 million of \$108.9 million as compared to net cash used in operating activities during the **nine three** months ended **September 30, 2022** **March 31, 2023**. The decrease in net cash used in operations was primarily **due driven by the increased cash receipts in the period related to higher sales offset partially by increases in operating expenses**. The primary uses of cash were for selling and marketing costs in connection with our commercialization of CAPLYTA, conducting clinical trials and non-clinical testing, funding recurring operating expenses, and **net product manufacturing**, **sales**.

Based on our current operating plans, we expect that our existing cash, cash equivalents, **marketable investment** securities, and product sales 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, primarily due to the continued commercialization of CAPLYTA for the treatment of schizophrenia and bipolar depression; the **pre-commercialization activities, commercialization activities and related infrastructure expansion in connection with the commercialization of CAPLYTA, if approved, for the treatment of MDD; the development of lumateperone in our late-stage clinical programs; the development of our other product candidates, including PDE1 inhibitors, ITI-1284, ITI-333 and programs, including PDE, ITI-1284, and ITI-333; ITI-1549; and infrastructure expansion and general operations**.

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. Subject to our ability to generate significant revenues from operations, we may 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.

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 condition** of the capital markets. Due to the volatile nature of the financial markets, equity and debt financing may be difficult to obtain.

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.

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If adequate funds are not available to us on a timely basis, we may be required to: (1) delay, limit, reduce or terminate non-clinical studies, clinical trials or other clinical development activities for one or more of our product candidates, including our lead product candidate lumateperone and our other product candidates; (2) delay, limit, reduce or terminate our discovery research or non-clinical development activities; (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; or (4) limit or reduce commercialization efforts related to CAPLYTA.

Our cash, cash equivalents, and investments are 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. **Since Beginning in** early 2022, interest rates **have risen which is began to rise**, increasing our interest income. **These rates began to stabilize in the second half of 2023 and have remained relatively consistent.** During **2023, there was a decrease in the three months ended March 31, 2024, we incurred** unrealized **loss losses** primarily due to **maturities of lower yielding investments. changes in interest rates.** Due to the short-term nature of these investments and our intention to hold these investments to maturity, we do not expect to recognize these losses. Even with the rise or further potential rise in interest rates, we do not expect interest income to be a significant source of funding. In addition, our investment portfolio historically has 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.

Our cash requirements in the short and long term consist **primarily** of operational, **manufacturing**, and **manufacturing capital** expenditures, a portion of which contain contractual or other obligations. We plan to fund our cash requirements with our current financial resources together with our anticipated receipts from product sales. We manage future cash requirements relative to our long-term business plans. Our primary uses of cash **and operating expenses** relate to marketing and manufacturing our products, paying employees and consultants, administering clinical trials, and providing technology and facility infrastructure to support our operations.

We have three kinds of long-term contractual commitments - operating leases, licensing and royalty commitments, and purchase obligations. Our operating lease for **approximately** 32,000 square feet of useable laboratory and office space, as amended, **had an original has a** term of 14.3 years ending in May 2029. **Refer to Note 7 - Right of Use Assets and Lease Liabilities to our condensed consolidated financial statements for further details.**

We entered into an exclusive license **agreement** with BMS for which we are obligated to make tiered single-digit percentage royalty payments on sales of licensed products. The amount of future royalty obligations are dependent on future net product sales of the licensed product. **The Company We** may also be obligated to make other milestone payments to BMS for each licensed product of up to an aggregate of \$14.75 million. **Refer to Note 8 - Commitments and Contingencies to our condensed consolidated financial statements for further details.**

In addition, we have entered into certain other long-term commitments for goods and services that are outstanding for periods greater than one **year. year** including clinical trial agreements. We **recently amended have** certain manufacturing service agreements committing the Company to certain minimum annual **purchase commitments for which we anticipate payments being made within the years 2025 purchases** through 2029. We also have entered into short-term agreements with various vendors and suppliers of goods and services in the normal course of operations through purchase orders. Such short-term agreements **are generally outstanding for periods less than a year and** are settled by cash payments upon delivery of goods and services. The nature of the work being conducted under these agreements is such that, in most cases, the services may be stopped on short notice without penalty. In such event, we would not be liable for the full amount of the agreement. **We also have entered into clinical trial agreements which may span over multiple years.**

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, 2022 December 31, 2023.** There have been no material changes to our critical accounting policies during the **nine-month three-month** period ended **September 30, 2023 March 31, 2024.**

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The discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP. The preparation of these financial statements requires management to make estimates and assumptions that affect reported amounts of assets and liabilities as of the date of the balance sheet and reported amounts of revenues and expenses for the

periods presented. Judgments must also be made about the disclosure of contingent liabilities. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. **Management makes estimates and exercises judgment in research and development, including clinical trial accruals.** Actual results may differ from those estimates and under different assumptions or conditions.

Recently Issued Accounting Pronouncements

In November 2023, the FASB issued ASU 2023-07, Segment Reporting (Topic 280): *Improvements to Reportable Segment Disclosures*, requiring public entities to disclose information about their reportable segments' significant expenses and other segment items on an interim and annual basis. Public entities with a single reportable segment are also required to apply the disclosure requirements. The standard is effective for annual reporting periods beginning after December 15, 2023, and for interim reporting periods beginning January 1, 2025, with early adoption permitted. We **review** currently evaluating the potential impact that this new accounting standards to determine the expected financial impact, if any, that the adoption of each such standard will have. Based on our assessment, all new accounting pronouncements were determined to be either not applicable or are expected to have minimal impact on our consolidated financial statements or and related disclosures.

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; the **duration and severity of the COVID-19 pandemic and its continued 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, **pre-clinical 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; candidates, including through our litigation against the ANDA Filers**; 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, inflation risk, capital market risk, **foreign currency fluctuations** and geopolitical instability; and our ability to attract and retain key scientific, management, or sales and marketing personnel.

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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: 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 indications; 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 and bipolar depression following commercial launch of the product 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**; challenges associated with supply and manufacturing activities, which in each case could limit our sales and the availability of our product; impacts on our business, including on the commercialization of CAPLYTA and our clinical trials, as a result of the conflicts in Ukraine and **Israel; the Middle East**; risks associated with our current and planned clinical trials; we may encounter unexpected safety or tolerability issues with CAPLYTA following commercial launch for the treatment of schizophrenia or bipolar depression 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; **there is no guarantee that a generic equivalent of CAPLYTA will not be approved and enter the market before the expiration of our patents**; our reliance on collaborative partners and other third parties for development, commercialization, manufacturing or supply of our product and product candidates; risks related to increased interest rates, high rates of inflation, global supply chain disruptions, and

geopolitical instability on our business; disruptions resulting from the impact of public health pandemics or epidemics (including, for example, the COVID-19 pandemic), man-made or natural disasters, cybersecurity incidents or other causes; 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, 2023 March 31, 2024, we had cash, cash equivalents, marketable investment securities and restricted cash of \$494.8 million approximately \$477.4 million, consisting of cash deposited in a highly rated financial institution institutions in the United States and in a short-term U.S. Treasury bonds, money market fund, funds, as well as 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 and we do not enter into investments for trading or speculative purposes. We believe that we do not have material exposure to high-risk investments such as mortgage-backed securities, auction rate securities or other special investment vehicles within our money-market fund investments. We believe that we do not have any material exposure to changes in fair value as a result of changes in interest rates. Since rates as we intend and have the ability to hold our investments to maturity. Beginning in early 2022, interest rates have risen which is began to rise, increasing our interest income. These rates began to stabilize in the second half of 2023 and have remained relatively consistent. During 2023, the first quarter of 2024, there was a decrease in an unrealized loss primarily due to maturities of lower yielding investments. This gain increases in interest rates that resulted in a lower net unrealized loss balance position of \$1.3 million \$0.4 million as of September 30, 2023 March 31, 2024.

Inflation Risk. Inflation generally may affect affects us by increasing our cost of labor, clinical trial costs, and costs of other outsourced activities. To date, inflation has not had a material impact on our business, but if business. Should global inflation increase in the global inflationary trends continue, future, we expect appreciable increases in clinical trial, selling, labor, and other operating costs. If our costs were to become subject to significant inflationary pressures, we may not be able to fully offset such higher costs through price increases of our product or cash flows from other sources. product. Our inability or failure to do so could adversely affect our business, financial condition and results of operations.

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Capital Market Risk. Although we receive product revenues from commercial sales of CAPLYTA, we continue to assess may in the need for additional funding future, depend on funds raised through other sources. One possible source of funding is through further equity securities offerings. Our ability to raise funds in this manner depends upon capital market forces affecting our stock price. price among other things.

Foreign Currency Risk. Due to our operations outside of the United States, we are exposed to market risk related to changes in foreign currency exchange rates. Historically, our foreign currency exposure has been limited so we have not hedged for this exposure. Changes in the relative values of currencies occur regularly and, in some instances, could materially adversely affect our business, our results of operations or our cash flows. For the three-month periods ended March 31, 2024 and 2023, changes in foreign currency exchange rates did not have a material impact on our historical financial position, our business, our financial condition, our results of operations or our cash flows.

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-month period ended September 30, 2023 March 31, 2024 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

As previously disclosed, in February 2024, we received notices from Alkem Laboratories Ltd., Aurobindo Pharma USA, Inc. and Aurobindo Pharma Ltd., Dr. Reddy's Laboratories Inc. (on behalf of Dr. Reddy's Laboratories Ltd.), MSN Laboratories Private Ltd., Sandoz Inc., Hetero USA, Inc. (the U.S. Regulatory Agent for Hetero Labs Limited Unit - V, a division of Hetero Labs Limited) and Zydus Pharmaceuticals (USA), Inc., which we refer to as ANDA Filers, that each company had filed an abbreviated new drug application, or ANDA, with the FDA seeking approval of generic version of CAPLYTA. The ANDAs each contained Paragraph IV Patent Certifications alleging that certain of our patents covering CAPLYTA are invalid and/or will not be infringed by each ANDA Filer's manufacture, use or sale of the medicine for which the ANDA was submitted.

On July 8, 2022, Under the Federal Food, Drug, and Cosmetic Act, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, or the FDCA, we had 45 days from receipt of the notice letters to commence patent infringement lawsuits against these generic drug manufacturers in a purported shareholder derivative complaint was federal district court to trigger a stay precluding the FDA's approval of any ANDA from being effective any earlier than 7.5 years from the date of approval of the CAPLYTA new drug application or entry of judgment holding the patents invalid, unenforceable, or not infringed, whichever occurs first. After conducting the necessary due diligence, and within the 45 day period required under the FDCA, we filed lawsuits on March 27, 2024 and March 28, 2024 in the Supreme U.S. Federal District Court for the State District of New York Jersey against the directors serving on the Company's board of directors and the Company as a nominal defendant alleging breach of fiduciary duty and unjust enrichment alleging that compensation awarded to the director defendants for service on the board of directors was excessive. On March 6, 2023, the parties filed a stipulation of settlement (the "Stipulation"). The Stipulation does not require any damages payments or disgorgement by defendants or the Company. The Stipulation provides that, going forward, the board of directors will amend its compensation policies for non-employee directors, including, inter alia, by capping annual equity compensation at the 75th percentile each of the annual equity grants for seven generic drug manufacturers who notified us of their ANDA filings. Our lawsuits seek a peer group of companies. Subject to declaratory judgment that our patents have been infringed by the terms and conditions of the Stipulation and final respective ANDA Filer, an order that any FDA approval of the Court, ANDA Filer's product be not earlier than the Company and/or its insurance carriers have agreed to pay up to \$375,000 in attorneys' fees to plaintiff's counsel. On April 12, 2023, the court granted preliminary approval date of the settlement expiration of our applicable patents, injunctions against the commercialization of the ANDA Filer's product prior to such expiration date, and on July 17, 2023 an award for attorneys' fees, costs and expenses.

While we intend to vigorously defend and enforce our intellectual property rights protecting CAPLYTA, we can offer no assurance as to when the court lawsuits will be decided, whether the lawsuits will be successful, or that a generic equivalent of CAPLYTA will not be approved and enter the Stipulation. market before the expiration of our patents.

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, 2022 December 31, 2023, filed with the Securities and Exchange Commission on March 1, 2023 February 22, 2024.

Item 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS AND ISSUER PURCHASES OF EQUITY SECURITIES

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, 2023 March 31, 2024.

Item 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

Item 5. OTHER INFORMATION

During the fiscal quarter ended September 30, 2023 March 31, 2024, the following executive officer modified his director adopted a "Rule 10b5-1 trading arrangement" (as defined in Item 408 of Regulation S-K of the Exchange Act):

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- On August 11, 2023 March 6, 2024, Michael I. Halstead, Executive Vice President, General Counsel and Secretary, modified his Robert Van Nostrand, a director of the Company, adopted a Rule 10b5-1 Trading Plan, originally adopted on March 15, 2023 and modified on May 8, 2023, to change the start date of the plan to November 13, 2023, and increase the number of shares to be sold under the plan. Sales Plan. The modified plan is intended to satisfy the affirmative defense of Rule 10b5-1(c) and provides for the sale of up to an aggregate of 137,872 20,000 shares of our common stock until March 28, 2024 June 28, 2024. These 20,000 shares of our common stock are issuable upon the exercise of stock options held by Mr. Van Nostrand that expire on June 30, 2024.

There were no "non-Rule 10b5-1 trading arrangements" (as defined in Item 408 of Regulation S-K of the Exchange Act) adopted, modified or terminated during the fiscal quarter ended September 30, 2023 March 31, 2024 by our directors and executive officers.

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Item 6. EXHIBITS

Exhibit Number	Exhibit Description	Filed Herewith	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/Reg. Number
10.1	Non-Employee Director Compensation Policy, as amended*	X			
10.2	Form of Performance-based Restricted Stock Unit Award Agreement*	X			
31.1	Certification of the Registrant's Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X			
31.2	Certification of the Registrant's Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X			
32	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X			
101	The following materials from the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2023 March 31, 2024, formatted in Inline XBRL (eXtensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets as of September 30, 2023 March 31, 2024 (unaudited) and December 31, 2022 December 31, 2023 (audited), (ii) Condensed Consolidated Statements of Operations (unaudited) for the three and nine months ended September 30, 2023 March 31, 2024 and 2022, 2023, (iii) Condensed Consolidated Statements of Comprehensive Loss (unaudited) for the three and nine months ended September 30, 2023 March 31, 2024 and 2022, 2023, (iv) Condensed Consolidated Statements of Stockholders' Equity (unaudited) for the three and nine months ended September 30, 2023 March 31, 2024 and 2022, 2023, (v) Condensed Consolidated Statements of Cash Flows (unaudited) for the nine three months ended September 30, 2023 March 31, 2024 and 2022, 2023, 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			

* Management contract or compensatory plan or arrangement.

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SIGNATURES

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

INTRA-CELLULAR THERAPIES, INC.

Date: November 2, 2023 May 7, 2024

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

Sharon Mates, Ph.D.

Chairman President and Chief Executive Officer

Date: November 2, 2023 May 7, 2024

By: /s/ Lawrence J. Hinline

Lawrence J. Hinline

Senior Vice President of Finance and Chief Financial Officer

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Exhibit 10.1

INTRA-CELLULAR THERAPIES, INC.

NON-EMPLOYEE DIRECTOR COMPENSATION POLICY

(adopted June 30, 2014; amended March 30, 2016, December 14, 2017, June 18, 2018, February 26, 2020, June 21, 2021, May 5, 2022, April 27, 2023 and April 22, 2024)

The Board of Directors of Intra-Cellular Therapies, Inc. (the "Company") has approved the following Non-Employee Director Compensation Policy (this "Policy"), which establishes compensation to be paid to non-employee directors of the Company, to provide an inducement to obtain and retain the services of qualified persons to serve as members of the Company's Board of Directors.

Applicable Persons

This Policy shall apply to each director of the Company who is not an employee of, or compensated consultant to, the Company or any Affiliate (each, an "Outside Director"). "Affiliate" shall mean an entity which is a direct or indirect parent or subsidiary of the Company, as determined pursuant to Section 424 of the Internal Revenue Code of 1986, as amended.

Compensation

A. General Compensation Limits

The following limits shall be in effect for payments and compensation to be paid to each Outside Director:

Annual Equity Grant Limits for Outside Directors:	The Annual Equity Grant (defined below) provided to each Outside Director will not exceed the 75th percentile of the total annual equity awards for the Company's Outside Director Compensation Peer Group (defined below), based on the total grant date fair value of the equity awards (the "Annual Equity Grant Limit")
Initial Equity Grant Limits for Newly-Appointed or Elected Outside Directors:	The Initial Equity Grant (defined below) provided to each newly-appointed or elected Outside Director will not exceed 1.75 times the most recent Annual Equity Grant made to Outside Directors, based on the total grant date fair value of the equity awards (the "Initial Equity Grant Limit")
Grant Date for Annual Equity Awards:	The Company will not grant Annual Equity Awards to Outside Directors on the same date that the Company grants annual equity awards to the Company's executive officers. In addition, any final deliberations or voting on the compensation of the Outside Directors (including any changes to the annual compensation package) will be made at a different Board (or committee) meeting than any final deliberations or voting on the compensation of executive officers (including any changes to the annual compensation package).

The preceding limits will remain in effect until July 1, 2027, unless otherwise amended and approved by a vote of the Company's stockholders.

Outside Director Compensation Peer Group: The Compensation Committee will use its reasonable judgment to select publicly traded, national and regional companies in the biopharmaceutical industries: (a) whose number of employees, stage of development, and relative complexity of clinical trials are similar to the Company's; (b) that are pre-revenue or had a recent commercial product launch; (c) with market values of approximately 0.25 times to four times the Company's market capitalization at the time; (d) against which the Company believes it competes for executive talent; and (e) whose compensation and financial data are available in proxy statements or through widely available compensation surveys (as such group is approved by the Compensation Committee, the "Outside Director Compensation Peer Group"). The Compensation Committee will annually (i) assess the Outside Compensation Peer Group and (ii) retain an independent compensation consultant and make a determination as to its independence. The independent compensation consultant will assist in the identification of the Outside Director Compensation Peer Group and will provide an annual update on recent developments and best practices concerning non-employee director and executive compensation matters to the Compensation Committee.

B. Equity Grants

1. Annual Stock Option Grants

Subject to the Annual Equity Grant Limit set forth in Section A above, each Outside Director shall be granted, under the Company's Amended and Restated 2018 Equity Incentive Plan or any successor plan (the "Equity Plan"), (i) a non-qualified stock option to purchase the number of shares of the Company's common stock, par value \$0.0001 per share ("Common Stock"), having an aggregate grant date fair value of \$675,000, valued based on a Black-Scholes valuation method (rounded down to the nearest whole share) (an "Annual Option Grant"), (ii) a restricted stock unit for the number of shares of Common Stock, having an aggregate grant date fair value of \$675,000, valued based on the closing price of the Common stock on The Nasdaq Global Select Market (or such other securities exchange on which the Common Stock is then traded) (rounded down to the nearest whole share) (an "Annual RSU Grant") or (iii) a non-qualified stock option to purchase a number of shares of Common Stock and a restricted stock unit for a number of shares of Common Stock having a combined aggregate grant date fair value of \$675,000, with the non-qualified stock option valued in accordance with (i) above and the restricted stock unit valued in accordance with (ii) above (an "Annual Option and RSU Grant"), each year on or about the date of the Company's annual meeting of stockholders (the Annual Option Grant, the Annual RSU Grant or the Annual Option and RSU Grant, as the case may be, the "Annual Equity Grant"); provided that the Annual Equity Grant made in connection with the 2027 Annual Meeting of Stockholders will be made solely in the form of an Annual RSU Grant (and not in the form of an Annual Option Grant or an Annual Option and RSU Grant); and provided, further, that the total aggregate grant date fair value of the Annual Equity Grant, calculated in accordance with this paragraph, shall not exceed the Annual Equity Grant Limit.

The foregoing Annual Equity Grants shall commence with the 2023 Annual Meeting of Stockholders.

2. Initial Stock Option Grants for Newly Appointed or Elected Directors

Subject to the Initial Equity Grant Limit set forth in Section A above, each new Outside Director shall be granted, under the Equity Plan, either (i) a non-qualified stock option to purchase the number of shares of Common Stock having an aggregate grant date fair value of \$1,000,000, valued based on a Black-Scholes valuation method (rounded down to the nearest whole share) (an "Initial Option Grant"), (ii) a restricted stock unit for the number of shares of Common Stock, having an aggregate grant date fair value of \$1,000,000, valued based on the closing price of the Common stock on The Nasdaq Global Select Market (or such other securities exchange on which the Common Stock is then traded) (rounded down to the nearest whole share) (an "Initial RSU Grant"), or (iii) a non-qualified stock option to purchase a number of shares of Common Stock and a restricted stock unit for a number of shares of Common Stock having a combined aggregate grant date fair value of \$1,000,000, with the non-qualified stock option valued in accordance with (i) above and the restricted stock unit valued in accordance with (ii) above (an "Initial Option and RSU Grant"), on or about the date that the Outside Director is first appointed or elected to the Board of Directors (the Initial Option Grant, the Initial RSU Grant or the Initial Option and RSU Grant, as the case may be, the "Initial Equity Grant"); provided that any Initial Equity Grant made on or after January 1, 2027 will be solely in the form of an Initial RSU Grant (and not an Initial Option Grant or an Initial Option and RSU Grant);

and provided, further, that the total aggregate grant date fair value of the Initial Equity Grant, calculated in accordance with this paragraph, shall not exceed the Initial Equity Grant Limit.

3. Terms of Equity Grants

All Annual Equity Grants and Initial Equity Grants to Outside Directors under this Policy shall vest in one year on the anniversary of the date of grant, subject to the Outside Director's continued service on the Board of Directors. Annual Option Grants and Initial Option Grants shall have a term of ten years, and shall have an exercise price equal to the fair market value of the Company's Common Stock as determined under the Equity Plan on the date of grant. The Annual Equity Grants and Initial Equity Grants shall become fully vested immediately prior to a Change of Control (as defined below).

"Change of Control" means the occurrence of any of the following events: (i) any "Person" (as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act")) becomes the "Beneficial Owner" (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly, of securities of the Company representing 50% or more of the total voting power represented by the Company's then outstanding voting securities (excluding for this purpose any such voting securities held by the Company or its affiliates or by any employee benefit plan of the Company) pursuant to a transaction or a series of related transactions; or (ii)(a) a merger or consolidation of the Company whether or not approved by the Board of Directors, other than a merger or consolidation which would result in the voting securities of the Company outstanding immediately prior thereto continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity or the parent of such corporation) more than 50% of the total voting power represented by the voting securities of the Company or such surviving entity or parent of such corporation, as the case may be, outstanding immediately after such merger or consolidation; or (b) the sale or disposition by the Company of all or substantially all of the Company's assets in a transaction requiring stockholder approval.

C. Cash Fees or Fully-Vested Stock or Fully Vested Stock Options in Lieu of Cash Fees

1. Annual Cash Fees

The following annual cash fees shall be paid to the Outside Directors serving on the Board of Directors and the Audit Committee, Compensation Committee and Nominating and Governance Committee, as applicable.

Board of Directors or Committee of Board of Directors	Annual Retainer Amount for Chair (or Lead Independent Director, as applicable)	Annual Retainer Amount for Other Members
Board of Directors	\$ 80,000	\$ 50,000
Audit Committee	\$ 25,000	\$ 12,000
Compensation Committee	\$ 20,000	\$ 10,000
Nominating and Governance Committee	\$ 12,750	\$ 5,000

2. Payment Terms for All Cash Fees

Cash fees payable to Outside Directors shall be paid quarterly in arrears as of the last business day of each fiscal quarter.

Following an Outside Director's first election or appointment to the Board of Directors, such Outside Director shall receive his or her cash compensation pro-rated during the first fiscal quarter in which he or she was initially

appointed or elected for the number of days during which he or she provides service. If an Outside Director dies, resigns or is removed during any quarter, he or she shall be entitled to a cash payment on a pro-rated basis through his or her last day of service that shall be paid on the last business day of the fiscal quarter.

3. Election to Receive Fully-Vested Shares of Common Stock or Fully Vested Stock Options in Lieu of Annual Cash Fees

In lieu of all or a portion of the annual cash fees, an Outside Director may elect by prior written notice to the Company to receive fully-vested shares of Common Stock (a "Stock Award") or fully-vested non-qualified stock options under the Equity Plan on the last business day of each fiscal quarter for the equivalent value of the cash fees due. Such grant shall be made automatically and without any action on the part of the Board of Directors under the Equity Plan. The number of shares with respect to a Stock Award shall be calculated by dividing the cash fees as determined above by the fair market value of the Common Stock as determined under the Equity Plan on the last business day of each fiscal quarter (rounded down to the nearest whole share). Should the Outside Director elect to receive stock options, the number of shares underlying a stock option shall be calculated by determining the number of shares that is equivalent to the cash fees due as determined above using the Black Scholes value applicable to the Company's stock option grants calculated on the last business day of each fiscal quarter (rounded down to the nearest whole share). Each stock option grant shall have a term of ten years, unless the Director ceases serving as a member of the Board of Directors, and shall have an exercise price equal to the fair market value of the Company's Common Stock as determined under the Equity Plan on the date of grant.

Expenses

Upon presentation of documentation of such expenses reasonably satisfactory to the Company, each Outside Director shall be reimbursed for his or her reasonable out-of-pocket business expenses incurred in connection with attending meetings of the Board of Directors and Committees thereof or in connection with other business related to the Board of Directors. Each Outside Director shall abide by the Company's travel and other expense policies applicable to Company personnel.

Amendments

The Compensation Committee or the Board of Directors shall review this Policy from time to time to assess whether any amendments in the type and amount of compensation provided herein should be adjusted in order to fulfill the objectives of this Policy.

Intra-Cellular Therapies, Inc.
Amended and Restated 2018 Equity Incentive Plan

Performance-Based Restricted Stock Unit Award Grant Notice

1. Name and Address of Participant:
2. Date of Grant of Award ("**Date of Grant**"):
3. Number of Target Award Shares/PSUs:
4. Number of Maximum Award Shares/PSUs:
5. Vesting of Award: Subject to Section 2 of the Performance-Based Restricted Stock Unit Award Agreement (the "**Agreement**"), which is available via Participant's [] account (such account, the "**Electronic Account**"), this Performance-Based Restricted Stock Unit Award will vest as follows:
 - A. Unless otherwise set forth herein in the event of a Change in Control, the number of Target Award Shares subject to this Performance-Based Restricted Stock Unit Award that shall be earned will be based on the achievement of the TSR Performance Milestone (as defined in Section 6.A below) and the Clinical Performance Milestone (as defined in Section 6.B below) (the "**Earned Shares**"), which Earned Shares shall vest in full on the date of certification by the Compensation Committee after [], but on or before [], of achievement of such performance milestones, subject to the Participant's Continuous Service through such vesting date.
 - B. In the event of a Change in Control prior to [], 100% of the TSR Target Award Shares (as defined in Section 6.A below) shall be deemed earned as of the effective date of the Change in Control and such Earned Shares shall vest in full on [], subject to the Participant's Continuous Service through such vesting date.
 - C. In the event of a Change in Control prior to [], if the Clinical Target Award Shares (as defined in Section 6.B below) have not previously vested in accordance with Section 5.A above, then 100% of the Clinical Target Award Shares shall be deemed earned as of the effective date of the Change in Control and such Earned Shares shall vest in full on [], subject to the Participant's Continuous Service through such vesting date.
6. Performance Milestones:
 - A. **TSR Performance Milestone.** A total of []% of the number of Target Award Shares (the "**TSR Target Award Shares**") shall be earned based upon the total shareholder return percentile achievement ("**TSR Percentile Achievement**")¹ for the [] year period beginning [] and ending [] (the "**Performance Period**") of the Company as compared

¹(Price End - Price Begin + Dividends)/Price Begin — with price determined as the average 30 calendar days prior to each measurement date.) For purposes of the foregoing, "Dividends" means any dividends per share that have an ex-dividend date during the Performance Period, assuming the reinvestment of such dividends as of the applicable ex-dividend date.

to the component companies of the Nasdaq Biotechnology Index that are in such Index during the entire Performance Period, with the number of shares of Common Stock (the "**Shares**") to be earned pursuant to this Section 6.A determined as follows (the "**TSR Performance Milestone**"):

[]

B. **Clinical Performance Milestone.** A total of []% of the number of Target Award Shares (the "**Clinical Target Award Shares**") shall be earned based upon substantial advancement of the Company's clinical developments programs, including the following (the "**Clinical Performance Milestone**"), as determined by the Compensation Committee in its sole discretion:

[]

Any unearned shares shall be returned to the Intra-Cellular Therapies, Inc. Amended and Restated 2018 Equity Incentive Plan (the "**Plan**") on the date that the performance milestones are determined.

The Participant must acknowledge receipt of this Performance-Based Restricted Stock Unit Award and agree to its terms and conditions, as set forth in this Performance-Based Restricted Stock Unit Award Grant Notice (this "**Grant Notice**"), the Electronic Account, the Agreement, and the Plan, by accepting the Performance-Based Restricted Stock Unit Award via the grant acceptance functionality in the Electronic Account within sixty (60) days following the Date of Grant; *provided, however*, that if the Participant does not accept the Performance-Based Restricted Stock Unit Award within sixty (60) days following the Date of Grant in accordance with the foregoing method, the Participant shall be deemed to have accepted the Performance-Based Restricted Stock Unit Award.

Capitalized terms not explicitly defined in this Grant Notice but defined in the Plan, the Agreement, or the Electronic Account will have the same definitions as in the Plan, the Agreement, or the Electronic Account.

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Intra-Cellular Therapies, Inc.
Amended and Restated 2018 Equity Incentive Plan

Performance-Based Restricted Stock Unit Award Agreement

This Performance-Based Restricted Stock Unit Award Agreement (this "**Agreement**") is made by and between you (the "**Participant**") and Intra-Cellular Therapies, Inc. (the "**Company**") as of the date of grant set forth in the Performance-Based Restricted Stock Unit Award Grant Notice sent to you under separate cover (the "**Grant Notice**") and your [] account (such date, the "**Date of Grant**", and such Grant Notice and account, taken together, the "**Account**").

WHEREAS, the Company has adopted the Intra-Cellular Therapies, Inc. Amended and Restated 2018 Equity Incentive Plan (the "**Plan**") to promote the interests of the Company by providing an incentive for Employees, Directors and Consultants of the Company and its Affiliates;

WHEREAS, pursuant to the provisions of the Plan, the Company desires to grant to the Participant performance-based restricted stock units ("**PSUs**") related to the Company's Common Stock, in accordance with the provisions of the Plan, all on the terms and conditions hereinafter set forth; and

WHEREAS, the Company and the Participant understand and agree that any terms used and not defined herein or in the Account have the meanings ascribed to such terms in the Plan.

NOW, THEREFORE, in consideration of the promises and the mutual covenants contained herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto hereby agree as follows:

1. **Grant of Award.** The Company hereby grants to the Participant an award for the number of PSUs set forth in the Account under "Number of Maximum Award Shares/PSUs" (the "**Award**"). Each PSU represents a contingent entitlement of the Participant to receive one share of Common Stock, on the terms and conditions and subject to all the limitations set forth in the Account, this Agreement and the Plan. The Participant (a) acknowledges receipt of, and understands and agrees to, the terms and conditions of the Award as set forth in the Account, this Agreement and the Plan and (b) acknowledges receipt of the stock plan prospectus for the Plan.

2. **Vesting of Award.**

(a) Subject to the terms and conditions set forth in this Agreement and the Plan, the Award granted hereby shall vest as set forth in the Account, provided that vesting shall cease upon the termination of the Participant's Continuous Service.

(b) Except as otherwise set forth in this Agreement:

(i) If the Participant ceases to be in Continuous Service for any reason prior to the vesting date set forth in the Account, then as of the date on which the Participant's Continuous Service terminates, all PSUs shall immediately be forfeited to the Company and this Agreement shall terminate and be of no further force or effect.

(ii) Notwithstanding the foregoing, if (a) the Participant is an Employee at the level of Vice President or above at the time of a termination of the Participant's Continuous Service and, at any time within ninety (90) days prior to or twelve (12) months following the effective date of a Change in Control (or such other period as is, or may be, set forth in an employment, severance or other similar written agreement between the Participant and the Company or any of its Affiliates), or (b) the Participant is an Employee below the level of Vice President or a Consultant at the time of a termination of the Participant's Continuous Service and, at any time within twelve (12) months following the effective

date of a Change in Control, the Participant's Continuous Service terminates by reason of (i) a resignation for Good Reason or (ii) an involuntary termination of the Participant's Continuous Service without Cause (each, a "**Qualifying Termination**"), then any shares underlying this Award that have been earned but have not become vested as of the effective date of the Change in Control or if later, as of the date of the Qualifying Termination (whether pursuant to this Agreement or other action of the Board or the Committee) shall become fully vested as of (x) the effective date of the Change in Control if the Participant's Qualifying Termination occurs prior to the effective date of the Change in Control and (y) the date of such Qualifying Termination if the Participant's Qualifying Termination occurs on or after the effective date of the Change in Control. In order to give effect to the intent of such accelerated vesting, if the Participant's Qualifying Termination occurs prior to the effective date of a Change in Control, then notwithstanding anything to the contrary in this Agreement or the Plan, in no event will any portion of this Award or Agreement be forfeited or terminate any earlier than the effective date of the Change in Control. In no event will any unearned shares become vested pursuant to this paragraph.

(c) Except as otherwise set forth in this Agreement and notwithstanding anything to the contrary in the Plan:

(i) In the event of a Corporate Transaction that is also a Change in Control, (x) Sections 9(c)(ii) and 9(c)(iii) of the Plan (which provides for certain treatment of Stock Awards upon a Corporate Transaction) will not apply to this Award and (y) for clarity, this Award will be subject to the Change in Control-related provisions set forth in the Account and this Agreement.

(ii) In the event of a Corporate Transaction that is not also a Change in Control, Section 9(c) of the Plan will apply to this Award; provided, however, that: (x) Section 9(c)(ii) of the Plan (which provides for accelerated vesting in certain circumstances) will apply to this Award only if the Corporate Transaction occurs prior to []; and (y) for clarity, if this Award is entitled to accelerated vesting pursuant to the foregoing clause (x) and Section 9(c)(ii) of the Plan, then for purposes of applying such Section, this Award shall be deemed earned at 100% of the number of TSR Target Award Shares and/or the Clinical Target Award Shares, as applicable, and such accelerated vesting shall apply only to such Earned Shares.

(d) The following terms shall have the following meanings for purposes of this Award:

(i) "**Change in Control**" means the occurrence of any of the following events: (i) any "Person" (as such term is used in Sections 13(d) and 14(d) of the Exchange Act) becomes the "Beneficial Owner" (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly, of securities of the Company representing 50% or more of the total voting power represented by the Company's then outstanding voting securities (excluding for this purpose any such voting securities held by the Company or its affiliates or by any employee benefit plan of the Company) pursuant to a transaction or a series of related transactions; or (ii)(a) a merger or consolidation of the Company whether or not approved by the Board, other than a merger or consolidation which would result in the voting securities of the Company outstanding immediately prior thereto continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity or the parent of such corporation) more than 50% of the total voting power represented by the voting securities of the Company or such surviving entity or parent of such corporation, as the case may be, outstanding immediately after such merger or consolidation; or (b) the sale or disposition by the Company of all or substantially all of the Company's assets in a transaction requiring stockholder approval.

(ii) “**Good Reason**” means the occurrence of (a) any event constituting “Good Reason” (or an analogous term) as set forth in any employment, consulting, severance or other similar written agreement between the Participant and the Company or any of its Affiliates and (b) any of the following events without the consent of the Participant: (i) if the Participant is an Employee at the level of Vice President or above, a material reduction or change in job duties, responsibilities or authority inconsistent with the Participant’s position with the Company and the Participant’s prior duties,

responsibilities or authority immediately prior to the Change in Control; (ii) for any Employee or Consultant, a relocation of the Participant’s primary workplace by more than 25 miles; or (iii) for any Employee or Consultant, a material reduction of the Participant’s base compensation; *provided, however*, that any event described in clause (b) above shall constitute Good Reason only if (x) the Participant provides the Company with written notice specifying the event alleged to constitute Good Reason within 60 days following the first occurrence of such event, (y) the Company fails to cure such event within 30 days after the Company’s receipt from the Participant of such written notice, and (z) the Participant’s termination of Continuous Service occurs within 30 days following the Company’s failure to cure such event (and in no event later than 120 days following the first occurrence of such event).

3. Issuance of Shares.

(a) The issuance of any shares of Common Stock in respect of this Award is (i) subject to satisfaction of the tax withholding obligations set forth in Section 9 and (ii) intended to comply with Treasury Regulations Section 1.409A-1(b)(4) and will be construed and administered in such a manner. The form of such issuance (e.g., a stock certificate or electronic entry evidencing such shares) will be determined by the Company.

(b) In the event one or more PSUs subject to this Award vests, the Company will issue to the Participant, on the applicable vesting date, one share of Common Stock for each PSU that vests on such date (and for purposes of this Agreement, such issuance date is referred to as the “**Original Issuance Date**”); *provided, however*, that if the Original Issuance Date falls on a date that is not a business day, such shares will instead be issued to the Participant on the next following business day.

(c) Notwithstanding the foregoing, if:

(i) this Award is otherwise subject to withholding taxes (as described in Section 9) on the Original Issuance Date,

(ii) the Original Issuance Date does not occur (x) during an “open window period” applicable to the Participant, as determined by the Company in accordance with the Company’s then-effective policy on trading in Company securities, or (y) on a date when the Participant is otherwise permitted to sell shares of Common Stock on an established stock exchange or stock market, and

(iii) the Company elects, prior to the Original Issuance Date, (x) not to satisfy such withholding taxes by withholding shares of Common Stock from the shares of Common Stock otherwise due, on the Original Issuance Date, to the Participant under this Award, (y) not to permit the Participant to enter into a “same day sale” commitment with a broker-dealer pursuant to Section 9 (including, but not limited to, under a previously established 10b5-1 trading plan entered into in compliance with the Company’s policies), and (z) not to permit the Participant to pay such withholding taxes in cash,

then the shares that would otherwise be issued to the Participant on the Original Issuance Date will not be issued to the Participant on the Original Issuance Date and will instead be issued to the Participant on the first business day when the Participant is not prohibited from selling shares of Common Stock on an established stock exchange or stock market, but in no event later than December 31 of the calendar year in which the Original Issuance Date occurs (that is, the last day of the Participant’s taxable year in which the Original Issuance Date occurs), or, if permitted in a manner that complies with Treasury Regulations Section 1.409A-1(b)(4), no later than the date that is the 15th day of the third calendar month of the year following the year in which the shares of Common Stock in respect of this Award are no longer subject to a “substantial risk of forfeiture” within the meaning of Treasury Regulations Section 1.409A-1(d).

4. **Prohibitions on Transfer and Sale.** This Award (including any additional PSUs received by the Participant as a result of stock dividends, stock splits or any other similar transaction affecting the

Company's securities without receipt of consideration) shall not be transferable by the Participant otherwise than (i) by will or by the laws of descent and distribution, or (ii) pursuant to a qualified domestic relations order as defined by the Internal Revenue Code or Title I of the Employee Retirement Income Security Act or the rules thereunder. Except as provided in the previous sentence, the shares of Common Stock to be issued pursuant to this Agreement shall be issued, during the Participant's lifetime, only to the Participant (or, in the event of legal incapacity or incompetence, to the Participant's guardian or representative). This Award shall not be assigned, pledged or hypothecated in any way (whether by operation of law or otherwise) and shall not be subject to execution, attachment or similar process. Any attempted transfer, assignment, pledge, hypothecation or other disposition of this Award or of any rights granted hereunder contrary to the provisions of this Section 4, or the levy of any attachment or similar process upon this Award shall be null and void.

5. **Adjustments.** The Plan contains provisions covering the treatment of Stock Awards and shares of Common Stock in a number of contingencies such as Capitalization Adjustments and Corporate Transactions. Provisions in the Plan for adjustment with respect to this Award and the related provisions with respect to successors to the business of the Company are hereby made applicable hereunder and are incorporated herein by reference, subject to the provisions of Section 2 of this Agreement.

6. **Securities Law Compliance.** The Participant specifically acknowledges and agrees that any sales of shares of Common Stock shall be made in accordance with the requirements of the Securities Act. The Company currently has an effective registration statement on file with the Securities and Exchange Commission with respect to the Common Stock to be granted hereunder. The Company intends to maintain this registration statement but has no obligation to do so. If the registration statement ceases to be effective for any reason, Participant will not be able to transfer or sell any of the shares of Common Stock issued to the Participant pursuant to this Agreement unless exemptions from registration or filings under applicable securities laws are available. Furthermore, despite registration, applicable securities laws may restrict the ability of the Participant to sell his or her Common Stock, including due to the Participant's affiliation with the Company. The Company shall not be obligated to either issue the Common Stock or permit the resale of any shares of Common Stock if such issuance or resale would violate any applicable securities law, rule or regulation.

7. **Rights as a Stockholder.** The Participant shall have no right as a stockholder, including voting and dividend rights, with respect to the PSUs subject to this Agreement.

8. **Incorporation of the Plan.** The Participant specifically understands and agrees that the PSUs and the shares of Common Stock to be issued under the Plan will be issued to the Participant pursuant to the Plan, a copy of which Plan the Participant acknowledges he or she has read and understands and by which Plan he or she agrees to be bound. The provisions of the Plan are incorporated herein by reference, subject to the provisions of Section 2 of this Agreement. In addition, this PSU (and any compensation paid or shares issued pursuant to this Agreement) is subject to recoupment in accordance with The Dodd–Frank Wall Street Reform and Consumer Protection Act and any implementing regulations thereunder, any clawback policy adopted by the Company and any compensation recovery policy otherwise required by applicable law. No recovery of compensation under such a clawback policy will be an event giving rise to a right to resign for “good reason” or for a “constructive termination” (or similar term) under any agreement with the Company.

9. **Tax Liability of the Participant and Payment of Taxes.** The Participant acknowledges and agrees that any income or other taxes due from the Participant with respect to this Award or the shares of Common Stock to be issued pursuant to this Agreement or otherwise sold shall be the Participant's responsibility. Without limiting the foregoing, the Participant agrees that if under applicable law the Participant will owe taxes at each vesting or settlement date on the portion of the Award then vested or settled, as applicable, the Company shall be entitled to immediate payment from the Participant of the amount of any tax or other amounts required to be withheld by the Company by applicable law or regulation. Any taxes or other amounts due shall be paid as follows:

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(a) subject to approval by the Board or Committee, as applicable, through reducing the number of shares of Common Stock entitled to be issued to the Participant on the applicable settlement date in an amount not in excess of the maximum amount of tax required to be withheld by law (or such other amount as may be permitted while still avoiding classification of this Award as a liability for financial accounting purposes). Fractional shares will not be retained to satisfy any portion of the Company's withholding obligation. Accordingly, the Participant agrees that in the event that the amount

of withholding required would result in a fraction of a share being owed, that amount will be satisfied by withholding the fractional amount from the Participant's paycheck;

(b) at the option of the Company, by requiring the Participant to deposit with the Company an amount of cash equal to the amount determined by the Company to be required to be withheld with respect to the statutory minimum amount of the Participant's total tax and other withholding obligations due and payable by the Company or otherwise withholding from the Participant's paycheck an amount equal to such amounts due and payable by the Company; or

(c) if the Company believes that the sale of shares can be made in compliance with applicable securities laws, authorizing, at a time when the Participant is not in possession of material nonpublic information, the sale by the Participant on the applicable vesting date of such number of shares of Common Stock as necessary to sell to satisfy the Company's withholding obligation, after deduction of the broker's commission, and the broker shall be required to remit to the Company the cash necessary in order for the Company to satisfy its withholding obligation. To the extent the proceeds of such sale exceed the Company's withholding obligation, the Company agrees to pay such excess cash to the Participant as soon as practicable. In addition, if such sale is not sufficient to pay the Company's withholding obligation, the Participant agrees to pay to the Company as soon as practicable, including through additional payroll withholding, the amount of any withholding obligation that is not satisfied by the sale of shares of Common Stock. The Participant agrees to hold the Company and the broker harmless from all costs, damages or expenses relating to any such sale. The Participant acknowledges that the broker is under no obligation to arrange for such sale at any particular price. In connection with such sale of shares of Common Stock, the Participant shall execute any such documents requested by the broker in order to effectuate the sale of shares of Common Stock and payment of the withholding obligation to the Company. The Participant acknowledges that this paragraph is intended to comply with Section 10b5-1(c)(1)(i)(B) under the Exchange Act.

The Company shall not deliver any shares of Common Stock to the Participant until it is satisfied that all required withholdings have been made.

10. Participant Acknowledgements and Authorizations.

The Participant acknowledges the following:

(a) The Company is not by the Plan or this Award obligated to continue the Participant as an employee, director or consultant of the Company or an Affiliate.

(b) The Plan is discretionary in nature and may be suspended or terminated by the Company at any time.

(c) The grant of this Award is considered a one-time benefit and does not create a contractual or other right to receive any other award under the Plan, benefits in lieu of awards or any other benefits in the future.

(d) The Plan is a voluntary program of the Company and future awards, if any, will be at the sole discretion of the Company, including, but not limited to, the timing of any grant, the amount of any award, vesting provisions and the purchase price, if any.

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(e) The value of this Award is an extraordinary item of compensation outside of the scope of the Participant's employment or consulting contract, if any. As such the Award is not part of normal or expected compensation for purposes of calculating any severance, resignation, redundancy, end of service payments, bonuses, long-service awards, pension or retirement benefits or similar payments. The future value of the shares of Common Stock is unknown and cannot be predicted with certainty.

(f) The Participant (i) authorizes the Company and each Affiliate and any agent of the Company or any Affiliate administering the Plan or providing Plan recordkeeping services, to disclose to the Company or any of its Affiliates such information and data as the Company or any such Affiliate shall request in order to facilitate the grant of the Award and the administration of the Plan; and (ii) authorizes the Company and each Affiliate to store and transmit such information in electronic form for the purposes set forth in this Agreement.

11. Notices. Any notices provided for in this Agreement or the Plan shall be given in writing (including electronically) and will be deemed effectively given upon receipt or, in the case of notices delivered by mail by the Company to the Participant, five days after deposit in the U.S. mail, postage prepaid, addressed to the Participant at the last address the Participant provided to the Company. The Company may, in its sole discretion,

decide to deliver any documents related to participation in the Plan and this Agreement by electronic means or to request the Participant's consent to participate in the Plan by electronic means. By accepting the Award in accordance with the procedures described in Section 18 of this Agreement, the Participant consents to receive such documents by electronic delivery and to participate in the Plan through an online or electronic system established and maintained by the Company or another third party designated by the Company.

12. Assignment and Successors.

(a) This Agreement is personal to the Participant and without the prior written consent of the Company shall not be assignable by the Participant otherwise than by will or the laws of descent and distribution. This Agreement shall inure to the benefit of and be enforceable by the Participant's legal representatives.

(b) This Agreement shall inure to the benefit of and be binding upon the Company and its successors and assigns.

13. Governing Law. This Agreement shall be construed and enforced in accordance with the laws of the State of Delaware, without giving effect to the conflict of law principles thereof. For the purpose of litigating any dispute that arises under this Agreement, whether at law or in equity, the parties hereby consent to exclusive jurisdiction in the state of New York and agree that such litigation shall be conducted in the state courts of the state of New York or the federal courts of the United States for the District of Manhattan.

14. Severability. If any provision of this Agreement is held to be invalid or unenforceable by a court of competent jurisdiction, then such provision or provisions shall be modified to the extent necessary to make such provision valid and enforceable, and to the extent that this is impossible, then such provision shall be deemed to be excised from this Agreement, and the validity, legality and enforceability of the rest of this Agreement shall not be affected thereby.

15. Entire Agreement. This Agreement, together with the Plan and the terms and conditions of the Award as set forth in the Account, constitutes the entire agreement and understanding between the parties hereto with respect to the subject matter hereof and supersedes all prior oral or written agreements and understandings relating to the subject matter hereof, with the exception of any employment, severance or other similar written agreement that would provide for more favorable vesting acceleration or other treatment of this Award upon the terms and conditions set forth therein (in which case such terms

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and conditions shall apply to this Award instead of the applicable terms and conditions of this Agreement); *provided, however*, that notwithstanding anything to the contrary in such agreement, any such vesting acceleration or other treatment shall apply only to the number of Target Award Shares subject to this Award. No statement, representation, warranty, covenant or agreement not expressly set forth in this Agreement shall affect or be used to interpret, change or restrict the express terms and provisions of this Agreement; *provided, however*, in any event, this Agreement shall be subject to and governed by the Plan.

16. Modifications and Amendments; Waivers and Consents. The terms and provisions of this Agreement may be modified or amended as provided in the Plan. Except as provided in the Plan, the terms and provisions of this Agreement may be waived, or consent for the departure therefrom granted, only by written document executed by the party entitled to the benefits of such terms or provisions. No such waiver or consent shall be deemed to be or shall constitute a waiver or consent with respect to any other terms or provisions of this Agreement, whether or not similar. Each such waiver or consent shall be effective only in the specific instance and for the purpose for which it was given, and shall not constitute a continuing waiver or consent.

Notwithstanding the foregoing or anything set forth in the Account, this Agreement or the Plan to the contrary, the Compensation Committee will have the authority to reduce the number of shares of Common Stock subject to this Award that are deemed earned (and, therefore, that may vest) from the number otherwise calculated under the terms set forth in the Account or this Agreement and may take into consideration such other factors as it determines appropriate, in its sole discretion, in determining the number of shares of Common Stock subject to this Award that are deemed earned (and, therefore, that may vest).

17. Section 409A. The Award of PSUs evidenced by this Agreement is intended to be exempt from the nonqualified deferred compensation rules of Section 409A of the Code as a "short term deferral" (as that term is used in the final regulations and other guidance issued under Section 409A of the Code, including Treasury Regulation Section 1.409A-1(b)(4)(i)), and shall be construed accordingly. However, if (i) this Award fails to satisfy the

requirements of the short-term deferral rule and is otherwise not exempt from, and therefore deemed to be deferred compensation subject to, Section 409A of the Code, (ii) the Participant is deemed by the Company at the time of the Participant's "separation from service" (as such term is defined in Treasury Regulations Section 1.409A-1(h) without regard to any alternative definition thereunder) to be a "specified employee" for purposes of Section 409A(a)(2)(B)(i) of the Code, and (iii) any of the payments set forth herein are issuable upon such separation from service, then to the extent delayed commencement of any portion of such payments is required to avoid a prohibited distribution under Section 409A(a)(2)(B)(i) of the Code and the related adverse taxation under Section 409A of the Code, such payments will not be provided to the Participant prior to the earliest of (a) the date that is six (6) months and one (1) day after the date of such separation from service, (b) the date of the Participant's death, or (c) such earlier date as permitted under Section 409A of the Code without the imposition of adverse taxation. Upon the first business day following the expiration of such applicable Code Section 409A(a)(2)(B)(i) period, all payments deferred pursuant to this Section 17 will be paid in a lump sum to the Participant, and any remaining payments due will be paid as otherwise provided herein. Each installment of PSUs that vests under this Award is a "separate payment" for purposes of Treasury Regulations Section 1.409A-2(b)(2).

18. Acceptance. The Participant must acknowledge receipt of the Award and agree to its terms and conditions, as set forth in the Account, this Agreement and the Plan, by accepting the Award via the grant acceptance functionality in the Account within sixty (60) days following the Date of Grant; *provided, however*, that if the Participant does not accept the Award within sixty (60) days following the Date of Grant in accordance with the foregoing method, the Participant shall be deemed to have accepted the Award.

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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 2, 2023 May 7, 2024

/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. Hinline, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 2, 2023 May 7, 2024

/s/ Lawrence J. Hinline

Lawrence J. Hinline

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, 2023 March 31, 2024 (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 2, 2023 May 7, 2024

/s/ Sharon Mates, Ph.D.

Sharon Mates, Ph.D.

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

Dated: November 2, 2023 May 7, 2024

/s/ Lawrence J. Hinline

Lawrence J. Hinline

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

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