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, 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	**36-4742850**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
135 Route 202/206, Suite 6 Bedminster, New Jersey	**07921**
(Address of principal executive offices)	**(Zip Code)**

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of October 28, 2024, the registrant had 106,017,103 shares of common stock outstanding.

Intra-Cellular Therapies, Inc.

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

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, 2024 (unaudited)	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	**$ 464,312**	$ 147,767
Investment securities, available-for-sale	**542,250**	350,174
Restricted cash	**1,750**	1,750
Accounts receivable, net	**145,608**	114,018
Inventory	**23,539**	11,647
Prepaid expenses and other current assets	**94,272**	42,443
Total current assets	**1,271,731**	667,799
Property and equipment, net	**2,005**	1,654
Right of use assets, net	**14,011**	12,928
Inventory, non-current	**30,479**	38,621
Other assets	**6,219**	7,293
Total assets	**$ 1,324,445**	$ 728,295
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	**$ 10,338**	$ 11,452
Accrued and other current liabilities	**51,540**	27,944
Accrued customer programs	**70,536**	53,173
Accrued employee benefits	**29,496**	27,364
Operating lease liabilities	**4,203**	3,612
Total current liabilities	**166,113**	123,545
Operating lease liabilities, non-current	**13,506**	13,326
Total liabilities	**179,619**	136,871
Stockholders' equity:		
Common stock, $0.0001 par value: 175,000,000 shares authorized at September 30, 2024 and December 31, 2023, respectively; 105,998,786 and 96,379,811 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	**11**	10
Additional paid-in capital	**2,818,137**	2,208,470
Accumulated deficit	**(1,674,951)**	(1,617,160)
Accumulated comprehensive income	**1,629**	104
Total stockholders' equity	**1,144,826**	591,424
Total liabilities and stockholders' equity	**$ 1,324,445**	$ 728,295

See accompanying notes to these condensed consolidated financial statements.

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,	
	2024	2023	**2024**	2023
Revenues				
Product sales, net	**$ 175,159**	$ 125,810	**$ 481,278**	$ 330,669
Grant revenue	**216**	363	**351**	1,602
Total revenues, net	**175,375**	126,173	**481,629**	332,271
Operating expenses:				
Cost of product sales	**15,304**	9,129	**36,558**	23,043
Selling, general and administrative	**132,101**	105,207	**366,760**	305,144
Research and development	**66,819**	41,550	**165,835**	129,368
Total operating expenses	**214,224**	155,886	**569,153**	457,555
Loss from operations	**(38,849)**	(29,713)	**(87,524)**	(125,284)
Interest income	**12,899**	5,498	**30,523**	14,377
Loss before provision for income taxes	**(25,950)**	(24,215)	**(57,001)**	(110,907)
Income tax expense	**(374)**	(43)	**(790)**	(188)
Net loss	**$ (26,324)**	$ (24,258)	**$ (57,791)**	$ (111,095)
Net loss per common share:				
Basic & Diluted	**$ (0.25)**	$ (0.25)	**$ (0.57)**	$ (1.16)
Weighted average number of common shares:				
Basic & Diluted	**105,768,386**	96,143,083	**102,135,530**	95,745,641

See accompanying notes to these condensed consolidated financial statements.

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,	
	2024	2023	**2024**	2023
Net loss	**$ (26,324)**	$ (24,258)	**$ (57,791)**	$ (111,095)
Other comprehensive gain:				
Unrealized gain on investment securities	**2,297**	933	**1,525**	2,855
Comprehensive loss	**$ (24,027)**	$ (23,325)	**$ (56,266)**	$ (108,240)

See accompanying notes to these condensed consolidated financial statements.

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, 2022	94,829,794	$ 9	$ 2,137,737	$ (1,477,486)	$ (4,190)	$ 656,070
Exercise of stock options and issuances of restricted stock	849,827	1	3,639	—	—	3,640
Stock issued for services	408	—	22	—	—	22
Share-based compensation	—	—	10,439	—	—	10,439
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

Intra-Cellular Therapies, Inc. and Subsidiary

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

	Common Stock		**Additional Paid-in Capital**	**Accumulated Deficit**	**Accumulated Comprehensive (Loss) Income**	**Total Stockholders' Equity**
	Shares	**Amount**				
Balance at December 31, 2023	**96,379,811**	**$ 10**	**$ 2,208,470**	**$ (1,617,160)**	**$ 104**	**$ 591,424**
Exercise of stock options and issuances of restricted stock	**1,097,668**	**—**	**9,989**	**—**	**—**	**9,989**
Stock issued for services	**339**	**—**	**23**	**—**	**—**	**23**
Share-based compensation	**—**	**—**	**13,843**	**—**	**—**	**13,843**
Net loss	**—**	**—**	**—**	**(15,247)**	**—**	**(15,247)**
Other comprehensive loss	**—**	**—**	**—**	**—**	**(534)**	**(534)**
Balance at March 31, 2024	**97,477,818**	**$ 10**	**$ 2,232,325**	**$ (1,632,407)**	**$ (430)**	**$ 599,498**
Common shares issued	**7,876,713**	**1**	**543,085**	**—**	**—**	**543,086**
Exercise of stock options and issuances of restricted stock	**270,026**	**—**	**2,093**	**—**	**—**	**2,093**
Stock issued for services	**345**	**—**	**23**	**—**	**—**	**23**
Share-based compensation	**—**	**—**	**16,370**	**—**	**—**	**16,370**
Net loss	**—**	**—**	**—**	**(16,220)**	**—**	**(16,220)**
Other comprehensive loss	**—**	**—**	**—**	**—**	**(238)**	**(238)**
Balance at June 30, 2024	**105,624,902**	**$ 11**	**$ 2,793,896**	**$ (1,648,627)**	**$ (668)**	**$ 1,144,612**
Exercise of stock options and issuances of restricted stock	**373,638**	**—**	**6,734**	**—**	**—**	**6,734**
Stock issued for services	**246**	**—**	**18**	**—**	**—**	**18**
Share-based compensation	**—**	**—**	**17,489**	**—**	**—**	**17,489**
Net loss	**—**	**—**	**—**	**(26,324)**	**—**	**(26,324)**
Other comprehensive gain	**—**	**—**	**—**	**—**	**2,297**	**2,297**
Balance at September 30, 2024	**105,998,786**	**$ 11**	**$ 2,818,137**	**$ (1,674,951)**	**$ 1,629**	**$ 1,144,826**

See accompanying notes to these condensed consolidated financial statements.

Intra-Cellular Therapies, Inc. and Subsidiary

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

	Nine Months Ended September 30,	
	2024	2023
Cash flows used in operating activities		
Net loss	**$ (57,791)**	$ (111,095)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	**399**	392
Share-based compensation	**47,702**	37,976
Stock issued for services	**64**	69
Amortization of premiums and accretion of discounts on investment securities, net	**(6,043)**	(5,861)
Changes in operating assets and liabilities:		
Accounts receivable, net	**(31,590)**	(27,481)
Inventory	**(3,750)**	(19,066)
Prepaid expenses and other assets	**(50,755)**	(16,805)
Accounts payable	**(1,114)**	218
Accrued and other current liabilities	**23,596**	8,172
Accrued customer programs	**17,363**	9,997
Accrued employee benefits	**2,132**	2,452
Operating lease liabilities, net	**(312)**	(1,106)
Net cash used in operating activities	**(60,099)**	(122,138)
Cash flows (used in) provided by investing activities		
Purchases of investments	**(482,077)**	(310,805)
Maturities of investments	**297,568**	369,192
Purchases of property and equipment	**(749)**	(268)
Net cash (used in) provided by investing activities	**(185,258)**	58,119
Cash flows provided by financing activities		
Proceeds from exercise of stock options	**18,816**	14,806
Proceeds from sale of common stock, net	**543,086**	—
Net cash provided by financing activities	**561,902**	14,806
Net increase (decrease) in cash, cash equivalents, and restricted cash	**316,545**	(49,213)
Cash, cash equivalents, and restricted cash at beginning of period	**149,517**	150,365
Cash, cash equivalents, and restricted cash at end of period	**$ 466,062**	$ 101,152
Non-cash investing and financing activities		
Right of use assets under operating leases	**$ 2,548**	$ —
Supplemental cash flow information		
Cash paid for taxes	**$ 1,364**	$ —

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,	
	2024	2023
Cash and cash equivalents	**$ 464,312**	$ 99,402
Restricted cash	**1,750**	1,750
Total cash, cash equivalents and restricted cash	**$ 466,062**	$ 101,152

See accompanying notes to these condensed consolidated financial statements.

Intra-Cellular Therapies, Inc.

Notes to Condensed Consolidated Financial Statements (Unaudited)

September 30, 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 psychiatric and neurological disorders. In December 2019, CAPLYTA® (lumateperone) was approved by the U.S. Food and Drug Administration ("FDA") for the treatment of schizophrenia in adults (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 (42 mg/day) and the Company initiated the commercial launch of CAPLYTA for the treatment of bipolar 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.

In April 2024, the Company completed a public offering of common stock in which the Company sold 7,876,713 shares of common stock at a public offering price of $73.00 per share for aggregate gross proceeds of $575.0 million. After deducting underwriting discounts, commissions and offering expenses, the net proceeds to the Company were approximately $543.1 million.

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 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 in psychiatric and neurological disorders.

Recent 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. The Company is currently evaluating the potential impact that this new standard will have on its consolidated financial statements and related disclosures.

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, 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 investment securities held at financial institutions. For the nine-month period ended September 30, 2024, 98% of product sales were generated from three major industry wholesalers.

Three individual customers accounted for approximately 37%, 33%, and 28% as well as 36%, 32%, and 29% of product sales for the nine-month periods ended September 30, 2024 and 2023, respectively. As of September 30, 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, 2024			
	Amortized Cost	**Unrealized Gains**	**Unrealized (Losses)**	**Estimated Fair Value**
U.S. Government Agency Securities	**$ 135,801**	**$ 158**	**$ (13)**	**$ 135,946**
FDIC Certificates of Deposit	**980**	**—**	**—**	**980**
Certificates of Deposit	**60,000**	**—**	**—**	**60,000**
Commercial Paper	**51,637**	**63**	**(1)**	**51,699**
Corporate Notes/Bonds	**315,499**	**1,453**	**(31)**	**316,921**
	$ 563,917	**$ 1,674**	**$ (45)**	**$ 565,546**

	December 31, 2023			
	Amortized Cost	Unrealized Gains	Unrealized (Losses)	Estimated Fair Value
U.S. Government Agency Securities	$ 150,651	$ 148	$ (204)	$ 150,595
FDIC Certificates of Deposit	4,410	2	(12)	4,400
Certificates of Deposit	60,000	—	—	60,000
Commercial Paper	78,610	59	(27)	78,642
Corporate Notes/Bonds	118,899	281	(143)	119,037
	$ 412,570	$ 490	$ (386)	$ 412,674

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, 2024 and December 31, 2023, the Company held $164.0 million and $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. Accrued interest receivable from investment securities as of September 30, 2024 and December 31, 2023 was $3.7 million and $2.3 million, respectively, and are included within prepaid expenses and other current assets.

The aggregate related fair value of investments with unrealized losses as of September 30, 2024 was $66.2 million, which consisted of $30.5 million of U.S. government agency securities, $6.0 million of commercial paper, and $29.7 million of corporate notes/bonds. $1.0 million of the aggregate fair value of investments with unrealized losses as of September 30, 2024 has been held in a continuous unrealized loss position for over 12 months, with the remaining $65.2 million held in a continuous unrealized loss position for less than 12 months. As of December 31, 2023, the aggregate related fair value of investments with unrealized losses was $165.2 million. $70.1 million of the aggregate fair value of investments with unrealized losses as of December 31, 2023 had been held in a continuous unrealized loss position for more than 12 months, with the remaining $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 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.

4. Fair Value Measurements

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 had no assets or liabilities that were measured using prices with significant unobservable inputs (Level 3 assets and liabilities) as of September 30, 2024 and December 31, 2023. The carrying value of cash held in money market funds of $225.1 million as of September 30, 2024 and $10.7 million as of 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 commercial paper of $6.4 million, corporate bonds of $4.8 million, and U.S. government agency securities of $12.1 million as of September 30, 2024 is included in cash and cash equivalents. The carrying value of cash held in U.S. government agency securities of $2.5 million and certificates of deposit of $60.0 million as of 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):

		Fair Value Measurements at Reporting Date Using		
	September 30, 2024	**Quoted Prices in Active Markets for Identical Assets (Level 1)**	**Significant Other Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**
Money Market Funds	**$ 225,099**	**$ 225,099**	**$ —**	**$ —**
U.S. Government Agency Securities	**135,946**	**—**	**135,946**	**—**
FDIC Certificates of Deposit	**980**	**—**	**980**	**—**
Certificates of Deposit	**60,000**	**—**	**60,000**	**—**
Commercial Paper	**51,699**	**—**	**51,699**	**—**
Corporate Notes/Bonds	**316,921**	**—**	**316,921**	**—**
	$ 790,645	**$ 225,099**	**$ 565,546**	**$ —**

		Fair Value Measurements at Reporting Date Using		
	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	$ 10,698	$ 10,698	$ —	$ —
U.S. Government Agency Securities	150,595	—	150,595	—
FDIC Certificates of Deposit	4,400	—	4,400	—
Certificates of Deposit	60,000	—	60,000	—
Commercial Paper	78,642	—	78,642	—
Corporate Notes/Bonds	119,037	—	119,037	—
	$ 423,372	$ 10,698	$ 412,674	$ —

5. Inventory

Inventory consists of the following (in thousands):

	September 30, 2024	December 31, 2023
Raw materials	**$ 30,479**	$ 38,621
Work in process	**13,048**	4,277
Finished goods	**10,491**	7,370
Total	**54,018**	50,268
Less: Current portion	**(23,539)**	(11,647)
Total inventory, non-current	**$ 30,479**	$ 38,621

As of September 30, 2024 and December 31, 2023, the Company has recorded $8.0 million and $7.7 million, respectively, in inventory on the condensed consolidated balance sheets which is subject to supplemental regulatory procedures but the Company believes it is probable that such inventory has future economic benefit.

6. Prepaid and Other Assets

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

	September 30, 2024	December 31, 2023
Prepaid operating expenses	**$ 31,400**	$ 19,465
Production campaign deposits	**30,139**	15,127
Clinical trial advances	**33,389**	11,630
Prefunded customer programs	**5,563**	3,514
Total	**100,491**	49,736
Less: Current portion	**(94,272)**	(42,443)
Total other assets	**$ 6,219**	$ 7,293

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 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. In May 2024, the Company entered into a long-term lease of office space in Bedminster, New Jersey. The lease has a term of 5.7 years ending in February 2030.

The Company has also entered into agreements (the "Vehicle Leases") with providers (the "Lessors") to acquire motor vehicles for certain employees. The Vehicle Leases provide for individual vehicle leases, 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 related Lessor may draw upon in the event the Company defaults on the related Vehicle Leases, which has been recorded as restricted cash on the condensed consolidated balance sheets.

The following table presents the weighted average remaining lease term, and the weighted average discount rates related to leases as of September 30, 2024 and December 31, 2023:

	September 30, 2024	December 31, 2023
Other information		
Weighted average remaining lease term	**4.7 years**	5.3 years
Weighted average discount rate	**8.82 %**	9.07 %

The following table presents the lease cost for the nine-month periods ended September 30, 2024 and 2023 (in thousands):

	Nine Months Ended September 30,	
	2024	2023
Lease cost		
Operating lease cost	**$ 3,027**	$ 2,921
Variable lease cost	**1,254**	1,130
Short-term lease cost	**1,854**	1,757
	$ 6,135	$ 5,808

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

Three months ending December 31, 2024	$ 1,112
Year ending December 31, 2025	4,436
Year ending December 31, 2026	4,513
Year ending December 31, 2027	4,573
Year ending December 31, 2028	4,707
Thereafter	2,457
Total	21,798
Less: Present value discount	(4,089)
Total operating lease liability	17,709
Less: Current portion	(4,203)
Operating lease liabilities, non-current	$ 13,506

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"), 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 $10.8 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 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.

Purchase Commitments

The Company enters into certain long-term commitments for goods and services that are outstanding for periods greater than one year. The manufacturing service agreements commit 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, 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 through 2027. Over the course of the vendors' manufacturing period, the Company will remit payments to each vendor based on the payment plan set forth in their respective agreements. The Company has paid deposits of $30.1 million and $15.1 million as of September 30, 2024 and December 31, 2023, respectively, related to these campaigns. Of the $30.1 million balance as of September 30, 2024, $24.0 million is recorded within prepaid expenses and other current assets as the campaigns are expected to be received within one year of the balance sheet date and $6.1 million is recorded within other assets on the condensed consolidated balance sheet as the campaigns are expected to be received after September 30, 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.

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 three and nine-month periods ended September 30, 2024 and 2023, was comprised of the following (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	**2024**	2023
Inventoriable costs	**$ 497**	$ 424	**$ 1,405**	$ 1,186
Selling, general and administrative	**11,898**	9,564	**31,923**	25,269
Research and development	**5,094**	4,323	**14,374**	11,521
Total share-based compensation expense	**$ 17,489**	$ 14,311	**$ 47,702**	$ 37,976

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, 2024, and changes during the nine-month period then ended, are summarized as follows:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Contractual Life
Outstanding at December 31, 2023	4,239,982	$ 28.22	5.2 years
Options granted 2024	34,539		
Options exercised 2024	(933,601)		
Options canceled or expired 2024	(11,460)		
Outstanding at September 30, 2024	3,329,460	$ 30.74	5.2 years
Vested and expected to vest at September 30, 2024	3,329,460	$ 30.74	
Exercisable at September 30, 2024	2,968,706	$ 28.00	4.8 years

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 period ended September 30, 2024 is summarized as follows:

	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 years
Time-based RSUs granted in 2024	1,100,255		
Time-based RSUs vested in 2024	(732,992)		
Time-based RSUs cancelled in 2024	(61,611)		
Outstanding at September 30, 2024	1,950,782	$ 60.35	1.2 years

As of September 30, 2024, there were $95.5 million of unrecognized compensation costs estimated related to unvested time-based RSUs.

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 periods ended September 30, 2024 and 2023:

	Three and Nine Months Ended September 30,	
	2024	2023
Stock options	**3,329,460**	4,385,555
RSUs	**2,175,284**	1,755,460

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

You should read the following in conjunction with our unaudited condensed consolidated financial statements and the related notes thereto that appear elsewhere in this Quarterly Report on Form 10-Q and the audited consolidated financial statements and notes thereto and under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K filed on February 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 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 psychiatric and neurological disorders.

Commercial Product

In December 2019, CAPLYTA® (lumateperone) was approved by the U.S. Food and Drug Administration (FDA), for the treatment of schizophrenia in adults (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 (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.

Clinical and Nonclinical Development Programs

Lumateperone Program

Lumateperone is in Phase 3 clinical development as a novel treatment for major depressive disorder, or MDD. In April 2024 and June 2024, we announced positive topline results from our Phase 3 clinical trials, Study 501 and Study 502, respectively, evaluating lumateperone 42 mg as an adjunctive therapy to antidepressants for the treatment of MDD. In both studies, lumateperone 42 mg given once daily as adjunctive therapy to antidepressants met the primary endpoint by demonstrating a statistically significant and clinically meaningful reduction in the Montgomery Asberg Depression Rating Scale (MADRS) total score compared to placebo at Week 6. In Study 501, 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). In Study 502, in the mITT study population, the LS mean reduction from baseline for lumateperone 42 mg was 14.7 points, versus 10.2 points for placebo (LS mean difference= -4.5 points; $p<0.0001$; ES= 0.56). Lumateperone 42 mg also met the key secondary endpoint in both studies 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 (Study 501: $p<0.0001$; ES= 0.67; Study 502: $p<0.0001$; ES= 0.51). In Study 501, 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 Study 502, numerical improvement versus placebo on the MADRS total score was seen as early as Week 1 and statistically significant efficacy was seen at Week 2 and maintained throughout the study, and statistically significant separation on the CGI-S versus placebo was observed starting at Week 3 and maintained throughout the study. In both Studies 501 and 502, 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 these studies. In the pooled safety data for Studies 501 and 502, the most commonly reported adverse events that were observed at a rate greater than or equal to 5% and greater than twice the rate of placebo in the total population were dizziness (16.6% v. 5.0%), dry mouth (12.6% v. 3.3%), somnolence (12.4% v. 2.3%), nausea (8.5% v. 4.0%) and fatigue (7.7% v. 1.7%).

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.

We recently completed clinical conduct of our open label roll-over study, Study 503, to assess long-term safety in patients with MDD. We expect to submit a supplemental new drug application, or sNDA, with the FDA for approval of lumateperone as an adjunctive therapy to antidepressants for the treatment of MDD in the fourth quarter of 2024.

We are currently conducting an additional global Phase 3 clinical trial, Study 505, evaluating lumateperone 42 mg as an adjunctive therapy to antidepressants for the treatment of MDD. Following our positive results in Studies 501 and 502, we have amended the entry criteria of Study 505 to obtain additional clinical experience with lumateperone in patients who have had an inadequate response to a greater number of antidepressants. The objective of this study is to further expand the large body of evidence supporting lumateperone antidepressant efficacy across different patient populations.

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 42 mg given once daily met the primary endpoint in the study by demonstrating a statistically significant and clinically meaningful reduction in the 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 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 vs. placebo; $p<0.0001$; ES= 0.67), and in the individual patient population of bipolar depression with mixed features (5.7 point reduction vs. placebo; $p<0.0001$; ES= 0.64). Additionally, lumateperone 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 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 ($p<0.0001$; ES=0.61).

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 fourth quarter of 2024.

Within the lumateperone portfolio, we have conducted or are 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. We expect to begin enrollment in the two double-blind, placebo-controlled studies in irritability associated with autism spectrum disorder in the fourth quarter of 2024. Also, in the second quarter of 2024, we initiated two multicenter, randomized, double-blind, placebo-controlled, Phase 3 studies evaluating lumateperone in adults in the acute treatment of manic or mixed episodes associated with bipolar I disorder (bipolar mania). 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 an LAI formulation. This study evaluated the pharmacokinetics, safety and tolerability of a lumateperone LAI in patients with stable symptoms of schizophrenia and was generally safe and well-tolerated. We are evaluating several additional formulations of a lumateperone LAI with treatment durations of one month and longer, and have commenced clinical conduct in a Phase 1 study with additional formulations of our LAI. Given the encouraging 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.

ITI-1284 Program

We are developing ITI-1284-ODT-SL for the treatment of generalized anxiety disorder, psychosis in Alzheimer's disease and agitation in patients with 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 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 patient enrollment is ongoing in our Phase 2 study evaluating ITI-1284-ODT-SL as adjunctive therapy to anti-anxiety medications in patients with generalized anxiety disorder. We expect to initiate patient enrollment in our Phase 2 study evaluating ITI-1284-ODT-SL as monotherapy in patients with generalized anxiety disorder in the fourth quarter of 2024. We have also initiated patient enrollment in a Phase 2 clinical study evaluating ITI-1284-ODT-SL in patients with psychosis associated with Alzheimer's disease and in a Phase 2 clinical study evaluating ITI-1284-ODT-SL in patients with agitation associated with Alzheimer's disease. We are continuing with Phase 1 studies with ITI-1284-ODT-SL, including drug-drug interaction studies.

PDE1 Program

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 this study by the end of 2025. We also have an active Investigational New Drug application, or IND, to evaluate our newest candidate within the PDE1 inhibitor program, ITI-1020, as a novel cancer immunotherapy. Our Phase 1 program with ITI-1020 in healthy volunteers is ongoing.

ITI-333 Program

We also have a development program with our ITI-333 compound as a potential treatment for substance use disorders, pain and psychiatric comorbidities including depression and anxiety. There is a pressing need to develop new drugs to treat opioid addiction and safe, effective, non-addictive treatments to manage pain. ITI-333 is a novel compound that uniquely combines activity as an antagonist at serotonin 5-HT2A receptors and a partial agonist at μ-opioid receptors. These combined actions support the potential utility of ITI-333 in the treatment of opioid use disorder and associated comorbidities (e.g., depression, anxiety, sleep disorders) without opioid-like safety and tolerability concerns. 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 an ongoing 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. In addition, we completed a multiple ascending dose study with ITI-333 in healthy volunteers. In this study, ITI-333 was generally safe and well-tolerated.

ITI-1500 Program

We also have the ITI-1500 program focused on the development of novel non-hallucinogenic psychedelics, which we refer to as neuroplastogens. Compounds in this series interact with serotonergic (5-HT2a) receptors in a unique way, potentially allowing the development of this new drug class in mood, anxiety and other neuropsychiatric disorders without the liabilities of known psychedelics including the hallucinogenic potential and risk for cardiac valvular pathologies. Our lead compound in this program, ITI-1549, is currently being evaluated in IND enabling studies and is expected to enter human testing in 2025.

Results of Operations

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

Revenues

Revenues are comprised primarily of net product sales of our commercial product, CAPLYTA, in the United States. Our net product sales of CAPLYTA represent sales primarily to wholesalers and specialty distributors and reflect certain adjustments deducted from gross product sales to arrive at product sales, 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.

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, incentives and related benefit costs of a dedicated sales force and commercial organization;
- 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 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, 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 and development of our product candidates are substantial, and we have not yet generated sufficient revenue to offset our operating 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.

A portion of product sold through September 30, 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. Because the Company's policy does not allow for the capitalization of 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 periods ended September 30, 2024 and 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 remainder of the year 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 and we exceed certain sales thresholds, the applicable royalty rate for payments we make under our License Agreement with Bristol Myers Squibb (BMS) increases, which results in an increase to cost of product sales.

We expect that our selling, general and administrative costs will increase from prior periods primarily due to costs associated with our recently completed and future sales force expansions, promotional activities to support the commercial sales of CAPLYTA, as well as costs associated with expanding our infrastructure and anticipated increases in professional fees. During the third quarter of 2024, we expanded our sales force by approximately 150 representatives who will focus on commercial sales of CAPLYTA to primary care physicians. We also expect to further expand our sales force in 2025. We also expect that research and development expenses will increase moderately as we are expanding our clinical trial programs and pre-clinical development activities. We granted significant share-based awards in 2024 and 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, selling, labor and other operational costs.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	**2024**	2023
Revenues				
Product sales, net	**$ 175,159**	$ 125,810	**$ 481,278**	$ 330,669
Grant revenue	**216**	363	**351**	1,602
Total revenues	**175,375**	126,173	**481,629**	332,271
Expenses				
Cost of product sales	**15,304**	9,129	**36,558**	23,043
Selling, general and administrative	**132,101**	105,207	**366,760**	305,144
Research and development	**66,819**	41,550	**165,835**	129,368
Total operating expenses	**214,224**	155,886	**569,153**	457,555
Loss from operations	**(38,849)**	(29,713)	**(87,524)**	(125,284)
Interest income	**12,899**	5,498	**30,523**	14,377
Income tax expense	**(374)**	(43)	**(790)**	(188)
Net loss	**$ (26,324)**	$ (24,258)	**$ (57,791)**	$ (111,095)

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

Product Sales, Net

Net product sales for the periods presented are comprised of sales of CAPLYTA for the treatment of schizophrenia and bipolar depression. Net product sales were $175.2 million and $481.3 million for the three and nine-month periods ended September 30, 2024 compared to $125.8 million and $330.7 million for the three and nine-month periods ended September 30, 2023, which represents increases of 39% and 46%, respectively. These increases are primarily due to continued growth in sales volume of CAPLYTA for the treatment of schizophrenia and for the treatment of bipolar depression, driven primarily by prescription growth.

Cost of Product Sales

Cost of product sales was $15.3 million and $36.6 million for the three and nine-month periods ended September 30, 2024, compared to $9.1 million and $23.0 million for the three and nine-month periods ended September 30, 2023, which represents increases of 68% and 59%, respectively. Cost of product sales consisted primarily of product royalty fees, direct costs and overhead, all of which increased as a result of the increased sales volume.

Selling, General and Administrative Expenses

Selling, general and administrative expenses for the three-month period ended September 30, 2024 were $132.1 million as compared to $105.2 million in the three-month period ended September 30, 2023, which represents an increase of 26%.

Selling costs were $98.7 million for the three-month period ended September 30, 2024 as compared to selling costs of $80.9 million in the same period in 2023, which represents an increase of 22%. This increase is primarily due to increases of salaries, benefits, and share-based compensation of $11.0 million mainly driven by the primary care sales force expansion that occurred this quarter, professional fees and other costs of $3.4 million and marketing and advertising costs of $3.4 million. Compensation and related benefit costs for our commercial functions for the three-month periods ended September 30, 2024 and 2023 constituted 35% and 35%, respectively, of our selling costs.

General and administrative expenses were $33.4 million for the three-month period ended September 30, 2024 as compared to $24.3 million in the same period in 2023, which represents an increase of 37%. This increase is due to increases in IT related services of $3.8 million, salaries of $3.0 million and professional fees and other costs of $2.3 million. Compensation and related benefit costs for our general and administrative functions for the three-month periods ended September 30, 2024 and 2023 constituted 24% and 18%, respectively, of our general and administrative costs.

Selling, general and administrative expenses for the nine-month period ended September 30, 2024 were $366.8 million as compared to $305.1 million in the nine-month period ended September 30, 2023, which represents an increase of 20%.

Selling costs were $279.3 million for the nine-month period ended September 30, 2024 as compared to selling costs of $233.5 million in the same period in 2023, which represents an increase of 20%. This increase is primarily due to increases of salaries, benefits and share-based compensation of $23.3 million mainly driven by the primary care sales force expansion that occurred this quarter, marketing and advertising costs of $11.2 million, commercialization costs of $9.2 million and professional fees and other costs of $2.1 million. Compensation and related benefit costs for our commercial functions for the nine-month periods ended September 30, 2024 and 2023 constituted 33% and 35%, respectively, of our selling costs.

General and administrative expenses were $87.5 million for the nine-month period ended September 30, 2024 as compared to $71.6 million in the same period in 2023, which represents an increase of 22%. This increase is due to increases in IT related services of $9.0 million, salaries of $4.7 million and professional fees and other costs of $2.2 million. Compensation and related benefit costs for our general and administrative functions for the nine-month periods ended September 30, 2024 and 2023 constituted 24% and 22%, respectively, of our general and administrative costs.

Research and Development Expenses

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	**2024**	2023
External service costs	**$ 53,188**	$ 29,123	**$ 126,029**	$ 94,579
Internal and other costs	**13,631**	12,427	**39,806**	34,789
Total research and development expenses	**$ 66,819**	$ 41,550	**$ 165,835**	$ 129,368

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	**2024**	2023
Lumateperone costs	**$ 40,605**	$ 23,149	**$ 100,328**	$ 78,510
Non-lumateperone costs	**16,383**	9,614	**37,859**	27,670
Overhead and other costs	**9,831**	8,787	**27,648**	23,188
Total research and development expenses	**$ 66,819**	$ 41,550	**$ 165,835**	$ 129,368

Research and development expenses were $66.8 million for the three-month period ended September 30, 2024 as compared to $41.6 million in the same period in 2023, which represents an increase of 61%. This increase is due primarily to increases of $17.4 million for lumateperone costs, $6.8 million for non-lumateperone costs and $1.0 million for overhead and other costs. External service costs increased by $24.0 million for the period due to the increased number of clinical trials for lumateperone and non-lumateperone projects. Internal and other costs increased by $1.2 million for the period due primarily to labor related costs and share-based compensation.

Research and development expenses were $165.8 million for the nine-month period ended September 30, 2024 as compared to $129.4 million in the same period in 2023, which represents an increase of 28%. This increase is due primarily to increases of $21.8 million for lumateperone costs, $10.2 million for non-lumateperone costs and $4.4 million for overhead and other costs. External service costs increased by $31.4 million for the period due to the increased number of clinical trials for lumateperone and non-lumateperone projects. Internal and other costs increased by $5.0 million for the period due primarily to labor related costs and share-based compensation.

Liquidity and Capital Resources

Sources of Liquidity

To date, we have funded our operations through proceeds from public and private offerings of our common stock and other securities, as well as collections from net product revenue related to the sales of CAPLYTA. As of September 30, 2024, our cash and cash equivalents, investment securities, and restricted cash totaled approximately $1.0 billion, which we believe, along with cash generated from ongoing operations, will enable us to fund our operating expenses and capital expenditure requirements for at least the foreseeable future from the filing date of this report. During that time, we expect to have increased net product revenue as well as increases in our operating expenses.

We balance the level of cash, cash equivalents and investments on hand with our projected needs. We then assess the availability of funding on favorable terms with minimal risk. Subject to market conditions, interest rates, results of our clinical trials, progress of our commercialization efforts and other factors, we may pursue opportunities to obtain additional financing in the future, which could include public or private sales of our equity securities, sales of debt securities, incurrence of debt from commercial lenders, strategic collaborations, and licensing a portion or all of our product candidates and technology. 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.

Our cash, cash equivalents, and investments are maintained in checking accounts, money market accounts, money market funds, U.S. government agency securities, certificates of deposit, commercial paper, corporate notes and corporate bonds at major financial institutions. Our aim is 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 because these financial institutions are highly-rated institutions and custodians of our investments.

Cash Flows

The following table summarizes our cash flows for the nine months ended September 30, 2024 and 2023 (in thousands):

	Nine Months Ended September 30,		
	2024	**2023**	**Change**
Net cash used in operating activities	**$ (60,099)**	$ (122,138)	$ 62,039
Net cash (used in) provided by investing activities	**(185,258)**	58,119	(243,377)
Net cash provided by financing activities	**561,902**	14,806	547,096
Net increase (decrease) in cash, cash equivalents, and restricted cash	**$ 316,545**	$ (49,213)	$ 365,758

Net cash used in operating activities totaled $60.1 million for the nine months ended September 30, 2024 compared to $122.1 million of net cash used in operating activities for the nine months ended September 30, 2023. This decrease in cash used in operations primarily resulted from an increase in our net product sales.

Net cash used in investing activities totaled $185.3 million for the nine months ended September 30, 2024 compared to $58.1 million of cash provided by investing activities for the nine months ended September 30, 2023. The increase in net cash used in investing activities was primarily due to an increase in purchases of investment securities.

Net cash provided by financing activities totaled $561.9 million for the nine months ended September 30, 2024 compared to $14.8 million of cash provided by financing activities for the nine months ended September 30, 2023. This increase in net cash provided by financing activities was attributable primarily to the completion of an underwritten public offering of shares of our common stock in April 2024 resulting in net proceeds of approximately $543.1 million, after deducting underwriting discounts and commissions and offering expenses.

Operational and Capital Funding Requirements

Our cash requirements in the short and long term consist of operational, manufacturing, and capital expenditures, a portion of which contain contractual or other obligations. Our material long-term contractual commitments are comprised of licensing and royalty commitments with BMS, operating leases for our office and laboratory spaces, and purchase obligations supporting our commercial and R&D operations. Refer to our discussion of Liquidity and Capital Resources in "Part II, Item 7 — Management's Discussion and Analysis of Financial Condition and Results of Operations," of our Annual Report on Form 10-K for the year ended December 31, 2023, and Note 7, Right of Use Assets and Lease Liabilities, and Note 8, Commitments and Contingencies, in the Notes to the Condensed Consolidated Financial Statements in Part I, Item 1, Financial Statements, of this Quarterly Report on Form 10-Q for the discussion of our contractual commitments.

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

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. 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 are currently evaluating the potential impact that this new standard will have on our consolidated financial statements 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: 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 supply and availability of and demand for our product; our recently completed and future sales force expansions; the initiation, cost, timing, progress and results of our development activities, non-clinical studies and clinical trials; the timing of and our ability to obtain and maintain regulatory approval, or submit an application for regulatory approval, of lumateperone and our other existing product candidates, any product candidates that we may develop, and any related restrictions, limitations, and/or warnings in the label of any approved product candidates; our plans to research, develop and commercialize lumateperone and our other current and future product candidates; the election by any collaborator to pursue research, development and commercialization activities; our ability to obtain future reimbursement and/or milestone payments from our collaborators; our ability to attract collaborators with development, regulatory and commercialization expertise; our ability to obtain and maintain intellectual property protection for our product candidates, 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.

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; whether CAPLYTA receives adequate reimbursement from third-party payers; 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; challenges associated with supply and manufacturing activities, which in each case could limit our sales and the availability of our product; 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; there is no guarantee that a generic equivalent of CAPLYTA will not be approved and enter the market before the expiration of our patents; there is no guarantee that our planned sNDA for the treatment of MDD will be submitted or approved, if at all, on the timeline that we expect; our other product candidates may not be successful or may take longer and be more costly than anticipated; product candidates that appeared promising in earlier research and clinical trials may not demonstrate safety and/or efficacy in larger-scale or later clinical trials or in clinical trials for other indications; our proposals with respect to the regulatory path for our product candidates may not be acceptable to the FDA; our reliance on collaborative partners and other third parties for development, commercialization, manufacturing or supply of our product and product candidates; risks related to changes in 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), the conflicts in the Ukraine, Russia or the Middle East, man-made or natural disasters, global economic uncertainty, market disruptions, 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, 2024, we had cash, cash equivalents, investment securities and restricted cash of approximately $1.0 billion, consisting of cash deposited in highly rated financial institutions in the United States and in short-term U.S. Treasury bonds, money market 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 as we intend and have the ability to hold our investments to maturity. During the third quarter of 2024, there was an unrealized gain due to a decline in interest rates that resulted in a net unrealized gain position of $1.6 million as of September 30, 2024.

Inflation Risk. Inflation generally affects us by increasing our cost of labor, clinical trial costs, and other outsourced activities. To date, inflation has not had a material impact on our business. Should global inflation increase in the future, we expect 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. Our inability or failure to do so could adversely affect our business, financial condition and results of operations.

Capital Market Risk. Although we receive product revenues from commercial sales of CAPLYTA, we may in the future raise funds through other sources. One possible source of funding is through further securities offerings. Our ability to raise funds in this manner depends upon capital market forces affecting our stock 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 nine-month periods ended September 30, 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, 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.

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 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 U.S. District Court for the District of New Jersey against each of the seven generic drug manufacturers who notified us of their ANDA filings. Our lawsuits seek a declaratory judgment that our patents have been infringed by the respective ANDA Filer, an order that any FDA approval of the ANDA Filer's product be not earlier than the date of the expiration of our applicable patents, injunctions against the commercialization of the ANDA Filer's product prior to such expiration date, and an award for attorneys' fees, costs and expenses. In the ANDA Filers' respective answers to our complaints filed in May, June and July 2024, five of the ANDA Filers asserted counterclaims against us seeking a declaratory judgment of noninfringement and invalidity of our patents.

On July 16, 2024, the U.S. District Court for the District of New Jersey issued an order consolidating the cases described above for all pretrial purposes. A scheduling conference for the consolidated cases was held on July 29, 2024 and on August 8, 2024, the U.S. District Court for the District of New Jersey issued a scheduling order that set the date for the bench trial to begin on October 27, 2026.

In July and August 2024, we received an additional notice from each of (i) Dr. Reddy's Laboratories Inc. and Dr. Reddy's Laboratories Ltd., and (ii) Alkem Laboratories Ltd., respectively, each of which is an ANDA Filer, that such ANDA Filer had filed an additional Paragraph IV Patent Certification alleging that an additional patent covering CAPLYTA is invalid and/or will not be infringed by such ANDA Filer's manufacture, use or sale of the medicine for which the ANDA was submitted. On August 29, 2024, we filed additional lawsuits in the U.S. District Court for the District of New Jersey against each of the seven ANDA Filers with respect to two additional patents covering CAPLYTA (including the patent referenced in the July and August ANDA Filer notices) seeking a declaratory judgment that our patents have been infringed by the respective ANDA Filer, an order that any FDA approval of the ANDA Filer's product be not earlier than the date of expiration of our applicable patents, injunctions against the commercialization of the ANDA Filer's product prior to such expiration date, and an award for attorneys' fees, costs and expenses. In the ANDA Filers' respective answers to these complaints filed up to the date of this report, two of the ANDA Filers asserted counterclaims against us seeking a declaratory judgment of noninfringement and invalidity of our patents. On October 15, 2024, the U.S. District Court for the District of New Jersey issued an order consolidating these additional cases with the consolidated case described above for all pretrial purposes.

While we intend to vigorously defend and enforce our intellectual property rights protecting CAPLYTA, we can offer no assurance as to when the lawsuits will be decided, whether the lawsuits will be successful, or that a generic equivalent of CAPLYTA will not be approved and enter the 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, 2023, filed with the Securities and Exchange Commission on February 22, 2024.

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

Unregistered Sales of Equity Securities

Not applicable.

Issuer Purchases of Equity Securities

We did not repurchase any of our equity securities during the quarter ended September 30, 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, 2024, the following director and executive officers adopted a "Rule 10b5-1 trading arrangement" (as defined in Item 408 of Regulation S-K of the Exchange Act):

- On August 13, 2024, Michael I. Halstead, President, adopted a Rule 10b5-1 Sales Plan having an end date of December 31, 2024. The plan is intended to satisfy the affirmative defense of Rule 10b5-1(c) and provides for the sale of up to an aggregate of 41,583 shares of our common stock upon the exercise of stock options. On August 13, 2024, Mr. Halstead adopted a subsequently commencing Rule 10b5-1 Sales Plan with a start date of January 2, 2025 and an end date of April 10, 2025. The plan is intended to satisfy the affirmative defense of Rule 10b5-1(c) and provides for the sale of (i) an aggregate of 32,717 shares of our common stock upon the vesting of restricted stock units and (ii) an indeterminate number of shares of our common stock sufficient to cover Mr. Halstead’s tax liability upon the vesting of performance restricted stock units for up to 11,017 shares of our common stock at maximum achievement of the performance vesting conditions.
- On September 3, 2024, Sharon Mates, Ph.D., Chairman and Chief Executive Officer, adopted a Rule 10b5-1 Sales Plan having an end date of December 16, 2024. The plan is intended to satisfy the affirmative defense of Rule 10b5-1(c) and provides for the sale of up to an aggregate of 102,697 shares of our common stock upon the exercise of stock options.

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

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	Offer Letter, dated as of August 2, 2024, by and between Intra-Cellular Therapies, Inc. and Sanjeev Narula*		8-K (Exhibit 10.1)	8/7/2024	001-36274
10.2	Employment Agreement, effective as of August 12, 2024, by and between Intra-Cellular Therapies, Inc. and Sanjeev Narula*		8-K (Exhibit 10.2)	8/7/2024	001-36274
10.3	Employee Proprietary Information, Inventions, and Non-Competition Agreement, effective as of August 12, 2024, by and between Intra-Cellular Therapies, Inc. and Sanjeev Narula*		8-K (Exhibit 10.3)	8/7/2024	001-36274
10.4	Separation Agreement, dated as of August 2, 2024, by and between Intra-Cellular Therapies, Inc. and Lawrence J. Hineline*		8-K (Exhibit 10.4)	8/7/2024	001-36274
10.5	Consulting Agreement, dated as of August 2, 2024, by and between Intra-Cellular Therapies, Inc. and Lawrence J. Hineline*		8-K (Exhibit 10.5)	8/7/2024	001-36274
10.6	Form of Release replacing the version included in each executive officer employment agreement.*	X			
10.7	Form of Amended and Restated Employee Proprietary Information, Inventions, and Non-Competition Agreement of Intra-Cellular Therapies, Inc. with each executive officer.*	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, 2024, formatted in Inline XBRL (eXtensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets as of September 30, 2024 (unaudited) and December 31, 2023, (ii) Condensed Consolidated Statements of Operations (unaudited) for the three and nine months ended September 30, 2024 and 2023, (iii) Condensed Consolidated Statements of Comprehensive Loss (unaudited) for the three and nine months ended September 30, 2024 and 2023, (iv) Condensed Consolidated Statements of Stockholders' Equity (unaudited) for the three and nine months ended September 30, 2024 and 2023, (v) Condensed Consolidated Statements of Cash Flows (unaudited) for the nine months ended September 30, 2024 and 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.

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: October 30, 2024

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

Date: October 30, 2024

By: /s/ Sanjeev Narula
Sanjeev Narula
Executive Vice President, Chief Financial Officer and Treasurer

Exhibit 10.6

Schedule B
RELEASE OF CLAIMS

This Release of Claims (***Release***") is made as of _____ by and between _____ ("***the Executive***") and Intra-Cellular Therapies, Inc. (the "***Company***") (together, the "***Parties***").

1. In consideration for Executive's execution of this Release, the Company will make a severance payment to Executive in the amount set forth in the Employment Agreement between the Executive and the Company. This amount will be paid following the Effective Date (as defined below) in accordance with the Employment Agreement, provided the Company has received the executed Agreement from Executive on or before that date. This payment will be subject to standard payroll deductions and withholdings. If Executive timely elects and remains eligible for continued coverage under COBRA, the Company will pay that portion of Executive's COBRA premiums it was paying prior to the Separation Date for the time period set forth in the Employment Agreement between the Executive and the Company.

2. Executive hereby releases, acquits and forever discharges the Company, its parents and subsidiaries, and their officers, directors, agents, servants, employees, stockholders, successors, assigns and affiliates, of and from any and all claims, liabilities, demands, causes of action, costs, expenses, attorneys fees, damages, indemnities and obligations of every kind and nature, in law, equity, or otherwise, which were known or through reasonable diligence should have been known, arising out of or in any way related to Releases, events, acts or conduct at any time prior to the date Executive executes this Settlement Release, including, but not limited to: all such claims and demands directly or indirectly arising out of or in any way connected with Executive's employment with the Company, including but not limited to, claims of intentional and negligent infliction of emotional distress, any and all tort claims for personal injury, claims or demands related to salary, bonuses, commissions, stock, stock options, or any other ownership interests in the Company, vacation pay, fringe benefits, expense reimbursements, severance pay, or any other form of compensation; claims pursuant to any federal, state or local law or cause of action including, but not limited to, any and all claims and causes of action that the Company, its parents and subsidiaries, and its and their respective officers, directors, agents, servants, employees, attorneys, shareholders, successors, assigns or affiliates:

- has violated its personnel policies, handbooks, contracts of employment, or covenants of good faith and fair dealing;

- has discriminated against Executive on the basis of age, race, color, sex (including sexual harassment), national origin, ancestry, disability, religion, sexual orientation, marital status, parental status, source of income, entitlement to benefits, any union activities or other protected category in violation of any local, state or federal law, constitution, ordinance, or regulation, including but not limited to: Title VII of the Civil Rights Act of 1964, as amended; 42 U.S.C. § 1981, as amended; the Equal Pay Act; the Americans With Disabilities Act; the Family and Medical Leave Act; the New York State Human Rights Law; the New York City Human Rights Law; the Employee Retirement Income Security Act; Section 510; and the National Labor Relations Act;

- has violated any statute, public policy or common law (including but not limited to claims for retaliatory discharge; negligent hiring, retention or supervision; defamation; intentional or negligent infliction of emotional distress and/or mental anguish; intentional interference with contract; negligence; detrimental reliance; loss of consortium to Executive or any member of Executive's family and/or promissory estoppel).

Excluded from this Release are any claims which cannot be waived by law. Executive is waiving, however, Executive's right to any monetary recovery should any governmental agency or entity, such as the EEOC or the DOL, pursue any claims on Executive's behalf. Executive acknowledges that Executive is knowingly and voluntarily waiving and releasing any rights Executive may have under the ADEA, as amended. Executive also acknowledges that (i) the consideration given to Executive in exchange for the waiver and release in this Release is in addition to anything of value to which Executive was already entitled, and (ii) that Executive has been paid for all time worked, have received all the leave, leaves of absence and leave benefits and protections for which Executive is eligible, and have not suffered any on-the-job injury for which Executive has not already filed a claim. Executive further acknowledges that Executive has been advised by this writing that: (a) Executive's waiver and release do not apply to any rights or claims that may arise after the execution date of this Release; (b) Executive has been advised hereby that Executive has the right to consult with an attorney prior to executing this Release; (c) Executive has twenty-one (21) days to consider this Release (although Executive may choose to voluntarily execute this Release earlier and if Executive does Executive will sign the Consideration Period waiver below); (d) Executive has seven (7) days following Executive's execution of this Release to revoke the Release; and (e) this Release shall not be effective until the date upon which the revocation period has expired unexercised (the "Effective Date"), which shall be the eighth day after Executive executes this Release.

Notwithstanding the foregoing, the waiver and release contained in this Release does not apply to any claim which, as a matter of law, cannot be released by private agreement. If any provision of the waiver and release contained in this Release is found to be unenforceable, it shall not affect the enforceability of the remaining provisions and all remaining provisions shall be enforceable to the fullest extent permitted by law. No provision of this Release shall prevent or restrict Executive from disclosing information about unlawful workplace acts, including but not limited to factual information relating to any claims of harassment, discrimination, or retaliation under Title VII the New York State Human Rights Law, including claims based on race, sexual orientation, religion, color, national origin, ancestry, disability, medical condition, and age. No provision of this Release is intended to limit, or shall be interpreted as limiting, Executive's right to file administrative charges with any Governmental Entity (as defined below) charged with enforcement of any law, including but not limited to the Equal Employment Opportunity Commission, New York State Division of Human Rights and the New York City Commission on Human Rights, the Securities and Exchange Commission, and National Labor Relations Board, and to participate in agency investigations. Additionally, nothing herein is intended to restrict, or shall be interpreted as restricting, Executive's right to engage in concerted activity protected by Section 7 of the National Labor Relations Act or Executive's right to file for or collect unemployment benefits and/or to seek and receive remedies for workplace injuries under the provisions of any applicable workers' compensation act.

Nothing in this Release shall prohibit or impede Executive from communicating, cooperating or filing a complaint with any U.S. or foreign federal, state or local governmental or law enforcement branch, federal or state attorney general, agency, entity, commission or other governmental authority or instrumentality of competent jurisdiction (collectively, a "Governmental Entity") or any attorney retained by Executive, with respect to possible violations of any U.S. or foreign federal, state or local law or regulation, or otherwise making disclosures to any Governmental Entity, in each case, that are protected under the whistleblower provisions of any such law or regulation; provided, that in each case such communications and disclosures are consistent with applicable law. Executive does not need the prior authorization of (or to give notice to) the Company regarding any such communication or disclosure.

3. On or before the last day of Executive's employment, Executive agrees to return to the Company all Company documents (and all copies thereof) and other Company property that Executive has had in Executive's possession at any time, including, but not limited to, Company files, notes, drawings, records, business plans and forecasts, financial information, specifications, computer-recorded information, tangible property (including, but not limited to, computers), credit cards, entry cards, identification badges and keys; and, any materials of any kind that contain or embody any proprietary or confidential information of the Company (and all reproductions thereof). Executive shall coordinate the return of Company property with the General Counsel, Chief Human Resources Officer, or other appropriate officer designated by the Board of Directors.

4. Executive further agrees that both during and after Executive's employment Executive acknowledges Executive's continuing obligations under Executive's Proprietary Information, Inventions and Non-Competition Agreement not to use or disclose any confidential or proprietary information of the Company and to refrain from certain solicitation and competitive activities.

5. It is understood that Executive shall hold the provisions of this Release in strictest confidence and shall not publicize or disclose it in any manner whatsoever; *provided, however*, that: (a) Executive may disclose this Release to Executive's immediate family; (b) Executive may disclose this Release in confidence to Executive's attorney, accountant, auditor, tax preparer, and financial advisor; and (c) Executive may disclose this Release insofar as such disclosure may be required by law.

6. Executive agrees not to disparage the Company, and the Company's attorneys, directors, managers, partners, employees, agents and affiliates, in any manner likely to be harmful to them or their business, business reputation or personal reputation; provided that Executive may respond accurately and fully to any question, inquiry or request for information when required by legal process.

7. This Release does not constitute an admission by the Company of any wrongful action or violation of any federal, state, or local statute, or common law rights, including those relating to the provisions of any law or statute concerning employment actions, or of any other possible or claimed violation of law or rights.

8. Executive agrees that upon any breach of this Release Executive will forfeit all amounts paid or owing to Executive under this Release. Executive further acknowledges that it may be impossible to assess the damages caused by violation of the terms of paragraphs 3, 4, 5 and 6 of this Release and further agree that any threatened or actual violation or breach of those paragraphs of this Release will constitute immediate and irreparable injury to the Company. Executive therefore agrees that any such breach of this Release is a material breach of this Release, and, in addition to any and all other damages and remedies available to the Company upon Executive's breach of this Release, the Company shall be entitled to an injunction to prevent Executive from violating or breaching this Release. Executive agrees that if the Company is successful in whole or part in any legal or equitable action against Executive under this Release, Executive agree to pay all of the costs, including reasonable attorney's fees, incurred by the Company in enforcing the terms of this Release.

9. This Release constitutes the complete, final and exclusive embodiment of the entire Release between the Parties with regard to this subject matter. It is entered into without reliance on any promise or representation, written or oral, other than those expressly contained herein, and it supersedes any other such promises, warranties or representations. This Release may not be modified or amended except in a writing signed by both Executive and a duly authorized officer of the Company. This Release will bind the heirs, personal representatives, successors and assigns of the Parties, and inure to the benefit of the Parties, their heirs, successors and assigns. If any provision of this Release is determined to be invalid or unenforceable, in whole or in part, this determination will not affect any other provision of this Release and the provision in question will be modified by the court so as to be rendered enforceable. This Release will be deemed to have been entered into and will be construed and enforced in accordance with the laws of the State of New York as applied to contracts made and to be performed entirely within New York.

IN WITNESS WHEREOF, the Parties have duly authorized and caused this Agreement to be executed as follows:

INTRA-CELLULAR THERAPIES, INC.

_____ **By:** _____

_____ _____

Date Date

Exhibit 10.7

INTRA-CELLULAR THERAPIES, INC.

[AMENDED AND RESTATED] EMPLOYEE PROPRIETARY INFORMATION, INVENTIONS, AND NON-COMPETITION AGREEMENT

In consideration of my employment or continued employment by **INTRA-CELLULAR THERAPIES, INC.** (the "**Company**"), and the compensation now and hereafter paid to me, I hereby agree as follows:

1. **NONDISCLOSURE.**

1.1 Recognition of Company's Rights; Nondisclosure. At all times during my employment and thereafter, I will hold in strictest confidence and will not disclose, use, lecture upon or publish any of the Company's Proprietary Information (defined below), except as such disclosure, use or publication may be required in connection with my work for the Company, or unless an officer of the Company expressly authorizes such in writing. I will obtain Company's written approval before publishing or submitting for publication any material (written, verbal, or otherwise) that relates to my work at Company and/or incorporates any Proprietary Information. I hereby assign to the Company any rights I may have or acquire in such Proprietary Information and recognize that all Proprietary Information shall be the sole property of the Company and its assigns. I have been informed and acknowledge that the unauthorized taking of the Company's trade secrets may subject me to civil and/or criminal penalties.

1.2 Proprietary Information. The term "**Proprietary Information**" shall mean any and all confidential and/or proprietary knowledge, data or information of the Company. By way of illustration but not limitation, "**Proprietary Information**" includes (a) tangible and intangible information relating to antibodies and other biological materials, cell lines, samples of assay components, media and/or cell lines and procedures and formulations for producing any such assay components, media and/or cell lines, formulations, products, processes, know-how, designs, formulas, methods, developmental or experimental work, clinical data, improvements, discoveries, plans for research, new products (**"Inventions"**); (b) marketing and selling, business plans, budgets and unpublished financial statements, licenses, prices and costs, suppliers and customers; and (c) information regarding the skills and compensation of other employees of the Company. Notwithstanding the foregoing, it is understood that, at all such times, I am free to use information which is generally known in the trade or industry, which is not gained as result of a breach of this Agreement, and my own, skill, knowledge, know-how and experience to whatever extent and in whichever way I wish.

1.3 Third Party Information. I understand, in addition, that the Company has received and in the future will receive from third parties confidential or proprietary information ("**Third Party Information**") subject to a duty on the Company's part to maintain the confidentiality of such information and to use it only for certain limited purposes. During the term of my employment and thereafter, I will hold Third Party Information in the strictest confidence and will not disclose to anyone (other than Company personnel who need to know such information in connection with their work for the Company) or use, except in connection with my work for the Company, Third Party Information unless expressly authorized by an officer of the Company in writing.

1.4 No Improper Use of Information of Prior Employers and Others. During my employment by the Company I will not improperly use or disclose any confidential information or trade secrets, if any, of any former employer or any other person to whom I have an obligation of confidentiality, and I will not bring onto the premises of the Company any unpublished documents or any property belonging to any former employer or any other person to whom I have an obligation of confidentiality unless consented to in writing by that former employer or person. I will use in the performance of my duties only information which is generally known and used by persons with training and experience comparable to my own, which is common knowledge in the industry or otherwise legally in the public domain, or which is otherwise provided or developed by the Company.

2. ASSIGNMENT OF INVENTIONS.

2.1 Proprietary Rights. The term "**Proprietary Rights**" shall mean all trade secret, patent, copyright, mask work and other intellectual property rights or "moral rights" throughout the world. "Moral rights" refers to any rights to claim authorship of an Invention or to object to or prevent the modification of any Invention, or to withdraw from circulation or control the publication or distribution of any Invention, and any similar right, existing under judicial or statutory law of any country in the world, or under any treaty, regardless of whether or not such right is denominated or generally referred to as a "moral right."

2.2 Prior Inventions. Inventions, if any, patented or unpatented, which I made prior to the commencement of my employment with the Company are excluded from the scope of this Agreement. To preclude any possible uncertainty, I have set forth on *Exhibit A* (Previous Inventions) attached hereto a complete list of all Inventions that I have, alone or jointly with others, conceived, developed or reduced to practice or caused to be conceived, developed or reduced to practice prior to the commencement of my employment with the Company, that I consider to be my property or the property of third parties and that I wish to have excluded from the scope of this Agreement (collectively referred to as "**Prior Inventions**"). If disclosure of any such Prior Invention would cause me to violate any prior confidentiality agreement, I understand that I am not to list such Prior Inventions in *Exhibit A* but am only to disclose a cursory name for each such invention, a listing of the party(ies) to whom it belongs and the fact that full disclosure as to such inventions has not been made for that reason. A space is provided on *Exhibit A* for such purpose. If no such disclosure is attached, I represent that there are no Prior Inventions. If, in the course of my employment with the Company, I incorporate a Prior Invention into a Company product, process or machine, the Company is hereby granted and shall have a nonexclusive, royalty-free, irrevocable, perpetual, worldwide license (with rights to sublicense through multiple tiers of sublicensees) to make, have made, modify, use and sell such Prior Invention.

Notwithstanding the foregoing, I agree that I will not incorporate, or permit to be incorporated, Prior Inventions in any Company Inventions without the Company's prior written consent.

2.3 Assignment of Inventions. Subject to Sections 2.4, and 2.6, I hereby assign and agree to assign in the future (when any such Inventions or Proprietary Rights are first reduced to practice or first fixed in a tangible medium, as applicable) to the Company all my right, title and interest in and to any and all Inventions (and all Proprietary Rights with respect thereto) whether or not patentable or registrable under copyright or similar statutes, made or conceived or reduced to practice or learned by me, either alone or jointly with others, during the period of my employment with the Company. Inventions assigned to the Company, or to a third party as directed by the Company pursuant to this Section 2, are hereinafter referred to as "**Company Inventions**."

2.4 Unassigned Inventions. I recognize that this Agreement will not be deemed to require assignment of any Invention that was developed entirely on my own time without using the Company's equipment, supplies, facilities, or trade secrets and neither related to the Company's actual or anticipated business, research or development, nor resulted from work performed by me for the Company.

2.5 Obligation to Keep Company Informed. During the period of my employment and for six (6) months after termination of my employment with the Company, I will promptly disclose to the Company fully and in writing all Inventions authored, conceived or reduced to practice by me, either alone or jointly with others. In addition, I will promptly disclose to the Company all patent applications filed by me or on my behalf within a year after termination of employment. The Company will keep in confidence and will not use for any purpose or disclose to third parties without my consent any confidential information disclosed in writing to the Company pursuant to this Agreement.

2.6 Government or Third Party. I also agree to assign all my right, title and interest in and to any particular Company Invention to a third party, including without limitation the United States, as directed by the Company.

2.7 Works for Hire. I acknowledge that all original works of authorship which are made by me (solely or jointly with others) within the scope of my employment and which are protectable by copyright are "works made for hire," pursuant to United States Copyright Act (17 U.S.C., Section 101).

2.8 Enforcement of Proprietary Rights. I will assist the Company in every proper way to obtain, and from time to time enforce, United States and foreign Proprietary Rights relating to Company Inventions in any and all countries. To that end I will execute, verify and deliver such documents and perform such other acts (including appearances as a witness) as the Company may reasonably request for use in applying for, obtaining, perfecting, evidencing, sustaining and enforcing such Proprietary Rights and the assignment thereof. In addition, I will execute, verify and deliver assignments of such Proprietary Rights to the Company or its designee. My obligation to assist the Company with respect to Proprietary Rights relating to such Company Inventions in any and all countries shall continue beyond the termination of my employment, but the Company shall compensate me at a reasonable rate after my termination for the time actually spent by me at the Company's request on such assistance.

In the event the Company is unable for any reason, after reasonable effort, to secure my signature on any document needed in connection with the actions specified in the preceding paragraph, I hereby irrevocably designate and appoint the Company and its duly authorized officers and agents as my agent and attorney in fact, which appointment is coupled with an interest, to act for and in my behalf to execute, verify and file any such documents and to do all other lawfully permitted acts to further the purposes of the preceding paragraph with the same legal force and effect as if executed by me. I hereby waive and quitclaim to the Company any and all claims, of any nature whatsoever, which I now or may hereafter have for infringement of any Proprietary Rights assigned hereunder to the Company.

2.9 Defend Trade Secrets Act. I hereby acknowledge notice under 18 U.S.C § 1833(b)(1), which states, in pertinent part: "An individual shall not be held criminally or civilly liable under any Federal or State trade secret law for the disclosure of a trade secret that (A) is made (i) in confidence to a Federal, State, or local government official, either directly or indirectly, or to an attorney; and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (B) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal."

2.10 Preserved Rights. No provision of this Agreement shall prevent or restrict me from disclosing information about unlawful workplace acts, including but not limited to factual information relating to any claims of harassment, discrimination, or retaliation under Title VII the New York State Human Rights Law or any other similar federal, state, or local law, including claims based on race, sexual orientation, religion, color, national origin, ancestry, disability, medical condition, and age. No provision of this Agreement is intended to limit, or shall be interpreted as limiting, my right to file administrative charges with any Governmental Entity (as defined below) charged with enforcement of any law, including but not limited to the Equal Employment Opportunity Commission, New York State Division of Human Rights and the New York City Commission on Human Rights, the Securities and Exchange Commission, and National Labor Relations Board, and to participate in agency investigations. Additionally, nothing herein is intended to restrict, or shall be interpreted as restricting, my right to engage in concerted activity protected by Section 7 of the National Labor Relations Act or my right to file for or collect unemployment benefits and/or to seek and receive remedies for workplace injuries under the provisions of any applicable workers' compensation act. Nothing in this Agreement shall prohibit or impede me from communicating, cooperating or filing a complaint with any U.S. or foreign federal, state or local governmental or law enforcement branch, federal or state attorney general, agency, entity, commission or other governmental authority or instrumentality of competent jurisdiction (collectively, a "Governmental Entity") or any attorney retained by me, with respect to possible violations of any U.S. or foreign federal, state or local law or regulation, or otherwise making disclosures to any Governmental Entity, in each case, that are protected under the whistleblower provisions of any such law or regulation (including, but not limited, under the federal securities laws, including the Dodd-Frank Act); provided, that in each case such communications and disclosures are consistent with applicable law. I do not need the prior authorization of (or to give notice to) the Company regarding any such communication or disclosure.

3. RECORDS. I agree to keep and maintain adequate and current records (in the form of notes, sketches, drawings and in any other form that may be required by the Company) of all Proprietary Information developed by me and all Inventions made by me during the period of my employment at the Company, which records shall be available to and remain the sole property of the Company at all times.

4. DUTY OF LOYALTY DURING EMPLOYMENT. I understand that my employment with the Company requires my full attention and effort. I agree that during the period of my employment by the Company I will not, without the Company's express written consent, engage in any employment or business activity other than for the Company, including but not limited to employment or business activity which is competitive with, or would otherwise conflict with, my employment by the Company.

5. NO SOLICITATION OF EMPLOYEES, CONSULTANTS, CONTRACTORS OR CUSTOMERS. I agree that for the period of my employment by the Company and for one (1) year after the date my employment by the Company ends for any reason, including but not limited to voluntary termination by me or involuntary termination by the Company, I will not, either directly or through others, (i) solicit or attempt to solicit any employee of the Company to end his or her relationship with the Company; and (ii) solicit any consultant, contractor, or customer of the Company, with whom I had contact or whose identity I learned as a result of my employment with the Company to diminish or materially alter its relationship with the Company.

The parties agree that for purposes of this Agreement, a customer is any person or entity to which the Company has provided goods or services at any time during the period commencing six (6) months prior to my employment with the Company and ending on the date my employment with the Company ends.

6. NON-COMPETE PROVISION. I agree that for the period of my employment with the Company, and for the period of one (1) year after the later of (1) the date my employment ends for any reason, including but not limited to voluntary termination by me or involuntary termination by the Company; or (2) the date a court of competent jurisdiction enters an order enforcing this provision, I will not provide services, similar to those I provided to the Company, to any person or entity in competition (as defined below) with the Company. I acknowledge that this non-compete provision is limited to the types of activities and services I provided in my employment with the Company.

At the present time, the Company engages in the development and commercialization of drugs that address medical needs in psychiatric and neurological disorders, including, without limitation, schizophrenia, bipolar disorder, major depressive disorder, generalized anxiety disorder, psychosis, agitation, Parkinson's Disease, Alzheimer's Disease, and autism spectrum disorder, and therefore entities and individuals which provide similar products or services are defined as in competition with the Company. The parties understand that the scope and nature of my activities and services, and the Company's business, products or services, may change as the Company develops. The parties agree that the scope of this provision will change to cover any changes in my activities or services, as well as any changes in the Company's business, products or services, during my employment.

7. NO CONFLICTING AGREEMENT OR OBLIGATION. I represent that my performance of all the terms of this Agreement and as an employee of the Company does not and will not breach any agreement or obligation of any kind made prior to my employment by the Company, including agreements or obligations I may have with prior employers or entities for which I have provided services. I have not entered into, and I agree I will not enter into, any agreement or obligation either written or oral in conflict herewith.

8. RETURN OF COMPANY DOCUMENTS. When I leave the employ of the Company, I will deliver to the Company any and all drawings, notes, memoranda, specifications, devices, formulas, and documents, together with all copies thereof, and any other material containing or disclosing any Company Inventions, Third Party Information or Proprietary Information of the Company. I further agree that any property situated on the Company's premises and owned by the Company, including disks and other storage media, filing cabinets or other work areas, is subject to inspection by Company personnel at any time with or without notice. Prior to leaving, I will cooperate with the Company in completing and signing the Company's termination statement.

9. LEGAL AND EQUITABLE REMEDIES. I recognize that in the course of employment with the Company, I will have access to Proprietary Information, to Third Party Information, and to employees, consultants, contractors, clients, and customers of the Company. I also recognize that the services I will be employed to provide are personal and unique. I understand that because of this the Company may sustain irreparable injury if I violate this Agreement. In order to limit or prevent such irreparable injury, the Company shall have the right to enforce this Agreement and any of its provisions by injunction, specific performance or other equitable relief, without bond and without prejudice to any other rights and remedies that the Company may have for a breach of this Agreement.

10. NOTICES. Any notices required or permitted hereunder shall be given to the appropriate party at the address specified below or at such other address as the party shall specify in writing. Such notice shall be deemed given upon personal delivery to the appropriate address or if sent by certified or registered mail, three (3) days after the date of mailing.

11. NOTIFICATION OF NEW EMPLOYER. In the event that I leave the employ of the Company, I authorize the Company to provide notice of my rights and obligations under this Agreement to my subsequent employer and to any other entity or person to whom I provide services.

12. GENERAL PROVISIONS.

12.1 Governing Law; Consent to Personal Jurisdiction. This Agreement will be governed by and construed according to the laws of the State of New York, as such laws are applied to agreements entered into and to be performed entirely within New York between New York residents. I hereby expressly consent to the personal jurisdiction of the state and federal courts for New York County, New York in any lawsuit filed there against me by Company arising from or related to this Agreement.

12.2 Severability. In case any one or more of the provisions, subsections, or sentences contained in this Agreement shall, for any reason, be held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect the other provisions of this Agreement, and this Agreement shall be construed as if such invalid, illegal or unenforceable provision had never been contained herein. Moreover, if any one or more of the provisions contained in this Agreement shall for any reason be held to be excessively broad as to duration, geographical scope, activity or subject, it shall be construed by limiting and reducing it, so as to be enforceable to the extent compatible with the applicable law as it shall then appear.

12.3 Successors and Assigns. This Agreement will be binding upon my heirs, executors, administrators and other legal representatives and will be for the benefit of the Company, its successors, and its assigns.

12.4 Survival. The provisions of this Agreement shall survive the termination of my employment and the assignment of this Agreement by the Company to any successor in interest or other assignee.

12.5 Employment At-Will. I agree and understand that I am employed at-will, and that nothing in this Agreement shall change this at-will status or confer any right with respect to continuation of employment by the Company, nor shall it interfere in any way with my right or the Company's right to terminate my employment at any time, with or without cause.

12.6 Waiver. No waiver by the Company of any breach of this Agreement shall be a waiver of any preceding or succeeding breach. No waiver by the Company of any right under this Agreement shall be construed as a waiver of any other right. The Company shall not be required to give notice to enforce strict adherence to all terms of this Agreement.

12.7 Entire Agreement. The obligations pursuant to Sections 1 and 2 of this Agreement shall apply to any time during which I was previously employed, or am in the future employed, by the Company as a consultant if no other agreement governs nondisclosure and assignment of inventions during such period. This Agreement is the final, complete and exclusive agreement of the parties with respect to the subject matter hereof and supersedes and merges all prior discussions between us. No modification of or amendment to this Agreement, nor any waiver of any rights under this Agreement, will be effective unless in writing and signed by the party to be charged. Any subsequent change or changes in my duties, salary or compensation will not affect the validity or scope of this Agreement.

[This Agreement shall be effective as of the first day of my employment with the Company, namely: [_____].] [This Agreement, effective as of [_____], amends and restates the Employee Proprietary Information, Inventions, and Non-Competition Agreement dated as of [____] by and between the Company and me.]

I HAVE READ THIS AGREEMENT CAREFULLY AND UNDERSTAND ITS TERMS. I HAVE COMPLETELY FILLED OUT EXHIBIT A TO THIS AGREEMENT.

Dated: _____, ____

_____

(Signature)

_____

(Printed Name)

ACCEPTED AND AGREED TO:

INTRA-CELLULAR THERAPIES, INC.

By:_____
Name:
Title:

_____
(Address)

Dated: _____, ____

Exhibit A

Previous Inventions

10

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: October 30, 2024

/s/ Sharon Mates, Ph.D.

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

Exhibit 31.2

CERTIFICATIONS UNDER SECTION 302

I, Sanjeev Narula, 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: October 30, 2024

/s/ Sanjeev Narula

Sanjeev Narula
Executive Vice President, Chief Financial Officer and Treasurer
(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, 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: October 30, 2024

/s/ Sharon Mates, Ph.D.

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

Dated: October 30, 2024

/s/ Sanjeev Narula

Sanjeev Narula
Executive Vice President, Chief Financial Officer and Treasurer
(principal financial officer)