Table of Contents

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2022

or

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

For the transition period from _____ to _____

Commission File Number: 001-36274

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

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

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

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

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

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

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

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

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

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

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

As of May 6, 2022, the registrant had 94,324,313 shares of common stock outstanding.

Intra-Cellular Therapies, Inc.

Index to Form 10-Q

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

PART I: FINANCIAL INFORMATION

Item 1. FINANCIAL STATEMENTS

Intra-Cellular Therapies, Inc. and Subsidiaries

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

	March 31, 2022 (Unaudited)	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	**$ 129,295**	$ 92,365
Investment securities, available-for-sale	**642,553**	319,968
Restricted cash	**1,400**	1,400
Accounts receivable, net	**32,832**	20,156
Inventory	**7,893**	7,948
Prepaid expenses and other current assets	**34,369**	25,444
Total current assets	**848,342**	467,281
Property and equipment, net	**2,185**	1,791
Right of use assets, net	**17,967**	20,764
Other assets	**86**	86
Total assets	**$ 868,580**	$ 489,922
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	**$ 11,649**	$ 8,691
Accrued and other current liabilities	**12,258**	11,073
Accrued customer programs	**10,888**	5,964
Lease liabilities, short-term	**7,636**	6,732
Accrued employee benefits	**16,643**	20,897
Total current liabilities	**59,074**	53,357
Lease liabilities	**16,756**	18,675
Total liabilities	**75,830**	72,032
Stockholders' equity:		
Common stock, $0.0001 par value: 175,000,000 and 100,000,000 shares authorized at March 31, 2022 and December 31, 2021, respectively; 94,020,425 and 81,886,965 shares issued and outstanding at March 31, 2022 and December 31, 2021, respectively	**9**	8
Additional paid-in capital	**2,089,418**	1,639,476
Accumulated deficit	**(1,293,349)**	(1,221,230)
Accumulated comprehensive loss	**(3,328)**	(364)
Total stockholders' equity	**792,750**	417,890
Total liabilities and stockholders' equity	**$ 868,580**	$ 489,922

See accompanying notes to these condensed consolidated financial statements.

Intra-Cellular Therapies, Inc. and Subsidiaries

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

	Three Months Ended March 31,	
	2022	2021
Revenues		
Product sales, net	**$ 34,755**	$ 15,579
Grant revenue	**241**	299
Total revenues	**34,996**	15,878
Operating expenses:		
Cost of product sales	**3,155**	1,455
Research and development	**29,043**	15,058
Selling, general and administrative	**75,460**	52,584
Total operating expenses	**107,658**	69,097
Loss from operations	**(72,662)**	(53,219)
Interest income	**548**	484
Loss before provision for income taxes	**(72,114)**	(52,735)
Income tax expense	**5**	5
Net loss	**$ (72,119)**	$ (52,740)
Net loss per common share:		
Basic & Diluted	**$ (0.78)**	$ (0.65)
Weighted average number of common shares:		
Basic & Diluted	**92,604,290**	80,946,450

See accompanying notes to these condensed consolidated financial statements.

Intra-Cellular Therapies, Inc. and Subsidiaries

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

	Three Months Ended March 31,	
	2022	2021
Net loss	**$ (72,119)**	$ (52,740)
Other comprehensive (loss):		
Unrealized loss on investment securities	**(2,964)**	(234)
Comprehensive loss	**$ (75,083)**	$ (52,974)

See accompanying notes to these condensed consolidated financial statements.

Intra-Cellular Therapies, Inc. and Subsidiaries

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 Income (Loss)	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2020	80,463,089	$ 8	$1,593,475	$ (937,104)	$ 481	$ 656,860
Exercise of stock options and issuances of restricted stock	669,182	—	1,432	—	—	1,432
Stock issued for services	1,578	—	54	—	—	54
Share-based compensation	—	—	6,778	—	—	6,778
Net loss	—	—	—	(52,740)	—	(52,740)
Other comprehensive loss	—	—	—	—	(234)	(234)
Balance at March 31, 2021	81,133,849	$ 8	$1,601,739	$ (989,844)	$ 247	$ 612,150

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2021	**81,886,965**	**$ 8**	**$1,639,476**	**$(1,221,230)**	**$ (364)**	**$ 417,890**
Common shares issued January 7, 2022	**10,952,381**	**1**	**433,724**	—	—	**433,725**
Exercise of stock options and issuances of restricted stock	**1,180,696**	**—**	**8,089**	**—**	**—**	**8,089**
Stock issued for services	**383**	**—**	**24**	—	—	**24**
Share-based compensation	**—**	**—**	**8,105**	**—**	**—**	**8,105**
Net loss	—	—	—	**(72,119)**	—	**(72,119)**
Other comprehensive loss	—	—	—	—	**(2,964)**	**(2,964)**
Balance at March 31, 2022	**94,020,425**	**$ 9**	**$2,089,418**	**$(1,293,349)**	**$ (3,328)**	**$ 792,750**

See accompanying notes to these condensed consolidated financial statements.

Intra-Cellular Therapies, Inc. and Subsidiaries

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

	Three Months Ended March 31,	
	2022	2021
Cash flows used in operating activities		
Net loss	**$ (72,119)**	$ (52,740)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	**171**	127
Share-based compensation	**8,105**	6,778
Stock issued for services	**24**	54
Amortization of premiums and discounts on investment securities, net	**(4,079)**	(1,086)
Changes in operating assets and liabilities:		
Accounts receivable, net	**(12,676)**	(2,897)
Inventory	**55**	(523)
Prepaid expenses and other assets	**(8,927)**	(259)
Accounts payable	**2,958**	3,219
Accrued liabilities and other	**(3,069)**	(1,624)
Accrued customer programs	**4.924**	1,222
Lease liabilities, net	**1,784**	(38)
Net cash used in operating activities	**(82,849)**	(47,767)
Cash flows provided by (used in) investing activities		
Purchases of investments	**(826,713)**	(34,148)
Maturities of investments	**505,244**	150,417
Purchases of property and equipment	**(566)**	—
Net cash provided by (used in) investing activities	**(322,035)**	116,269
Cash flows provided by financing activities		
Proceeds of public offering, net	**433,725**	—
Proceeds from exercise of stock options	**8,089**	1,432
Net cash provided by financing activities	**441,814**	1,432
Net increase in cash, cash equivalents, and restricted cash	**36,930**	69,934
Cash, cash equivalents, and restricted cash at beginning of period	**93,765**	61,446
Cash, cash equivalents, and restricted cash at end of period	**$ 130,695**	$ 131,380
Non-cash investing and financing activities		
Right of use assets under operating leases	**$ —**	$ 9,179

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

	March 31,	
	2022	**2021**
Cash and cash equivalents	**$129,295**	$129,980
Restricted cash	**1,400**	1,400
Total cash, cash equivalents and restricted cash	**$130,695**	$131,380

See accompanying notes to these condensed consolidated financial statements.

Intra-Cellular Therapies, Inc.

Notes to Condensed Consolidated Financial Statements (Unaudited)

March 31, 2022

1. Organization

Intra-Cellular Therapies, Inc. (the "Company"), through its wholly-owned operating subsidiaries, ITI, Inc. ("ITI") and ITI Limited, is a biopharmaceutical company focused on the discovery, clinical development and commercialization of innovative, small molecule drugs that address underserved medical needs primarily in neuropsychiatric and neurological disorders by targeting intracellular signaling mechanisms within the central nervous system ("CNS"). In December 2019, the U.S. Food and Drug Administration ("FDA") approved CAPLYTA® (lumateperone) for the treatment of schizophrenia in adults (42mg/day). The Company initiated the commercial launch of CAPLYTA in late March 2020. Additionally, in December 2021, the FDA approved CAPLYTA for the treatment of depressive episodes associated with bipolar I or II disorder in adults, as monotherapy and as adjunctive therapy with lithium or valproate (42mg/day). In addition, in April 2022, the FDA approved two new 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 for patients with moderate or severe hepatic impairment (Child-Pugh class B or C). As used in these Notes to Condensed Consolidated Financial Statements, "CAPLYTA" refers to lumateperone approved by the FDA for the treatment of schizophrenia and bipolar depression in adults, and "lumateperone" refers to, where applicable, CAPLYTA as well as lumateperone for the treatment of indications beyond schizophrenia and bipolar depression. Lumateperone is in Phase 3 clinical development as a novel treatment for major depressive disorder.

On January 7, 2022, the Company completed a public offering of common stock in which the Company sold 10,952,381 shares of common stock at a public offering price of $42.00 per share for aggregate gross proceeds of $460.0 million. After deducting underwriting discounts, commissions and offering expenses, the net proceeds to the Company were approximately $433.7 million. In order to further its commercial activities and research projects and support its collaborations, the Company may require additional financing until such time, if ever, that revenue streams are sufficient to generate consistent positive cash flow from operations. The Company currently projects that its cash, cash equivalents and investments will be sufficient to fund operating expenses and capital expenditures for at least one year from the date that these financial statements are filed with the Securities and Exchange Commission (the "SEC"). Possible sources of funds include public or private sales of the Company's equity securities, sales of debt or convertible debt securities, the incurrence of debt from commercial lenders, strategic collaborations, licensing a portion or all of the Company's products, product candidates and technology and, to a much lesser extent, grant funding.

On January 6, 2020, the Company filed an automatic shelf registration statement on Form S-3 with the SEC, which became effective upon filing, on which the Company registered for sale an unlimited amount of any combination of its common stock, preferred stock, debt securities, warrants, rights, and/or units from time to time and at prices and on terms that the Company may determine, so long as the Company continues to satisfy the requirements of a "well-known seasoned issuer" under SEC rules. This registration statement will remain in effect for up to three years from the date it became effective.

2. Summary of Significant Accounting Policies

Basis of Presentation

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

Recent Accounting Pronouncements

Management has evaluated all accounting pronouncements issued through the date of the condensed consolidated financial statements and does not believe that any recently issued, but not yet effective, pronouncements, if currently adopted, would have a material effect on the Company's financial statements.

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, 2021.

Concentration of Credit Risk

Financial instruments which potentially subject the Company to concentrations of credit risk consist of accounts receivable, net from customers and cash, cash equivalent and investments held at financial institutions. As of March 31, 2022 and 2021, all of the Company's accounts receivable, net arose from product sales in the United States. For the three-month periods ended March 31, 2022 and 2021, respectively, 97% and 96% of sales were from three major wholesalers accounting for approximately 43%, 28%, and 26%, and 40%, 29%, and 27% of product sales, for the same periods. The percentage of the total net product sales by individual customers has not significantly changed since product launch in 2020. All customers have standard payment terms which generally require payment within 60 days. As of March 31, 2022, the Company continues to believe that such customers are of high credit quality.

3. Investment Securities

Investment securities consisted of the following (in thousands):

	March 31, 2022			
	Amortized Cost	Unrealized Gains	Unrealized (Losses)	Estimated Fair Value
	(Unaudited)			
U.S. Government Agency Securities	$238,221	$ 2	$ (1,127)	$237,096
Certificates of Deposit	11,475	—	(17)	11,458
Commercial Paper	164,733	—	(330)	164,403
Corporate Notes/Bonds	286,442	5	(1,860)	284,587
	$700,871	$ 7	$ (3,334)	$697,544

	December 31, 2021			
	Amortized Cost	Unrealized Gains	Unrealized (Losses)	Estimated Fair Value
U.S. Government Agency Securities	$ 71,752	$ —	$ (100)	$ 71,652
Certificates of Deposit	26,232	1	—	26,233
Commercial Paper	55,955	—	(36)	55,919
Corporate Notes/Bonds	166,394	19	(249)	166,164
	$320,333	$ 20	$ (385)	$319,968

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 March 31, 2022 and December 31, 2021, the Company held $159.9 million and $67.2 million, respectively, of available-for-sale investment securities with contractual maturity dates more than one year and less than two years.

The aggregate related fair value of investments with unrealized losses as of March 31, 2022 was $658.6 million, which consisted of $222.1 million from U.S. government agency securities, $1.0 million of certificates of deposit, $164.4 million of commercial paper, and $271.1 million of corporate notes/bonds. $21.9 million of the aggregate fair value of investments with unrealized losses as of March 31, 2022 has been held in a continuous unrealized loss position for over 12 months, with the remaining $636.7 million held in a continuous unrealized loss position for less than 12 months. As of December 31, 2021, the aggregate related fair value of investments with unrealized losses was $263.5 million. $9.5 million of the aggregate fair value of investments with unrealized losses as of December 31, 2021 has been held in a continuous unrealized loss position for over than 12 months, with the remaining $254.1 million held in a continuous unrealized loss position for less than 12 months.

The Company reviewed all of the investments which were in a loss position at the respective balance sheet dates, as well as the remainder of the portfolio. The Company has analyzed the unrealized losses and determined that market conditions were the primary factor driving these changes. After analyzing the securities in an unrealized loss position, the portion of these losses that relate to changes in credit quality is insignificant. The Company does not intend to sell these securities, nor is it more likely than not that the Company will be required to sell them prior to the end of their contractual terms. Furthermore, the Company does not believe that these securities expose the Company to undue market risk or counterparty credit risk.

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 has no assets or liabilities that were measured using quoted prices for significant unobservable inputs (Level 3 assets and liabilities) as of March 31, 2022 or December 31, 2021. The carrying value of cash held in money market funds of approximately $65.9 million as of March 31, 2022 and $56.5 million as of December 31, 2021 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 approximately $50.0 million and the carrying value of cash held in U.S. Government Agency Securities of approximately $5.0 million as of March 31, 2022 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):

	March 31, 2022	Fair Value Measurements at Reporting Date Using		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money Market Funds	$ 65,866	$ 65,866	$ —	$ —
U.S. Government Agency Securities	237,096	—	237,096	—
Certificates of Deposit	11,458	—	11,458	—
Commercial Paper	164,403	—	164,403	—
Corporate Notes/Bonds	284,587	—	284,587	—
	$763,410	**$ 65,866**	**$ 697,544**	**$ —**

	December 31, 2021	Fair Value Measurements at Reporting Date Using: Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money Market Funds	$ 56,539	$ 56,539	$ —	$ —
U.S. Government Agency Securities	71,652	—	71,652	—
Certificates of Deposit	26,233	—	26,233	—
Commercial Paper	55,919	—	55,919	—
Corporate Notes/Bonds	166,164	—	166,164	—
	$ 376,507	**$ 56,539**	**$ 319,968**	**$ —**

5. Inventory

Inventory consists of the following (in thousands):

	March 31, 2022	December 31, 2021
Raw materials	**$ 2,470**	$ 2,484
Work in process	**1,198**	2,407
Finished goods	**4,225**	3,057
	$ 7,893	$ 7,948

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

6. 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 September 2018, the Company further amended the lease to obtain an additional office space beginning October 1, 2018 and to extend the term of the lease for previously acquired space. The lease, as amended, has a term of 14.3 years ending in May 2029.

In February 2019, the Company entered into a long-term lease for office space in Towson, Maryland beginning March 1, 2019. The Towson lease had a term of 3.2 years ending in April 2022 and includes limited rent abatement and escalation provisions. In April 2022, we amended the lease to obtain an additional 736 square feet of office space beginning May 1, 2022 and to extend the term of the lease for the previously acquired space. The Towson lease, as amended, has a term of 4 years ending in April 2026.

On May 17, 2019, the Company entered into an agreement (the "Vehicle Lease") with a company (the "Lessor") to acquire motor vehicles for certain employees. The Vehicle Lease provides for individual leases for the vehicles, which at each lease commencement was determined to qualify for operating lease treatment. The Company began leasing vehicles under the Vehicle Lease in March 2020. The contractual period of each lease is 12 months, followed by month-to-month renewal periods. The Company estimates the lease term for each vehicle to be 30 months based on industry standards. The Company is required to maintain an irrevocable $1.4 million letter of credit that the Lessor may draw upon in the event the Company defaults on the Vehicle Lease, which has been recorded as restricted cash on the condensed consolidated balance sheet.

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

Maturity analyses under the lease agreements are as follows (in thousands):

	Real Estate	Fleet
Nine months ending December 31, 2022	$ 2,609	$ 2,871
Year ending December 31, 2023	3,566	1,669
Year ending December 31, 2024	3,675	—
Year ending December 31, 2025	3,787	—
Year ending December 31, 2026	3,903	—
Thereafter	9,937	—
Total	27,477	4,540
Less: Present value discount	(7,578)	(48)
Total Lease liability	19,899	4,492
Less: Current portion	(3,327)	(4,308)
Long-term lease liabilities	$ 16,572	$ 184

7. Commitments and Contingencies

License and Royalty Commitments

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

Under the agreement, the Company has made payments of $10.75 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.

In September 2016, the Company transferred certain of its rights under the BMS agreement to its wholly owned subsidiary, ITI Limited. In connection with the transfer, the Company guaranteed ITI Limited's performance of its obligations under the BMS agreement. The Company expensed approximately $1.7 million and $0.8 million, respectively, for the three-month periods ended March 31, 2022 and 2021, in cost of product sales to satisfy its obligation under the BMS agreement.

Research and Other Commitments

As of March 31, 2022, the Company has committed to purchasing production campaigns for various raw materials and API from each of its supply vendors – Siegfried Evionnaz SA ("Siegfried") and Lonza Ltd. ("Lonza"). The campaigns are expected to be received into inventory during 2022 and 2023. The Company had paid deposits of $17.0 million and $9.5 million as of March 31, 2022 and December 31, 2021, respectively, for the Siegfried and Lonza campaigns, which are recorded within prepaid expenses and other current assets. Over the course of the vendors' manufacturing period, the Company will remit payments to each vendor based on the payment plan within the executed agreements.

8. Share-Based Compensation

On June 18, 2018, the Company's stockholders approved the 2018 Equity Incentive Plan (the "2018 Plan"). The 2018 Plan provided for the granting of share-based awards, such as stock options, restricted common stock, restricted stock units ("RSUs") and stock appreciation rights to employees, directors and consultants as determined by the Board of Directors. On May 27, 2020, the Company's stockholders approved the Amended and Restated 2018 Equity Incentive Plan (the "Amended 2018 Plan"), which amended and restated the 2018 Plan. The Amended 2018 Plan provides for the granting of up to 6,500,000 additional share-based awards, such as stock options, restricted common stock, RSUs and stock appreciation rights to employees, directors and consultants as determined by the Board of Directors. In December 2019, the Company adopted the 2019 Inducement Award Plan (the "2019 Inducement Plan") for the grant of equity awards of up to 1,000,000 shares of common stock to newly hired employees.

Information regarding the stock options activity, including with respect to grants to employees, directors and consultants as of March 31, 2022, and changes during the three-month period then ended, are summarized as follows:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Contractual Life
Outstanding at December 31, 2021	5,451,398	$ 21.09	6.1 years
Options granted 2022	457,394	$ —	
Options exercised 2022	(425,458)	$ —	
Options canceled or expired 2022	(6,341)	$ —	
Outstanding at March 31, 2022	5,476,993	$ 24.19	6.2 years
Vested and expected to vest at March 31, 2022	5,476,993	$ 24.19	
Exercisable at March 31, 2022	4,154,045	$ 19.25	5.3 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 and changes during the three-month period ended March 31, 2022 are summarized as follows:

	Number of Shares	Weighted-Average Grant Date Fair Value Per Share	Weighted-Average Contractual Life
Outstanding at December 31, 2021	1,529,652	$ 26.95	1.5 years
Time based RSUs granted in 2022	578,623	$ —	
Time based RSUs vested in 2022	(748,455)	$ —	
Time based RSUs cancelled in 2022	(10,448)	$ —	
Outstanding at March 31, 2022	1,349,372	$ 42.23	1.6 years

The Company recognized non-cash share-based compensation expense related to time based RSUs for the three months ended March 31, 2022 and 2021 of approximately $4.1 million and $3.4 million, respectively. As of March 31, 2022, there was approximately $55.1 million of unrecognized compensation costs related to unvested time based RSUs.

9. Loss Per Share

The following awards were excluded in the calculation of diluted loss per share because their effect could be anti-dilutive as applied to the loss from operations for the three months ended March 31, 2022 and 2021:

	Three Months Ended March 31,	
	2022	2021
Stock options	5,476,993	5,929,884
RSUs	1,349,372	1,669,434
TSR RSUs	97,507	68,598

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

You should read the following in conjunction with our unaudited condensed consolidated financial statements and the related notes thereto that appear elsewhere in this Quarterly Report on Form 10-Q and the audited consolidated financial statements and notes thereto and under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K filed on March 1, 2022. In addition to historical information, the following discussion and analysis includes forward-looking information that involves risks, uncertainties and assumptions. Our actual results and the timing of events could differ materially from those anticipated by these forward-looking statements as a result of many factors, including those discussed under "Risk Factors" in our Annual Report on Form 10-K filed on March 1, 2022, as updated from time to time in our subsequent periodic and current reports filed with the SEC.

Overview

We are a biopharmaceutical company focused on the discovery, clinical development and commercialization of innovative, small molecule drugs that address underserved medical needs primarily in neuropsychiatric and neurological disorders by targeting intracellular signaling mechanisms within the central nervous system, or CNS. In December 2019, CAPLYTA (lumateperone) was approved by the U.S. Food and Drug Administration, or FDA, for the treatment of schizophrenia in adults (42mg/day) and we initiated the commercial launch of CAPLYTA in late March 2020. In support of our commercialization efforts, we employ a national sales force. In December 2021, CAPLYTA was approved by the FDA for the treatment of bipolar depression in adults (42mg/day). CAPLYTA is the only FDA-approved treatment for depressive episodes associated with bipolar I or II disorder (bipolar depression) in adults as monotherapy and as adjunctive therapy with lithium or valproate. We initiated the commercial launch of CAPLYTA for the treatment of bipolar depression in late December 2021. In support of the commercial launch of lumateperone for the treatment of bipolar depression, we have expanded our sales force from approximately 240 sales representatives to approximately 320 sales representatives. In addition, in April 2022, the FDA approved two new 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 for patients with moderate or severe hepatic impairment (Child-Pugh class B or C). As used in this report, "CAPLYTA" refers to lumateperone approved by the FDA for the treatment of schizophrenia in adults and for the treatment of bipolar depression in adults, and "lumateperone" refers to, where applicable, CAPLYTA as well as lumateperone for the treatment of indications beyond schizophrenia and bipolar depression.

Lumateperone is in Phase 3 clinical development as a novel treatment for major depressive disorder, or MDD. Patient enrollment in Study 501 and Study 502, our global Phase 3 clinical trials evaluating lumateperone 42 mg as an adjunctive therapy to antidepressants for the treatment of MDD is ongoing. We expect to file an sNDA with the FDA for approval of lumateperone as an adjunctive therapy to antidepressants for the treatment of MDD in 2024. 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. We expect to complete Study 403 in the second half of 2022 and following completion we intend to discuss the results with the FDA to determine whether Study 403, as amended, will provide supportive data for a potential future regulatory filing for this indication.

We have also initiated a Phase 3 study evaluating lumateperone for the prevention of relapse in patients with schizophrenia. The study is being conducted in five phases consisting of a screening phase, a 6-week, open-label run-in phase during which all patients will receive 42 mg of lumateperone per day, a 12-week, open-label stabilization phase during which all patients will receive 42 mg of lumateperone per day; a double-blind treatment phase 26 weeks in duration during which patients receive either 42 mg of lumateperone per day or placebo (1:1 ratio) and a 2-week safety follow-up phase. This study is being conducted in accordance with our post approval marketing commitment to the FDA in connection with the approval of CAPLYTA for the treatment of schizophrenia as is typical for antipsychotics.

Within the lumateperone portfolio, we are also developing a long-acting injectable, or LAI, formulation to provide more treatment options to patients suffering from mental illness. We have completed the preclinical development of an LAI formulation, and in December 2020, we initiated a Phase 1 single ascending dose study of lumateperone LAI, a formulation of lumateperone designed to be administered subcutaneously and to maintain therapeutic levels of lumateperone for at least one month. This study is evaluating the pharmacokinetics, safety and tolerability of lumateperone LAI in patients with stable symptoms of schizophrenia. We are now exploring alternate sites of injection with this formulation as well as progressing other formulations. This will assist us in evaluating dosing strategies and formulation for our efficacy studies. The goal of our program is to develop LAI formulations that are effective, safe and well-tolerated with treatment durations of one month and longer. Given the encouraging tolerability data to date with oral lumateperone, we believe that an LAI option, in particular, may lend itself to being an important formulation choice for certain patients.

We are developing ITI-1284-ODT-SL for the treatment of behavioral disturbances in patients with dementia, the treatment of dementia-related psychosis and for the treatment of certain depressive disorders in the elderly. ITI-1284-ODT-SL is a deuterated form of lumateperone, a new molecular entity formulated as an oral disintegrating tablet for sublingual administration. ITI-1284-ODT-SL is formulated as an oral solid dosage form that dissolves almost instantly when placed under the tongue, allowing for ease of use in the elderly and may be particularly beneficial for patients who have difficulty swallowing conventional tablets. Phase 1 single and multiple ascending dose studies in healthy volunteers and healthy elderly volunteers (> than 65 years of age) evaluated the safety, tolerability and pharmacokinetics of ITI-1284-ODT-SL. In these studies, there were no reported serious adverse events in either age group. In the elderly cohort, reported adverse events were infrequent with the most common adverse event being transient dry mouth (mild). Based on these results, we have initiated our program evaluating ITI-1284-ODT-SL for the treatment of agitation in patients with probable Alzheimer's disease. We are in discussions with the FDA regarding the non-clinical toxicological profile of ITI-1284-ODT-SL. 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 may be required to conduct additional toxicology studies in non-rodent species. This could delay the commencement of our clinical program. We expect to commence clinical conduct in this program in 2022. Additional studies in dementia-related psychosis and certain depressive disorders in the elderly are also planned for late 2022 or early 2023.

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 CNS and non-CNS conditions with a focus on diseases where excessive PDE1 activity has been demonstrated and increased inflammation is an important contributor to disease pathogenesis. Our potential disease targets include heart failure, immune system regulation, neurodegenerative diseases, cancers and other non-CNS disorders. 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 commenced patient enrollment in the third quarter of 2017 in 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 the fourth quarter of 2018, we announced that the Phase 1/2 clinical trial of lenrispodun had been completed and topline results demonstrated lenrispodun was generally well-tolerated with a favorable safety profile and clinical signs consistent with improvements in motor symptoms and dyskinesias. We have initiated our Phase 2 clinical program with lenrispodun for Parkinson's disease and expect to commence patient enrollment in the first half of 2022. In addition, in the second quarter of 2020, we announced topline results from Study ITI-214-104, a Phase 1/2 translational study of single ascending doses of lenrispodun in patients with chronic systolic heart failure with reduced ejection fraction. In this study, lenrispodun improved cardiac output by increasing heart contractility and decreasing vascular resistance. Agents that both increase heart contractility (inotropism) and decrease vascular resistance (vasodilation) are called inodilators. Inodilators in current clinical use are associated with the development of arrhythmias, which are abnormal heart rhythms that, when serious, can impair heart function and lead to mortality. Lenrispodun, which acts through a novel mechanism of action, was not associated with arrhythmias in this study and was generally well-tolerated in all patients.

We also have a development program with our ITI-333 compound as a potential treatment for substance use disorders, pain and psychiatric comorbidities including depression and anxiety. There is a pressing need to develop new drugs to treat opioid addiction and for safe, effective, non-addictive treatments to manage pain. ITI-333 is a novel compound that uniquely combines activity as an antagonist at serotonin 5-HT2A receptors and a partial agonist at μ-opioid receptors. These combined actions support the potential utility of ITI-333 in the treatment of opioid use disorder and associated comorbidities (e.g., depression, anxiety, sleep disorders) without opioid-like safety and tolerability concerns. In December 2020, we initiated a Phase 1 single ascending dose study evaluating the safety, tolerability and pharmacokinetics of ITI-333 in healthy volunteers. This study was recently completed and ITI-333 achieved plasma exposures at or above those required for efficacy and was generally safe and well-tolerated. We have received a grant from the National Institute on Drug Abuse under the Helping to End Addiction Long-term Initiative, or NIH HEAL Initiative, that we expect will fund a significant portion of the early stage clinical development costs associated with this program.

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

COVID-19

In December 2019, a novel strain of coronavirus, SARS-CoV-2, which causes coronavirus disease 2019, or COVID-19, surfaced in Wuhan, China. Since then, SARS-CoV-2 and COVID-19 have spread to countries worldwide, including the United States. The COVID-19 pandemic continues to evolve, and to date has led to the implementation of various responses, including government-imposed quarantines, travel restrictions and other public health safety measures. As a result of the COVID-19 pandemic, or similar pandemics, we may experience disruptions that could severely impact our business, including our ability to successfully commercialize our only commercial product, CAPLYTA, in the United States, and these disruptions could negatively impact our sales of CAPLYTA. Depending on the severity of the pandemic, our commercial organization, sales force and medical organization may have significantly reduced personal interactions with physicians and customers and may need to conduct many promotional activities virtually, and we may elect to cease in-person interactions with physicians and customers entirely for some period of time in the interest of employee and community safety. In addition, this could result in a decrease in the number of patient visits to healthcare providers. Business interruptions from the current or future pandemics may also adversely impact the third parties we rely on to sufficiently manufacture CAPLYTA and to produce our product candidates in quantities we require, which may impair the commercialization and our research and development activities.

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

In response to the COVID-19 pandemic, in March 2020, the FDA announced its intention to temporarily postpone most inspections of foreign manufacturing facilities and products, as well as routine surveillance inspections of domestic manufacturing facilities, and it also provided guidance regarding the conduct of clinical trials, which has been further updated several times since that time. In mid-2020, the FDA noted it was continuing to ensure timely reviews of applications for medical products during the COVID-19 pandemic in line with its user fee performance goals and conducting mission-critical domestic and foreign inspections to ensure compliance of manufacturing facilities with FDA quality standards. The FDA subsequently publicized its development and use of an internal rating system, called the COVID-19 Advisory Rating system, to assist in determining when and where it is safest to conduct such inspections based on data about the virus's trajectory in a given country, state and locality and the rules and guidelines that are put in place by foreign, state and local governments. As of October 2021, FDA is either continuing to, on a case-by-case basis, conduct only "mission-critical" inspections, or, where possible to do so safely, resuming prioritized domestic inspections, which generally include pre-approval inspections, or PAIs. Foreign PAIs that are not deemed mission-critical remain postponed, while those deemed mission-critical will be considered for inspection on a case-by-case basis. FDA will use similar data to inform resumption of other prioritized operations abroad as it becomes feasible and advisable to do so.

During the global response to the COVID-19 pandemic, moreover, there have been strategic redeployments of government resources to priority projects, including FDA and EMA resources and staff, which could have an impact on the timeline for review and approval of new marketing applications. Over the course of the pandemic, FDA's new drug review programs continued to meet key performance goals related to working with applicants and approving NDAs and NDA supplements, although the agency has also stated that the uncertainty of the COVID-19 situation may make it difficult to sustain that level of performance indefinitely. The FDA may not be able to maintain its normal pace with respect to new drug applications and delays or setbacks are possible in the future. The FDA has told industry that it intends to be as transparent as possible about its workload and performance metrics as the situation evolves, and also that it intends to communicate proactively with applicants during the review cycle regarding the need for a pre-approval inspection and whether such PAI is considered "mission-critical."

Should FDA determine that a PAI is necessary for approval of an NDA or NDA supplement and such an inspection cannot be completed during the review cycle due to restrictions on travel or other safety protocols, FDA has stated that it generally intends to issue a complete response letter. Further, if there is inadequate information to make a determination on the acceptability of a facility, FDA may defer action on the application until an inspection can be completed. Such decisions will be based on the totality of the information available to the FDA, including considerations of whether it can obtain existing inspection reports from trusted foreign regulatory partners through mutual recognition and confidentiality agreements and/or secure additional records from the applicant, the manufacturing facility, or other inspected entities. Accordingly, FDA has encouraged applicants to effectively communicate with all of their facilities and sites to ensure timely responses to any inquiries from FDA for information needed to support its assessment of pending drug applications. FDA has also stated that it is using all available tools and sources of information to support regulatory decisions on NDAs such as the historical compliance status of a manufacturing facility and other risk-benefit considerations pertaining to the proposed new drug product and its manufacturing process and facilities. In addition, whether or not FDA considers a facility inspection to be "mission-critical" involves several factors related to the public health benefits of the proposed new drug product,

including but not limited to whether the candidate has been granted breakthrough therapy designation and whether the candidate is intended to treat or prevent a serious disease or medical condition for which there is no other appropriate substitute. Regulatory authorities outside the United States, including but not limited to the EMA, may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic.

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

Results of Operations

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

Revenues

Net revenues from product sales consist of sales of CAPLYTA, which was approved by the FDA for the treatment of schizophrenia in adults in December 2019 and for the treatment of bipolar depression in adults in December 2021. We initiated the commercial launch of CAPLYTA in late March 2020. During the three months ended March 31, 2022 and 2021, net sales increased from approximately $15.6 million for the three-month period ended March 31, 2021 to approximately $34.8 million for the three-month period ended March 31, 2022. In addition, we had approximately $0.2 million of grant revenues for the three-month period ended March 31, 2022, compared to approximately $0.3 million of grant revenues for the three-month period ended March 31, 2021. We have received and may continue to receive grants from U.S. government agencies and foundations.

Expenses

The process of researching, developing and commercializing drugs for human use is lengthy, unpredictable and subject to many risks. We are unable, with certainty, to estimate either the costs or the timelines in which those costs will be incurred. The costs associated with the commercialization of CAPLYTA are substantial and will be incurred prior to our generating sufficient revenue to offset these costs. Costs for the clinical development of lumateperone-related projects, including for the treatment of MDD, consumes and, together with our other anticipated clinical development programs, will continue to consume a large portion of our current, as well as projected, resources. We intend to pursue other disease indications that lumateperone may address, but there are significant costs associated with pursuing FDA approval for those indications, which would include the cost of additional clinical trials.

Our PDE, ITI-1284 and ITI-333 development programs are currently in clinical stage development. Our other programs are still in the preclinical stages and will require extensive funding not only to complete preclinical testing, but also to commence and complete clinical trials. Expenditures that we incur on these programs will be subject to availability of funding in addition to the funding required for the advancement of lumateperone. Any failure or delay in the advancement of lumateperone could require us to re-allocate resources from our other programs to the advancement of lumateperone, which could have a material adverse impact on the advancement of these other programs and on our results of operations.

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

Costs of product sales are comprised of:

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

Research and development costs are comprised of:

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

Selling expenses are incurred in three major categories:

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

General and administrative expenses are incurred in three major categories:

- salaries and related benefit costs;
- patent, legal, and professional costs; and
- office and facilities overhead.

Product sold through March 31, 2022 consisted of drug product that was previously charged to research and development expense prior to FDA approval of CAPLYTA and other direct, indirect, and overhead costs required to make final product for sale. Because the Company's policy does not allow for the capitalization of pre-approval product, the cost of drug product sold is lower than it would have been and has a positive impact on our cost of product sales for the three-month periods ended March 31, 2022 and 2021. The Company's reported cost of product sales as a percentage of product sales, net was 9.1% or approximately $3.2 million for the three-month period ended March 31, 2022, as compared to 9.3% or approximately $1.5 million for the three-month period ended March 31, 2021, of which more than half related to royalty payments accrued to BMS.

We expect to continue to have this favorable impact on cost of product sales and related product gross margins until our sales of CAPLYTA include drug product that is manufactured entirely after the FDA approval. We are currently unable to estimate how long it will be until we begin selling product entirely manufactured post FDA approval.

We expect that research and development expenses will increase as we proceed with our clinical trials, including increased manufacturing of drug product for clinical trials and pre-clinical development activities. We also expect that our selling, general and administrative costs will increase from prior periods primarily due to costs associated with promotional activities to support the commercial sales of CAPLYTA as well as costs associated with building and maintaining infrastructure, which will include hiring additional personnel and increasing technological capabilities. We granted significant share-based awards in 2021 and 2022. We expect to continue to grant share-based awards in the future due to our growing employee base, which will increase our share-based compensation expense in future periods.

The following table sets forth our revenues, operating expenses, interest income and income tax expense for the three-month periods ended March 31, 2022 and 2021 (in thousands):

	For the Three Months Ended March 31,	
	2022	2021
	(Unaudited)	
Revenues		
Product sales, net	**$ 34,755**	$ 15,579
Grant revenue	**241**	299
Total revenues, net	**34,996**	15,878
Expenses		
Cost of product sales	**3,155**	1,455
Research and development	**29,043**	15,058
Selling, general and administrative	**75,460**	52,584
Total costs and expenses	**107,658**	69,097
Loss from operations	**(72,662)**	(53,219)
Interest income	548	484
Income tax expense	**(5)**	(5)
Net loss	**$ (72,119)**	$(52,740)

Comparison of Three-Month Periods Ended March 31, 2022 and March 31, 2021

Total Revenues, Net

Total revenues, net for the three-month period ended March 31, 2022 were approximately $35.0 million compared to $15.9 million for the three-month period ended March 31, 2021. Net product sales were approximately $34.8 million for the three-month period ended March 31, 2022 and $15.6 million for the three-month period ended March 31, 2021. Net product revenue in 2021 were comprised of sales of CAPLYTA for the treatment of schizophrenia, while net product revenue in 2022 was comprised of sales of CAPLYTA for the treatment of schizophrenia and bipolar depression. In addition, revenue from a government grant was approximately $0.2 million and $0.3 million for the three-month period ended March 31, 2022 and 2021, respectively.

Cost of Product Sales

Cost of product sales was approximately $3.2 million and $1.5 million for the three-month period ended March 31, 2022 and 2021, respectively. Cost of product sales consisted primarily of product royalty fees, overhead and direct costs. Product sold through March 31, 2022 consisted of drug product that was previously charged to research and development expense prior to FDA approval of CAPLYTA and other direct, indirect and overhead costs required to make final product for sale. This minimal cost drug product had a positive impact on our cost of product sales and related product gross margins for the three-month period ended March 31, 2022 and 2021.

We will continue to have a lower cost of product sales that excludes the cost of the drug product that was incurred prior to FDA approval until our sales of CAPLYTA include drug product that is entirely manufactured after the FDA approval. We expect that this will be the case for the near-term and, as a result, our cost of product sales will be less than we anticipate it will be in future periods.

Research and Development Expenses

The following tables set forth our research and development expenses for the three-month periods ended March 31, 2022 and 2021 (in thousands):

	Three Months Ended March 31,	
	2022	2021
External costs	**19,293**	7,312
Internal costs	**9,750**	7,746
Total research and development expenses	**$ 29,043**	$ 15,058
Lumateperone costs	**17,473**	8,527
Non-lumateperone project costs	**9,007**	3,688
Stock based compensation	**2,371**	2,322
Overhead	**192**	521
Total research and development expenses	**$ 29,043**	$ 15,058

Research and development expenses increased to $29.0 million for the three-month period ended March 31, 2022 as compared to $15.1 million for the three-month period ended March 31, 2021, representing an increase of approximately $13.9 million, or 93%. This increase is due primarily to an increase of $8.9 million for lumateperone clinical trial and other costs, and approximately $5.3 million for other projects including the ITI-1284, ITI-214, and ITI-333 programs, among others, and is offset by a decrease of approximately $0.3 million of overhead costs. Internal costs increased by approximately $2.0 million for the period due primarily to labor related costs and share-based compensation.

As the development of lumateperone and non-lumateperone progress, we anticipate research and development costs to increase moderately due primarily to pre-clinical testing and conducting ongoing and planned Phase 1, 2, 3 and other clinical trials in the next several years. We are also required to complete non-clinical testing to obtain FDA approval and manufacture material needed for clinical trial use, which includes non-clinical testing of the drug product, and manufacturing of drug product in anticipation of possible additional FDA approvals of lumateperone for indications beyond schizophrenia and bipolar depression.

We currently have several projects, in addition to lumateperone, that are in the research and development stages. We have used internal resources and incurred expenses not only in relation to the development of lumateperone, but also in connection with these additional projects as well, including our PDE program. We have not, however, reported these costs on a project-by-project basis, as these costs are broadly spread among these projects. The external costs for these projects have been modest and are reflected in the table above in this section "*—Research and Development Expenses*."

The research and development process necessary to develop a pharmaceutical product for commercialization is subject to extensive regulation by numerous governmental authorities in the United States and other countries. This process typically takes years to complete and requires the expenditure of substantial resources. The steps required before a drug may be marketed in the United States generally include the following:

- completion of extensive pre-clinical laboratory tests, animal studies, and formulation studies in accordance with the FDA's Good Laboratory Practice, or GLP, regulations;
- submission to the FDA of an Investigational New Drug application, or IND, for human clinical testing, which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the drug for each proposed indication;
- submission to the FDA of a New Drug Application, or NDA, after completion of all clinical trials;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the active pharmaceutical ingredient, or API, and finished drug product are produced and tested to assess compliance with current Good Manufacturing Practices, or cGMPs;
- satisfactory completion of FDA inspections of clinical trial sites to assure that data supporting the safety and effectiveness of product candidates has been generated in compliance with Good Clinical Practices; and
- FDA review and approval of the NDA prior to any commercial marketing or sale of the drug in the United States.

The successful development of our product candidates and the approval process requires substantial time, effort and financial resources, and is uncertain and subject to a number of risks. We cannot be certain that any of our product candidates will prove to be safe and effective, will meet all of the applicable regulatory requirements needed to receive and maintain marketing approval, or will be granted marketing approval on a timely basis, if at all. Data from pre-clinical studies and clinical trials are susceptible to varying interpretations that could delay, limit or prevent regulatory approval or could result in label warnings related to or recalls of approved products. We, the FDA, or other regulatory authorities may suspend clinical trials at any time if we or they believe that the subjects participating in such trials are being exposed to unacceptable risks or if such regulatory agencies find deficiencies in the conduct of the trials or other problems with our product candidates. Other risks associated with our product candidates are described in the section entitled "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2021, as updated by the section entitled "Risk Factors" in this Quarterly Report on Form 10-Q and from time to time in our other periodic and current reports filed with the SEC.

Selling, General and Administrative Expenses

Selling, general and administrative costs for the three-month period ended March 31, 2022 were $75.5 million as compared to $52.6 million in the three-month period ended March 31, 2021, which represents an increase of 44%, which was due to an increase in selling costs and an increase in general and administrative expenses as discussed below.

Selling costs were $56.1 million for the three-month period ended March 31, 2022 as compared to selling costs of $38.3 million in the same period in 2021, which represents an increase of 46%. This increase is primarily due to increased sales related labor costs of approximately $7.6 million, $6.5 million in commercialization, marketing and advertising expenses, and approximately $3.6 million in travel and other costs. Salaries, bonuses and related benefit costs for our sales and marketing functions for the three months ended March 31, 2022 and 2021 constituted approximately 43% and 40%, respectively, of our selling costs.

General and administrative expenses were $19.4 million in the three-month period ended March 31, 2022 as compared to $14.3 million for the same period in 2021, an increase of 36%. This increase is primarily due to increases in stock-based compensation of $1.3 million, labor related costs of approximately $0.9 million, approximately $1.0 million in IT costs, and the remainder for insurance, professional fees, and other expenses. Salaries, bonuses and related benefit costs for our general and administrative functions for the three months ended March 31, 2022 and 2021 constituted approximately 53% and 57%, respectively, of our general and administrative costs.

We expect selling, general and administrative costs to increase moderately in 2022 as compared to 2021. We are expanding marketing, promotional, and advertising costs and increasing efforts to educate physicians, expand market access, and enhance our administrative infrastructure.

Liquidity and Capital Resources

From inception through March 31, 2022, we have financed the Company primarily through the issuance of public and private offerings of our common stock and other securities, and to a far lesser extent, through proceeds from grants from government agencies and foundations. Through March 31, 2022, we have collected approximately $136.9 million from product sales of CAPLYTA, which we believe will increase going forward. We do not believe that grant revenue will be a significant source of funding in the future.

On January 7, 2022, the Company completed a public offering of common stock in which the Company sold 10,952,381 shares of common stock at a public offering price of $42.00 per share for aggregate gross proceeds of $460.0 million. After deducting underwriting discounts, commissions and offering expenses, the net proceeds to the Company were approximately $433.7 million.

As of March 31, 2022, we had a total of approximately $773.2 million in cash and cash equivalents, available-for-sale investment securities and restricted cash, and approximately $59.1 million of short-term liabilities consisting entirely of liabilities from operations, including approximately $7.6 million of short-term lease obligations. In the three months ended March 31, 2022, we spent approximately $116.8 million in cash for operations and equipment. During this period, we collected $32.7 million from product sales and $0.5 million of interest income, resulting in net cash used of $82.8 million. The use of cash was primarily for selling and marketing costs in connection with our commercialization of CAPLYTA, conducting clinical trials and non-clinical testing, funding recurring operating expenses, and product manufacturing.

Based on our current operating plans, we expect that our existing cash, cash equivalents and marketable securities will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months from the filing date of this quarterly report. During that time, we expect that our expenses will increase substantially due primarily to the commercialization of CAPLYTA for the treatment of schizophrenia and bipolar depression; the development of lumateperone in our late-stage clinical programs; the development of our other product candidates, including ITI-214; the continuation of manufacturing activities for anticipated future product sales and in connection with the development of lumateperone; and infrastructure expansion and general operations.

For the remainder of 2022, we expect to spend up to $385 million primarily relating to the marketing and commercialization of CAPLYTA, lumateperone clinical development including clinical trial conduct, regulatory activities, manufacturing and inventory production, expansion of our administrative infrastructure and other development activities. Our other development activities will include efforts relating to our ITI-1284, lenrispodun and ITI-333 programs, among others. However, the COVID-19 pandemic may negatively impact our commercialization of CAPLYTA, our ability to complete our ongoing or planned nonclinical and clinical trials, our ability to obtain approval of any product candidates from the FDA or other regulatory authorities, and our workforce and therefore our research, development and commercialization activities. This may ultimately have a material adverse effect on our liquidity, although we are unable to make any prediction with certainty given the rapidly changing nature of the pandemic and governmental and other responses to it.

We may require additional financing in the future to continue to fund our operations. We believe that we have the funding in place to commercialize CAPLYTA in patients with schizophrenia and bipolar depression. We also plan to fund additional clinical trials of lumateperone for the treatment of depressive disorders and other CNS disorders; preclinical and clinical development of our ITI-007 long acting injectable development program; clinical development of ITI-1284, continued clinical development of our PDE product candidates, including lenrispodun; research and preclinical development of our other product candidates. We have incurred losses in every year since inception with the exception of 2011, when we received an up-front fee and a milestone payment related to a license agreement that has been terminated. These losses have resulted in significant cash used in operations.

In the three months ended March 31, 2022, we spent approximately $116.8 million in cash for operations and equipment. We have sources of cash which included $32.7 million of collected product sales and $0.5 million of interest income, resulting in net cash used in operations of $82.8 million. While we have several research and development programs underway, the lumateperone program has advanced the furthest and will continue to consume increasing amounts of cash for conducting clinical trials. As we continue to conduct the activities necessary to pursue FDA approval of lumateperone beyond schizophrenia and bipolar depression and our other product candidates, as well as commercialization efforts, we expect the amount of cash to be used to fund operations to increase over the next several years.

We seek to balance the level of cash, cash equivalents and investments on hand with our projected needs and to allow us to withstand periods of uncertainty relative to the availability of funding on favorable terms. Subject to our ability to generate significant revenues from operations, we may need to satisfy our future cash needs through public or private sales of our equity securities, sales of debt securities, incurrence of debt from commercial lenders, strategic collaborations, licensing a portion or all of our product candidates and technology and, to a lesser extent, grant funding. On January 6, 2020, we filed an automatic shelf registration statement on Form S-3 with the SEC, which became effective upon filing, on which we registered for sale an unlimited amount of any combination of its common stock, preferred stock, debt securities, warrants, rights, and/or units from time to time and at prices and on terms that we may determine, so long as we continue to satisfy the requirements of a “well-known seasoned issuer” under SEC rules. This registration statement will remain in effect for up to three years from the date it became effective.

We cannot be sure that future funding will be available to us when we need it on terms that are acceptable to us, or at all. We sell securities and incur debt when the terms of such transactions are deemed favorable to us and as necessary to fund our current and projected cash needs. The amount of funding we raise through sales of our common stock or other securities depends on many factors, including, but not limited to, the magnitude of sales of CAPLYTA, the status and progress of our product development programs, projected cash needs, availability of funding from other sources, our stock price and the status of the capital markets. Due to the volatile nature of the financial markets, equity and debt financing may be difficult to obtain. Additionally, the continued spread of COVID-19 and uncertain market conditions may limit our ability to access any financing. In addition, any unfavorable results in the commercialization of CAPLYTA and unfavorable development or delay in the progress of our lumateperone program could have a material adverse impact on our ability to raise additional capital.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our existing stockholders will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of our stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring debt, making capital expenditures or declaring dividends. If we raise additional funds through government or other third-party funding, marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us.

If adequate funds are not available to us on a timely basis, we may be required to: (1) delay, limit, reduce or terminate nonclinical studies, clinical trials or other clinical development activities for one or more of our product candidates, including our lead product candidate lumateperone, lenrispodun, and our other product candidates; (2) delay, limit, reduce or terminate our discovery research or pre-clinical development activities; (3) enter into licenses or other arrangements with third parties on terms that may be unfavorable to us or sell, license or relinquish rights to develop or commercialize our product candidates, technologies or intellectual property at an earlier stage of development and on less favorable terms than we would otherwise agree; or (4) limit or reduce commercialization efforts related to CAPLYTA.

Our cash is maintained in checking accounts, money market accounts, money market mutual funds, U.S. government agency securities, certificates of deposit, commercial paper, corporate notes and corporate bonds at major financial institutions. Due to the recent history of low interest rates available for these instruments, we have been earning limited interest income. During the three -months ended March 31, 2022, interest rates have risen. This trend has resulted in approximately $3.3 million of unrealized loss on investments during the three months ended March 31, 2022. We believe due to the short-term nature of these investments; we do not expect to recognize these losses. Even with the rise or further potential rise in interest rates, we do not expect interest income to be a significant source of funding over the next several quarters. In addition, our investment portfolio historically has not been adversely impacted by problems in the credit markets, but there can be no assurance that our investment portfolio will not be adversely affected in the future.

In 2014, we entered into a long-term lease with a related party which, as amended, provided for a lease of 16,753 square feet of useable laboratory and office space located at 430 East 29th Street, New York, New York 10016. Concurrent with this lease, we entered into a license agreement to occupy certain vivarium related space in the same facility for the same term, rent and escalation provisions as the lease. This license has the primary characteristics of a lease and is characterized as a lease in accordance with ASU 2016-02 for accounting purposes. In September 2018, we further amended the lease to obtain an additional 15,534 square feet of office space beginning October 1, 2018 and to extend the term of the lease for previously acquired space. The lease, as amended, has a term of 14.3 years ending in May 2029. In February 2019, we entered into a long-term lease for 3,164 square feet of office space in Towson, Maryland beginning March 1, 2019. The Towson lease had a term of 3.2 years ending in April 2022. In April 2022, we amended the lease to obtain an additional 736 square feet of office space beginning May 1, 2022 and to extend the term of the lease for the previously acquired space. The Towson lease, as amended, has a term of four years ending in April 2026. On May 17, 2019, we entered into a vehicle fleet lease with a company to acquire motor vehicles for certain employees. The vehicle fleet lease provides for individual leases for the vehicles, which at each lease commencement was determined to qualify for operating lease treatment. We began leasing vehicles under the vehicle fleet lease in March 2020. Restricted cash of $1.4 million on our condensed consolidated balance sheet as of March 31, 2022 and 2021 relates to a letter of credit issued as part of the vehicle fleet lease.

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, 2021. There have been no material changes to our critical accounting policies during the three months ended March 31, 2022.

The discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or U.S. GAAP. The preparation of these financial statements requires management to make estimates and assumptions that affect reported amounts of assets and liabilities as of the date of the balance sheet and reported amounts of revenues and expenses for the periods presented. Judgments must also be made about the disclosure of contingent liabilities. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Management makes estimates and exercises judgment in research and development, including clinical trial accruals. Actual results may differ from those estimates and under different assumptions or conditions.

Recently Issued Accounting Pronouncements

We review new accounting standards to determine the expected financial impact, if any, that the adoption of each such standard will have. For the recently issued accounting standards that we believe may have an impact on our financial statements, see “Recent Accounting Pronouncements” in Note 2 to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q, and “Recently Issued Accounting Standards” in Note 2 to our audited consolidated financial statements and “Recently Issued Accounting Pronouncements” in Part II, Item 7, in our Annual Report on Form 10-K for the year ended December 31, 2021 filed on March 1, 2022.

Certain Factors That May Affect Future Results of Operations

The SEC encourages companies to disclose forward-looking information so that investors can better understand a company’s future prospects and make informed investment decisions. This Quarterly Report on Form 10-Q contains such “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. These statements involve known and unknown risks, uncertainties and other important factors which may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. Forward-looking statements include, but are not limited to, statements about: the accuracy of our estimates regarding expenses, revenues, uses of cash, cash equivalents and investment securities, capital requirements and the need for additional financing; our expectations regarding our commercialization of CAPLYTA, including the impact of COVID-19 on the commercialization of CAPLYTA and our ability to adapt our approach as appropriate; the duration and severity of the COVID-19 pandemic and its impact on our business; the supply and availability of and demand for our product; the initiation, cost, timing, progress and results of our development activities, non-clinical studies and clinical trials; the timing of and our ability to obtain and maintain regulatory approval, or submit an application for regulatory approval, of lumateperone and our other existing product candidates, any product candidates that we may develop, and any related restrictions, limitations, and/or warnings in the label of any approved product candidates; our plans to research, develop and commercialize lumateperone and our other current and future product candidates; the election by any collaborator to pursue research, development and commercialization activities; our ability to obtain future reimbursement and/or milestone payments from our collaborators; our ability to attract collaborators with development, regulatory and commercialization expertise; our ability to obtain and maintain intellectual property protection for our product candidates; our ability to successfully commercialize lumateperone and our other product candidates; the performance of our third-party suppliers and manufacturers and our ability to obtain alternative sources of raw materials; our ability to obtain additional financing; our use of the proceeds from our securities offerings; our exposure to investment risk, interest rate risk and capital market risk; and our ability to attract and retain key scientific, management, or sales and marketing personnel.

Words such as “may,” “anticipate,” “estimate,” “expect,” “may,” “project,” “intend,” “plan,” “believe,” “potential,” “predict,” “project,” “likely,” “will,” “would,” “could,” “should,” “continue” and words and terms of similar substance used in connection with any discussion of future operating or financial performance, identify forward-looking statements. All forward-looking statements are management’s present expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those described in the forward-looking statements. These risks and uncertainties include, but are not limited to, the following: there are no guarantees that CAPLYTA will be commercially successful; we may encounter issues, delays or other challenges in commercializing CAPLYTA; the COVID-19 pandemic may negatively impact our commercial plans and sales for CAPLYTA; the COVID-19 pandemic may negatively impact the conduct of, and the timing of enrollment, completion and reporting with respect to, our clinical trials; whether CAPLYTA receives adequate reimbursement from third-party payors; the degree to which CAPLYTA receives acceptance from patients and physicians for its approved indications; challenges associated with execution of our sales activities, which in each case could limit the potential of our product; results achieved in CAPLYTA in the treatment of schizophrenia and bipolar depression following commercial launch of the product may be

different than observed in clinical trials, and may vary among patients; any other impacts on our business as a result of or related to the COVID-19 pandemic; challenges associated with supply and manufacturing activities, which in each case could limit our sales and the availability of our product; impacts on our business, including on the commercialization of CAPLYTA and our clinical trials, as a result of the conflict in Ukraine; risks associated with our current and planned clinical trials; we may encounter unexpected safety or tolerability issues with CAPLYTA following commercial launch for the treatment of schizophrenia or bipolar depression or in ongoing or future trials and other development activities; our other product candidates may not be successful or may take longer and be more costly than anticipated; product candidates that appeared promising in earlier research and clinical trials may not demonstrate safety and/or efficacy in larger-scale or later clinical trials or in clinical trials for other indications; our proposals with respect to the regulatory path for our product candidates may not be acceptable to the FDA; our reliance on collaborative partners and other third parties for development, commercialization, manufacturing or supply of our product and product candidates; and the other risk factors detailed under the heading "Risk Factors" in our most recent Annual Report on Form 10-K, as updated under the heading "Risk Factors" from time to time in our subsequent periodic and current reports filed with the SEC.

In light of these assumptions, risks and uncertainties, the results and events discussed in the forward-looking statements contained in this Quarterly Report on Form 10-Q or in any document incorporated by reference might not occur. Stockholders are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the date of this Quarterly Report on Form 10-Q. We are not under any obligation, and we expressly disclaim any obligation, to update or alter any forward-looking statements, whether as a result of new information, future events or otherwise. All subsequent forward-looking statements attributable to the Company or to any person acting on its behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section.

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Sensitivity. As of March 31, 2022, we had cash, cash equivalents, marketable securities and restricted cash of approximately $773.2 million consisting of cash deposited in a highly rated financial institution in the United States and in a short-term U.S. Treasury money market fund, 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, although the recent increase in interest rates has resulted in our unrealized loss on investments, net, as of March 31, 2022 of approximately $3.3 million and an unrealized loss on investments, net, as of December 2021 totaling approximately $0.4 million. We plan on holding those investments to maturity, and should interest rates rise, there would be no recognition of impairment required. Declines in interest rates, however, would reduce future investment income.

Inflation Risk. Inflation generally may affect us by increasing our cost of labor and clinical trial costs. We do not believe that inflation has had a material effect on our business, financial condition or results of operations. 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 continue to depend on funds raised through other sources. One possible source of funding is through further equity offerings. Our ability to raise funds in this manner depends upon capital market forces affecting our stock price.

Item 4. CONTROLS AND PROCEDURES

(a) *Evaluation of Disclosure Controls and Procedures*. Our principal executive officer and principal financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act) as of the end of the period covered by this Form 10-Q, have concluded that, based on such evaluation, our disclosure controls and procedures were effective at a reasonable assurance level to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate, to allow timely decisions regarding required disclosure.

(b) *Changes in Internal Controls*. There were no changes in our internal control over financial reporting identified in connection with the evaluation of such internal control that occurred during the three months ended March 31, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II: OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS

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

Item 1A. RISK FACTORS

Except as set forth below, there have been no material changes to the risk factors discussed in Item 1A. Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2021, filed with the Securities and Exchange Commission on March 1, 2022.

We rely on third parties to conduct our clinical trials and perform data collection and analysis, which may result in costs and delays that prevent us from successfully commercializing our product candidates.

Although we design and manage our current preclinical studies and clinical trials, we do not now have the ability to conduct clinical trials for our product candidates on our own. In addition to our collaborators, we rely on contract research organizations, medical institutions, clinical investigators, and contract laboratories to perform data collection and analysis and other aspects of our clinical trials. In addition, we also rely on third parties to assist with our preclinical studies, including studies regarding biological activity, safety, absorption, metabolism, and excretion of product candidates.

Our preclinical activities or clinical trials may be delayed, suspended, or terminated if: the quality or accuracy of the data obtained by the third parties on whom we rely is compromised due to their failure to adhere to our clinical protocols or regulatory requirements or if for other reasons, these third parties do not successfully carry out their contractual duties or fail to meet regulatory obligations or expected deadlines, or these third parties need to be replaced.

If the third parties on whom we rely fail to perform, our development costs may increase, our ability to obtain regulatory approval, and consequently, to commercialize our product candidates may be delayed or prevented altogether. We currently use several contract research organizations to perform services for our preclinical studies and clinical trials. While we believe that there are numerous alternative sources to provide these services, in the event that we seek such alternative sources, we may not be able to enter into replacement arrangements without delays or incurring additional expenses.

Further, we are currently conducting clinical trials for our product candidates in many countries, including the United States and Europe, including Russia and Ukraine, and may expand to other geographies. Timely enrollment of, completion of and reporting on our clinical trials is dependent upon these global clinical trial sites which are, or in the future may be, adversely affected by political instability or conflict. For example, in connection with Studies 501, 502 and 503 for MDD and Study 403 for major depressive episodes with mixed features in bipolar disorder, we have third-party clinical sites located in Ukraine and Russia, which are experiencing significant conflict. Political instability and conflict in Ukraine and Russia, and any other areas in the world where we have clinical operations, may delay our trials and negatively affect our business and operations in those regions.

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

Unregistered Sales of Equity Securities

Not applicable.

Issuer Purchases of Equity Securities

We did not repurchase any of our equity securities during the quarter ended March 31, 2022.

Item 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

Item 5. OTHER INFORMATION

Not applicable.

Item 6. EXHIBITS

Exhibit Number	Exhibit Description	Filed Herewith	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/ Reg. Number
3.1	Restated Certificate of Incorporation of Registrant, as amended.		10-Q (Exhibit 3.1)	8/9/2021	001-36274
10.1	Non-Employee Director Compensation Policy, as amended.*	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 March 31, 2022, formatted in Inline XBRL (eXtensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets as of March 31, 2022 (unaudited) and December 31, 2021 (audited), (ii) Condensed Consolidated Statements of Operations (unaudited) for the three months ended March 31, 2022 and 2021, (iii) Condensed Consolidated Statements of Comprehensive Loss (unaudited) for the three months ended March 31, 2022 and 2021, (iv) Condensed Consolidated Statements of Stockholders' Equity (unaudited) for the three months ended March 31, 2022 and 2021, (v) Condensed Consolidated Statements of Cash Flows (unaudited) for the three months ended March 31, 2022 and 2021, 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: May 10, 2022

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

Date: May 10, 2022

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

INTRA-CELLULAR THERAPIES, INC.

NON-EMPLOYEE DIRECTOR COMPENSATION POLICY

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

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

Applicable Persons

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

Compensation

A. Equity Grants

1. Annual Stock Option Grants

Each Outside Director shall be granted, automatically and without any action on the part of the Board of Directors, under the Company's Amended and Restated 2018 Equity Incentive Plan or any successor plan (the "Equity Plan"), a non-qualified stock option to purchase the number of shares of the Company's common stock, par value $0.0001 per share ("Common Stock"), having an aggregate grant date fair value of $675,000, valued based on a Black-Scholes valuation method (rounded down to the nearest whole share), each year on the date of the Company's annual meeting of stockholders; provided, however, that if there has been no annual meeting of stockholders held by the first business day of the third fiscal quarter, each Outside Director shall be granted, automatically and without any action on the part of the Board of Directors such annual stock option grant on the first business day of the third fiscal quarter of such year.

The foregoing annual stock option grants shall commence with the 2022 Annual Meeting of Stockholders.

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

Each new Outside Director shall be granted, automatically and without any action on the part of the Board of Directors, under the Equity Plan, a non-qualified stock option to purchase the number of shares of Common Stock having an aggregate grant date fair value of $1,000,000, valued based on a Black-Scholes valuation method (rounded down to the nearest whole share), on the date that the Outside Director is first appointed or elected to the Board of Directors.

3. Terms of Equity Grants

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

"Change of Control" means the occurrence of any of the following events: (i) any "Person" (as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act")) becomes the

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

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

1. Annual Cash Fees

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

Board of Directors or Committee of Board of Directors	Annual Retainer Amount for Chair (or Lead Independent Director, as applicable)	Annual Retainer Amount for Other Members
Board of Directors	$ 75,000	$50,000
Audit Committee	$ 20,000	$10,000
Compensation Committee	$ 15,000	$ 8,000
Nominating and Governance Committee	$ 10,000	$ 5,000

2. Payment Terms for All Cash Fees

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

Following an Outside Director's first election or appointment to the Board of Directors, such Outside Director shall receive his or her cash compensation pro-rated during the first fiscal quarter in which he or she was initially appointed or elected for the number of days during which he or she provides service. If an Outside Director dies, resigns or is removed during any quarter, he or she shall be entitled to a cash payment on a pro-rated basis through his or her last day of service that shall be paid on the last business day of the fiscal quarter.

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

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

Expenses

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

Amendments

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

Exhibit 31.1

CERTIFICATIONS UNDER SECTION 302

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

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

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

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

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

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

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

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

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

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

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

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

Date: May 10, 2022

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

Exhibit 31.2

CERTIFICATIONS UNDER SECTION 302

I, Lawrence J. Hineline, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: May 10, 2022

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

Exhibit 32

CERTIFICATIONS UNDER SECTION 906

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), each of the undersigned officers of Intra-Cellular Therapies, Inc., a Delaware corporation (the "Company"), does hereby certify, to such officer's knowledge, that:

The Quarterly Report for the quarter ended March 31, 2022 (the "Form 10-Q") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: May 10, 2022

/s/ Sharon Mates, Ph.D.

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

Dated: May 10, 2022

/s/ Lawrence J. Hineline

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