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

# FORM 10-Q

**(Mark One)**

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

**For the quarterly period ended March 31, 2023**

**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 2, 2023, the registrant had 95,925,601 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 subsidiary. "ITI" refers to our wholly-owned subsidiary ITI, Inc.

## PART I: FINANCIAL INFORMATION

### Item 1. FINANCIAL STATEMENTS

Intra-Cellular Therapies, Inc. and Subsidiary

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

| | March 31, 2023 (Unaudited) | December 31, 2022 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | **$ 75,727** | $ 148,615 |
| Investment securities, available-for-sale | **462,981** | 443,290 |
| Restricted cash | **1,750** | 1,750 |
| Accounts receivable, net | **81,545** | 75,189 |
| Inventory | **28,341** | 23,920 |
| Prepaid expenses and other current assets | **55,750** | 45,193 |
| Total current assets | **706,094** | 737,957 |
| Property and equipment, net | **1,779** | 1,913 |
| Right of use assets, net | **14,199** | 14,824 |
| Other assets | **86** | 86 |
| Total assets | **$ 722,158** | $ 754,780 |
| **Liabilities and stockholders' equity** | | |
| Current liabilities: | | |
| Accounts payable | **$ 8,441** | $ 10,395 |
| Accrued and other current liabilities | **21,067** | 19,657 |
| Accrued customer programs | **29,892** | 25,621 |
| Accrued employee benefits | **16,656** | 22,996 |
| Operating lease liabilities | **3,531** | 4,567 |
| Total current liabilities | **79,587** | 83,236 |
| Operating lease liabilities, non-current | **14,961** | 15,474 |
| Total liabilities | **94,548** | 98,710 |
| Stockholders' equity: | | |
| Common stock, $0.0001 par value: 175,000,000 shares authorized at March 31, 2023 and December 31, 2022; 95,680,029 and 94,829,794 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively | **10** | 9 |
| Additional paid-in capital | **2,151,837** | 2,137,737 |
| Accumulated deficit | **(1,521,539)** | (1,477,486) |
| Accumulated comprehensive loss | **(2,698)** | (4,190) |
| Total stockholders' equity | **627,610** | 656,070 |
| Total liabilities and stockholders' equity | **$ 722,158** | $ 754,780 |

*See accompanying notes to these condensed consolidated financial statements.*

Intra-Cellular Therapies, Inc. and Subsidiary

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

| | Three Months Ended March 31, | |
|---|---|---|
| | **2023** | 2022 |
| Revenues | | |
| Product sales, net | **$ 94,731** | $ 34,755 |
| Grant revenue | **575** | 241 |
| Total revenues, net | **95,306** | 34,996 |
| Operating expenses: | | |
| Cost of product sales | **6,751** | 3,155 |
| Selling, general and administrative | **98,923** | 75,460 |
| Research and development | **38,024** | 29,043 |
| Total operating expenses | **143,698** | 107,658 |
| Loss from operations | **(48,392)** | (72,662) |
| Interest income | **4,349** | 548 |
| Loss before provision for income taxes | **(44,043)** | (72,114) |
| Income tax expense | **(10)** | (5) |
| Net loss | **$ (44,053)** | $ (72,119) |
| Net loss per common share: | | |
| Basic & Diluted | **$ (0.46)** | $ (0.78) |
| Weighted average number of common shares: | | |
| Basic & Diluted | **95,134,694** | 92,604,290 |

*See accompanying notes to these condensed consolidated financial statements.*

Intra-Cellular Therapies, Inc. and Subsidiary

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

| | Three Months Ended March 31, | |
|---|---|---|
| | **2023** | 2022 |
| Net loss | **$ (44,053)** | $ (72,119) |
| Other comprehensive gain (loss): | | |
| Unrealized gain (loss) on investment securities | **1,492** | (2,964) |
| Comprehensive loss | **$ (42,561)** | $ (75,083) |

*See accompanying notes to these condensed consolidated financial statements.*

Intra-Cellular Therapies, Inc. and Subsidiary

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

| | Common Stock | | Additional Paid-in Capital | Accumulated Deficit | Accumulated Comprehensive Loss | 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 |

| | Common Stock | | Additional Paid-in Capital | Accumulated Deficit | Accumulated Comprehensive (Loss) Income | Total Stockholders' Equity |
|---|---|---|---|---|---|---|
| | Shares | Amount | | | | |
| Balance at December 31, 2022 | **94,829,794** | **$ 9** | **$ 2,137,737** | **$ (1,477,486)** | **$ (4,190)** | **$ 656,070** |
| Exercise of stock options and issuances of restricted stock | **849,827** | **1** | **3,639** | — | — | **3,640** |
| Stock issued for services | **408** | — | **22** | — | — | **22** |
| Share-based compensation | — | — | **10,439** | — | — | **10,439** |
| Net loss | — | — | — | **(44,053)** | — | **(44,053)** |
| Other comprehensive gain | — | — | — | — | **1,492** | **1,492** |
| Balance at March 31, 2023 | **95,680,029** | **$ 10** | **$ 2,151,837** | **$ (1,521,539)** | **$ (2,698)** | **$ 627,610** |

*See accompanying notes to these condensed consolidated financial statements.*

Intra-Cellular Therapies, Inc. and Subsidiary

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

| | Three Months Ended March 31, | |
|---|---|---|
| | **2023** | **2022** |
| **Cash flows used in operating activities** | | |
| Net loss | **$ (44,053)** | $ (72,119) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation | **134** | 171 |
| Share-based compensation | **10,439** | 8,105 |
| Stock issued for services | **22** | 24 |
| Amortization of premiums and accretion of discounts on investment securities, net | **(1,737)** | (4,079) |
| Changes in operating assets and liabilities: | | |
| Accounts receivable, net | **(6,356)** | (12,676) |
| Inventory | **(4,421)** | 55 |
| Prepaid expenses and other assets | **(10,557)** | (8,927) |
| Accounts payable | **(1,954)** | 2,958 |
| Accrued and other current liabilities | **1,410** | 1,185 |
| Accrued customer programs | **4,271** | 4,924 |
| Accrued employee benefits | **(6,340)** | (4,254) |
| Operating lease liabilities, net | **(924)** | 1,784 |
| Net cash used in operating activities | **(60,066)** | (82,849) |
| **Cash flows (used in) provided by investing activities** | | |
| Purchases of investments | **(108,457)** | (826,713) |
| Maturities of investments | **91,995** | 505,244 |
| Purchases of property and equipment | **—** | (566) |
| Net cash used in investing activities | **(16,462)** | (322,035) |
| **Cash flows provided by financing activities** | | |
| Proceeds of public offering, net | **—** | 433,725 |
| Proceeds from exercise of stock options | **3,640** | 8,089 |
| Net cash provided by financing activities | **3,640** | 441,814 |
| Net (decrease) increase in cash, cash equivalents, and restricted cash | **(72,888)** | 36,930 |
| Cash, cash equivalents, and restricted cash at beginning of period | **150,365** | 93,765 |
| Cash, cash equivalents, and restricted cash at end of period | **$ 77,477** | $ 130,695 |
| **Non-cash investing and financing activities** | | |
| Right of use assets under operating leases | **$ —** | $ — |

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, | |
|---|---|---|
| | **2023** | **2022** |
| Cash and cash equivalents | **$ 75,727** | $ 129,295 |
| Restricted cash | **1,750** | 1,400 |
| Total cash, cash equivalents and restricted cash | **$ 77,477** | $ 130,695 |

*See accompanying notes to these condensed consolidated financial statements.*

Intra-Cellular Therapies, Inc.

Notes to Condensed Consolidated Financial Statements (Unaudited)

March 31, 2023

## 1. Organization

Intra-Cellular Therapies, Inc. (the "Company"), through its wholly-owned operating subsidiary, ITI, Inc. ("ITI"), is a biopharmaceutical company focused on the discovery, clinical development and commercialization of innovative, small molecule drugs that address underserved medical needs primarily in neuropsychiatric and neurological disorders by targeting intracellular signaling mechanisms within the central nervous system ("CNS"). In December 2019, CAPLYTA® (lumateperone) was approved by the U.S. Food and Drug Administration ("FDA") for the treatment of schizophrenia in adults (42mg/day) and the Company initiated the commercial launch of CAPLYTA in March 2020. In December 2021, CAPLYTA was approved by the FDA for the treatment of bipolar depression in adults (42mg/day). The Company initiated the commercial launch of CAPLYTA for the treatment of bipolar depression in December 2021. Additionally, 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). The commercial launch of these special population doses occurred in August 2022. As used in these Notes to Condensed Consolidated Financial Statements, "CAPLYTA" refers to lumateperone approved by the FDA for the treatment of schizophrenia in adults and 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.

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.

## 2. Summary of Significant Accounting Policies

### Basis of Presentation

The accompanying condensed consolidated financial statements of Intra-Cellular Therapies, Inc. and its wholly owned subsidiary have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative U.S. 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, 2022.

**Concentration of Credit Risk**

Financial instruments which potentially subject the Company to concentrations of credit risk consist of accounts receivable, net from customers and cash, cash equivalents and investments held at financial institutions. As of March 31, 2023, all of the Company's accounts receivable, net arose from product sales in the United States. For the three-month periods ended March 31, 2023 and 2022, 97% of sales were from three major wholesalers accounting for approximately 37%, 31%, and 29%, and 43%, 28%, and 26% of product sales, for the same periods, respectively. The percentage of the total net product sales by individual customers has not significantly changed since inception. All customers have standard payment terms which generally require payment within 60 days. As of March 31, 2023, 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, 2023 | | | |
|---|---|---|---|---|
| | Amortized Cost | Unrealized Gains | Unrealized (Losses) | Estimated Fair Value |
| | (Unaudited) | | | |
| U.S. Government Agency Securities | **$ 189,812** | **$ 31** | **$ (1,145)** | **$ 188,698** |
| FDIC Certificates of Deposit | **3,909** | **—** | **(64)** | **3,845** |
| Certificates of Deposit | **25,000** | **—** | **—** | **25,000** |
| Commercial Paper | **89,176** | **—** | **(206)** | **88,970** |
| Corporate Notes/Bonds | **157,782** | **—** | **(1,314)** | **156,468** |
| | **$ 465,679** | **$ 31** | **$ (2,729)** | **$ 462,981** |

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

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, 2023 and December 31, 2022, the Company held $40.9 million and $71.5 million, respectively, of available-for-sale investment securities with contractual maturity dates more than one year and less than two years, with the remainder of the available-for-sale investment securities having contractual maturity dates less than one year.

Unrealized losses as of March 31, 2023 approximate 1% of the estimated fair value of investments. The aggregate related fair value of investments with unrealized losses as of March 31, 2023 was $398.2 million, which consisted of $148.9 million from U.S. government agency securities, $3.8 million of certificates of deposit, $89.0 million of commercial paper, and $156.5 million of corporate notes/bonds. $142.4 million of the aggregate fair value of investments with unrealized losses as of March 31, 2023 has been held in a continuous unrealized loss position for over 12 months, with the remaining $255.8 million held in a continuous unrealized loss position for less than 12 months. As of December 31, 2022, the aggregate related fair value of investments with unrealized losses was $438.3 million. $49.1 million of the aggregate fair value of investments with unrealized losses as of December 31, 2022 has been held in a continuous unrealized loss position for over than 12 months, with the remaining $389.2 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 prices with significant unobservable inputs (Level 3 assets and liabilities) as of March 31, 2023 and December 31, 2022. The carrying value of cash held in money market funds of $30.9 million as of March 31, 2023 and $12.2 million as of December 31, 2022 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 $14.9 million, U.S. government agency securities of $20.5 million and certificates of deposit of $7.5 million as of December 31, 2022 are 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, 2023 | 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 | **$ 30,917** | **$ 30,917** | | **$ —** |
| U.S. Government Agency Securities | **188,698** | **—** | **188,698** | **—** |
| FDIC Certificates of Deposit | **3,845** | **—** | **3,845** | **—** |
| Certificates of Deposit | **25,000** | **—** | **25,000** | **—** |
| Commercial Paper | **88,970** | **—** | **88,970** | **—** |
| Corporate Notes/Bonds | **156,468** | **—** | **156,468** | **—** |
| | **$ 493,898** | **$ 30,917** | **$ 462,981** | **$ —** |

| | December 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 | $ 12,203 | $ 12,203 | $ — | $ — |
| U.S. Government Agency Securities | 186,750 | — | 186,750 | — |
| FDIC Certificates of Deposit | 4,086 | — | 4,086 | — |
| Certificates of Deposit | 7,500 | — | 7,500 | — |
| Commercial Paper | 100,445 | — | 100,445 | — |
| Corporate Notes/Bonds | 187,448 | — | 187,448 | — |
| | $ 498,432 | $ 12,203 | $ 486,229 | $ — |

**5. Inventory**

Inventory consists of the following (in thousands):

| | March 31, 2023 | December 31, 2022 |
|---|---|---|
| Raw materials | **$ 21,716** | $ 17,227 |
| Work in process | **3,230** | 2,594 |
| Finished goods | **3,395** | 4,099 |
| | **$ 28,341** | $ 23,920 |

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

The Company has also 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 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 between 12 months and 30 months. Leases which the Company determined to have a lease term of 12 months or less will be treated as short-term in accordance with the accounting policy election and are not recognized on the balance sheet. Each lease permits either party to terminate the lease at any time via written notice to the other party. The Company neither acquires ownership of, nor has the option to purchase the vehicles at any time. The Company is required to maintain an irrevocable $1.75 million letter of credit that the Lessor may draw upon in the event the Company defaults on the Vehicle Lease, which has been recorded as restricted cash on the condensed consolidated balance sheets.

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

The following tables present the lease balances within the condensed consolidated balance sheets, weighted average remaining lease term, and the weighted average discount rates related to leases as of March 31, 2023 and December 31, 2022 and operating cash outflows as of March 31, 2023 and 2022 (in thousands, except years and percentages):

| | March 31, 2023 | December 31, 2022 |
|---|---|---|
| **Other information** | | |
| Weighted average remaining lease term | **6.3 years** | 5.9 years |
| Weighted average discount rate | **9.07 %** | 8.76 % |

| | March 31, 2023 | March 31, 2022 |
|---|---|---|
| **Lease cost** | | |
| Operating lease cost | **$ 1,085** | $ 1,456 |
| Variable lease cost | **404** | 403 |
| Short-term lease cost | **672** | — |
| | **$ 2,161** | $ 1,859 |

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

| | | |
|---|---|---|
| Nine months ending December 31, 2023 | $ | 2,766 |
| Year ending December 31, 2024 | | 3,792 |
| Year ending December 31, 2025 | | 3,907 |
| Year ending December 31, 2026 | | 3,974 |
| Year ending December 31, 2027 | | 4,022 |
| Thereafter | | 5,915 |
| Total | | 24,376 |
| Less: Present value discount | | (5,884) |
| Total operating lease liability | | 18,492 |
| Less: Current portion | | (3,531) |
| Operating lease liabilities, non-current | $ | 14,961 |

**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 $14.75 million. The Company is also obliged to make tiered single digit percentage royalty payments ranging between 5 – 9% on sales of licensed products. The Company is obliged to pay to BMS a percentage of non-royalty payments made in consideration of any sublicense.

The agreement extends, and royalties are payable, on a country-by-country and product-by-product basis, through the later of ten 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.

The Company expensed approximately $4.7 million and $1.7 million, respectively, for the three-month periods ended March 31, 2023 and 2022, in cost of product sales to satisfy its obligation under the BMS agreement.

*Purchase Commitments*

The Company enters into certain other long-term commitments for goods and services that are outstanding for periods greater than one year. The Company recently amended certain manufacturing service agreements committing the Company to certain minimum annual purchase commitments for which the Company anticipates making payments within the years 2025 through 2029. As of March 31, 2023, the Company has committed to purchasing production campaigns for various raw materials including active pharmaceutical ingredients (API) and its intermediates from each of its supply vendors. The campaigns are expected to be received into inventory during 2023 and 2024. The Company has paid deposits of $23.0 million and $21.6 million as of March 31, 2023 and December 31, 2022, respectively, for the various 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**

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

| | Three Months Ended March 31, | |
|---|---|---|
| | **2023** | 2022 |
| Inventoriable costs | **$ 342** | $ 335 |
| Selling, general and administrative | **6,980** | 5,734 |
| Research and development | **3,117** | 2,036 |
| Total share-based compensation expense | **$ 10,439** | $ 8,105 |

Information regarding the stock options activity, including with respect to grants to employees and directors as of March 31, 2023, 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, 2022 | 4,785,972 | $ 26.27 | 5.8 years |
| Options granted 2023 | 239,767 | | |
| Options exercised 2023 | (262,815) | | |
| Options canceled or expired 2023 | (24,961) | | |
| Outstanding at March 31, 2023 | 4,737,963 | $ 27.76 | |
| Vested and expected to vest at March 31, 2023 | 4,737,963 | $ 27.76 | |
| Exercisable at March 31, 2023 | 3,867,634 | $ 22.98 | |

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, 2023 is summarized as follows:

| | Number of Shares | Weighted-Average Grant Date Fair Value Per Share | Weighted-Average Contractual Life |
|---|---|---|---|
| Outstanding at December 31, 2022 | 1,274,664 | $ 42.76 | 0.8 years |
| Time-based RSUs granted in 2023 | 1,007,920 | | |
| Time-based RSUs vested in 2023 | (651,445) | | |
| Time-based RSUs cancelled in 2023 | (17,568) | | |
| Outstanding at March 31, 2023 | 1,613,571 | $ 48.42 | |

As of March 31, 2023, there was approximately $76.0 million of unrecognized compensation costs estimated related to unvested time-based RSUs.

**9. Loss Per Share**

The following share-based 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-month periods ended March 31, 2023 and 2022:

| | Three Months Ended March 31, | |
|---|---|---|
| | **2023** | **2022** |
| Stock options | **4,737,963** | 5,476,993 |
| RSUs | **1,829,155** | 1,446,879 |

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

*You should read the following in conjunction with our unaudited condensed consolidated financial statements and the related notes thereto that appear elsewhere in this Quarterly Report on Form 10-Q and the audited consolidated financial statements and notes thereto and under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K filed on March 1, 2023. In addition to historical information, the following discussion and analysis includes forward-looking information that involves risks, uncertainties and assumptions. Our actual results and the timing of events could differ materially from those anticipated by these forward-looking statements as a result of many factors, including those discussed under "Risk Factors" in our Annual Report on Form 10-K filed on March 1, 2023, 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 March 2020. In December 2021, CAPLYTA was approved by the FDA for the treatment of bipolar depression in adults (42mg/day). We initiated the commercial launch of CAPLYTA for the treatment of bipolar depression in December 2021. Additionally, in April 2022, the FDA approved two 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). We initiated the commercial launch of these special population doses in August 2022. As used in this report, "CAPLYTA" refers to lumateperone approved by the FDA for the treatment of schizophrenia in adults and for the treatment of bipolar depression in adults, and "lumateperone" refers to, where applicable, CAPLYTA as well as lumateperone for the treatment of indications beyond schizophrenia and bipolar depression.

Lumateperone is in Phase 3 clinical development as a novel treatment for major depressive disorder, or MDD. Patient enrollment in Study 501 and Study 502, global Phase 3 clinical trials evaluating lumateperone 42 mg as an adjunctive therapy to antidepressants for the treatment of MDD, is ongoing. In addition, we recently initiated a third global Phase 3 trial, Study 505, also evaluating lumateperone 42 mg as an adjunctive therapy to antidepressants for the treatment of MDD. Study 505 is intended to serve as a potential additional registration trial in support of a supplemental New Drug Application, or sNDA, for approval of lumateperone as an adjunctive therapy to antidepressants for the treatment of MDD, if needed. This is a common strategy employed in mood disorder development programs. Subject to the results of Study 501 and Study 502, 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. In March 2023, we announced positive topline results from Study 403 as lumateperone 42mg given once daily met the primary endpoint in the study by demonstrating a statistically significant and clinically meaningful reduction in the Montgomery Asberg Depression Rating Scale (MADRS) total score compared to placebo at Week 6 in the combined patient population of MDD with mixed features and bipolar depression with mixed features (5.7 point reduction v. placebo; $p<0.0001$; Cohen's d effect size (ES) of 0.64). Robust results were also seen in the individual patient population of MDD with mixed features (5.9 point reduction v. placebo; $p<0.0001$; ES= 0.67), and in the individual patient population of bipolar depression with mixed features (5.7 point reduction v. placebo; $p<0.0001$; ES= 0.64). Additionally, lumateperone 42mg met the key secondary endpoint in the study by demonstrating a statistically significant and clinically meaningful reduction in the clinician's assessment of improvement in the overall severity on the Global Impression of Severity Scale (CGI-S) score compared to placebo at Week 6 in the combined patient population of MDD with mixed features and bipolar depression with mixed features ($p<0.0001$; ES= 0.59) and in the individual patient population of MDD with mixed features ($p=0.0003$; ES= 0.57), as well as the individual patient population of bipolar depression with mixed features $p<0.0001$; ES=0.61). Lumateperone was generally safe and well tolerated, with a side effect profile consistent with prior lumateperone trials. Following reporting of topline results, we expect to discuss the results with the FDA to determine next steps for this program.

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 pre-clinical development of an LAI formulation, and we have conducted a Phase 1 single ascending dose study with this formulation. This study evaluated the pharmacokinetics, safety and tolerability of lumateperone LAI in patients with stable symptoms of schizophrenia. We completed this study, and it was safe and well-tolerated. We are evaluating several additional formulations of the lumateperone LAI with treatment durations of one month and longer. Pre-clinical development on these additional formulations is ongoing and expected to be completed in 2023. We plan to initiate Phase 1 single ascending dose studies with these formulations in 2023. 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 agitation in patients with dementia, the treatment of dementia-related psychosis and 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 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 are conducting additional toxicology studies. We expect to commence clinical conduct in a Phase 2 study in agitation in patients with Alzheimer’s disease in 2023. Additional studies in psychosis in patients with Alzheimer's disease and generalized anxiety disorder are also planned for 2023. We are continuing with Phase 1 studies with ITI-1284-ODT-SL, including drug-drug interaction studies.

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 immune system regulation, neurodegenerative diseases, cancers and other non-CNS disorders. Lenrispodun (ITI-214) is our lead compound in this program. Following the favorable safety and tolerability results in our Phase 1 program, we initiated our development program for lenrispodun for Parkinson’s disease and conducted a Phase 1/2 clinical trial of lenrispodun in patients with Parkinson’s disease to evaluate safety and tolerability in this patient population, as well as motor and non-motor exploratory endpoints. In this study, lenrispodun was generally well-tolerated with a favorable safety profile and clinical signs consistent with improvements in motor symptoms and dyskinesias. We have initiated our Phase 2 clinical program with lenrispodun for Parkinson’s disease, which began patient enrollment in the first quarter of 2023. We also have an active Investigational New Drug application to evaluate our newest candidate within the PDE 1 inhibitor program, ITI-1020, as a novel cancer immunotherapy. We recently commenced patient enrollment in a Phase 1 program with ITI-1020 in healthy volunteers.

We also have a development program with our ITI-333 compound as a potential treatment for substance use disorders, pain and psychiatric comorbidities including depression and anxiety. There is a pressing need to develop new drugs to treat opioid addiction and safe, effective, non-addictive treatments to manage pain. ITI-333 is a novel compound that uniquely combines activity as an antagonist at serotonin 5-HT2A receptors and a partial agonist at μ-opioid receptors.

These combined actions support the potential utility of ITI-333 in the treatment of opioid use disorder and associated comorbidities (e.g., depression, anxiety, sleep disorders) without opioid-like safety and tolerability concerns. We have conducted a Phase 1 single ascending dose study evaluating the safety, tolerability and pharmacokinetics of ITI-333 in healthy volunteers. In this study, ITI-333 achieved plasma exposures at or above those required for efficacy and was generally safe and well-tolerated. We have commenced a neuroimaging study to investigate brain occupancy for receptors that play a role in substance use disorder and also have applicability for pain. The results of this study will support the dose selection for future studies. We commenced a multiple ascending dose study in the first quarter of 2023. 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, we may continue to experience disruptions, which could severely impact our business, including our ability to successfully commercialize our only commercial product, CAPLYTA, in the United States, and could negatively impact our sales of CAPLYTA. Our commercial organization, sales force and medical organization have had, and, depending on the severity and duration of the pandemic, may continue to have significantly reduced personal interactions with physicians and customers and may need to continue 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, the pandemic may continue to impact the willingness of patients to visit their healthcare provider. 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, Europe and Asia, 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.

The COVID-19 pandemic continues to 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 pre-clinical 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. In addition, in April 2022, the FDA approved two new dosage strengths of CAPLYTA for certain patients. We initiated the commercial launch of CAPLYTA in March 2020. During the three-month period ended March 31, 2023, net product sales increased to approximately $94.7 million from approximately $34.8 million for the three-month period ended March 31, 2022.

***Expenses***

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

Our PDE, ITI-1284 and ITI-333 development programs are currently in clinical development. Our other programs are still in the pre-clinical stages and will require extensive funding not only to complete pre-clinical testing, but also to commence and complete clinical trials. Expenditures that we incur 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) selling expenses; (iii) general and administrative expenses; and (iv) research and development expenses.

Costs of product sales are comprised of:

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

Selling expenses are incurred in three major categories:

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

General and administrative expenses are incurred in three major categories:

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

Research and development costs are comprised of:

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

Product sold through March 31, 2023 consisted of active pharmaceutical ingredient (API) and drug product that was previously charged to research and development expenses prior to FDA approval of CAPLYTA and other direct, indirect, and overhead costs required to make final product for sale. 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, 2023 and 2022. We expect to continue to have this favorable impact on cost of product sales and related product gross margins until the cost of our sales of CAPLYTA include drug product that is manufactured entirely after the FDA approval. We expect that this will be the case for the near-term and, as a result, our cost of product sales will be less than we anticipate it will be in future periods.

We expect that research and development expenses will increase considerably 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 2023 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. In addition, inflation generally may affect us by increasing clinical trial and other operational costs. To date, inflation has not had a material impact on our business, but if the global inflationary trends continue, we expect appreciable increases in clinical trial, selling, labor, and other operating costs.

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

| | Three Months Ended March 31, | |
|---|---|---|
| | **2023** | 2022 |
| | **(Unaudited)** | |
| **Revenues** | | |
| Product sales, net | **$ 94,731** | $ 34,755 |
| Grant revenue | **575** | 241 |
| **Total revenues** | **95,306** | 34,996 |
| **Expenses** | | |
| Cost of product sales | **6,751** | 3,155 |
| Selling, general and administrative | **98,923** | 75,460 |
| Research and development | **38,024** | 29,043 |
| **Total operating expenses** | **143,698** | 107,658 |
| **Loss from operations** | **(48,392)** | (72,662) |
| Interest income | **4,349** | 548 |
| Income tax expense | **(10)** | (5) |
| **Net loss** | **$ (44,053)** | $ (72,119) |

***Comparison of Three-Month Periods Ended March 31, 2023 and March 31, 2022***

*Product Sales, Net*

Net product sales were $94.7 million and $34.8 million, respectively, for the three-month periods ended March 31, 2023 and 2022. Net product revenue was comprised of sales of CAPLYTA for the treatment of schizophrenia and bipolar depression.

*Cost of Product Sales*

Cost of product sales was $6.8 million and $3.2 million, respectively, for the three-month periods ended March 31, 2023 and 2022. Cost of product sales consisted primarily of product royalty fees, overhead and direct costs. Drug product costs, including certain direct, indirect, and overhead costs, for product sales through March 31, 2023 were previously charged to research and development expenses prior to FDA approval in December 2019 and are not a component of cost of product sales. This minimal cost drug product had a favorable impact on our cost of product sales and related product gross margins for the three-month periods ended March 31, 2023 and 2022.

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.

*Selling, General and Administrative Expenses*

Selling, general and administrative costs for the three-month period ended March 31, 2023 were $98.9 million as compared to $75.5 million in the three-month period ended March 31, 2022, which represents an increase of 31%.

Selling costs were $76.5 million for the three-month period ended March 31, 2023 as compared to selling costs of $56.1 million in the same period in 2022, which represents an increase of 36%. This increase is primarily due to increases of marketing and advertising expenses of $19.4 million, and sales related labor costs of $1.1 million. Salaries, bonuses and related benefit costs for our sales and marketing functions for the three-month periods ended March 31, 2023 and 2022 constituted 33% and 43%, respectively, of our selling costs.

General and administrative expenses were $22.4 million in the three-month period ended March 31, 2023 as compared to $19.4 million for the same period in 2022, an increase of 15%. This increase is due to increases in labor related costs of $0.8 million, share-based compensation of $1.2 million, and insurance and other expenses of $1.0 million. Salaries, bonuses and related benefit costs for our general and administrative functions for the three-month periods ended March 31, 2023 and 2022 constituted 55% and 53%, respectively, of our general and administrative costs.

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

*Research and Development Expenses*

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

| | Three Months Ended March 31, | |
|---|---|---|
| | **2023** | 2022 |
| External costs | **$ 27,729** | $ 19,293 |
| Internal costs | **10,295** | 9,750 |
| **Total research and development expenses** | **$ 38,024** | $ 29,043 |

| | Three Months Ended March 31, | |
|---|---|---|
| | **2023** | 2022 |
| Lumateperone costs | **$ 24,094** | $ 17,473 |
| Non-lumateperone costs | **7,534** | 6,242 |
| Overhead and other costs | **6,396** | 5,328 |
| **Total research and development expenses** | **$ 38,024** | $ 29,043 |

Research and development expenses increased to $38.0 million for the three-month period ended March 31, 2023 as compared to $29.0 million for the three-month period ended March 31, 2022, representing an increase of $9.0 million, or 31%. This increase is due primarily to an increase of $6.6 million for lumateperone project costs, $1.3 million for non-lumateperone projects, and $1.1 million for overhead and other costs. External costs increased by $8.4 million for the period due to the increased lumateperone and non-lumateperone project costs. Internal costs increased by $0.5 million for the period due primarily to labor related costs and share-based compensation.

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

The successful development of our product candidates and the approval process requires substantial time, effort and financial resources, and is uncertain and subject to a number of risks. We cannot be certain that any of our product candidates will prove to be safe and effective, will meet all of the applicable regulatory requirements needed to receive and maintain marketing approval, or will be granted marketing approval on a timely basis, if at all. Data from non-clinical studies and clinical trials are susceptible to varying interpretations that could delay, limit or prevent regulatory approval or could result in label warnings related to or recalls of approved products. We, the FDA, or other regulatory authorities may suspend clinical trials at any time if we or they believe that the subjects participating in such trials are being exposed to unacceptable risks or if such regulatory agencies find deficiencies in the conduct of the trials or other problems with our product candidates. Other risks associated with our product candidates are described in the section titled "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2022, as updated by the section titled "Risk Factors" in this Quarterly Report on Form 10-Q and from time to time in our other periodic and current reports filed with the SEC.

**Liquidity and Capital Resources**

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

As of March 31, 2023, our cash and cash equivalents and available-for-sale investment securities totaled $540.5 million, which included $1.75 million in restricted cash. We invest cash in excess of our immediate requirements with regard to liquidity and capital preservation in a variety of interest-bearing instruments, including obligations of U.S. government agencies and money market accounts. Wherever possible, we seek to minimize the potential effects of concentration and degrees of risk. Although we maintain cash balances and investments with financial institutions in excess of insured limits, we do not anticipate any losses with respect to such balances.

During the three-months ended March 31, 2023, we used $60.1 million of cash in operating activities, a decrease of $22.8 million as compared to the three-months ended March 31, 2022. The decrease in cash used in operations was primarily due to the lower net loss in the current period as compared to the prior period. 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, marketable securities, and product sales will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months from the filing date of this quarterly report. During that time, we expect that our expenses will increase, primarily due to the continued commercialization of CAPLYTA for the treatment of schizophrenia and bipolar depression; the development of lumateperone in our late-stage clinical programs; the development of our other product candidates, including ITI-1284, ITI-214, and ITI-333; and infrastructure expansion and general operations.

We seek to balance the level of cash, cash equivalents and investments on hand with our projected needs and to allow us to withstand periods of uncertainty relative to the availability of funding on favorable terms. Subject to our ability to generate significant revenues from operations, we may need to satisfy our future cash needs through public or private sales of our equity securities, sales of debt securities, incurrence of debt from commercial lenders, strategic collaborations, licensing a portion or all of our product candidates and technology and, to a lesser extent, grant funding.

We cannot be sure that future funding will be available to us when we need it on terms that are acceptable to us, or at all. We sell securities and incur debt when the terms of such transactions are deemed favorable to us and as necessary to fund our current and projected cash needs. The amount of funding we raise through sales of our common stock or other securities depends on many factors, including, but not limited to, the magnitude of sales of CAPLYTA, the status and progress of our product development programs, projected cash needs, availability of funding from other sources, our stock price and the status of the capital markets. Due to the volatile nature of the financial markets, equity and debt financing may be difficult to obtain.

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

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

Our cash 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. Since early 2022, interest rates have risen which is increasing our interest income. Due to recent uncertainty in the banking industry, interest rates dropped in March 2023 causing a gain in investments held over various maturities. This gain resulted in a lower net unrealized loss balance of $2.7 million as of March 31, 2023. Due to the short-term nature of these investments and our intention to hold these investments to maturity, we do not expect to recognize these losses. Even with the rise or further potential rise in interest rates, we do not expect interest income to be a significant source of funding. In addition, our investment portfolio historically has not been adversely impacted by problems in the credit markets, but there can be no assurance that our investment portfolio will not be adversely affected in the future.

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

We have three kinds of long-term contractual commitments - operating leases, licensing and royalty commitments, and purchase obligations. Our operating lease for approximately 32,000 square feet of useable laboratory and office space, as amended, has a term of 14.3 years ending in May 2029.

We entered into an exclusive license with Bristol-Myers Squibb Company (BMS), for which we are obligated to make tiered single-digit percentage royalty payments on sales of licensed products. As of March 31, 2023, we have outstanding royalty liabilities of $4.7 million. The amount of future royalty obligations are dependent on future net product sales of the licensed product. The Company may also be obligated to make other milestone payments to BMS for each licensed product of up to an aggregate of $14.75 million.

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

**Critical Accounting Policies and Estimates**

Our critical accounting policies are those policies which require the most significant judgments and estimates in the preparation of our condensed consolidated financial statements. We evaluate our estimates, judgments, and assumptions on an ongoing basis. Actual results may differ from these estimates under different assumptions or conditions. A summary of our critical accounting policies is presented in Part II, Item 7, of our Annual Report on Form 10-K for the year ended December 31, 2022. There have been no material changes to our critical accounting policies during the three-month period ended March 31, 2023.

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

**Recently Issued Accounting Pronouncements**

We review new accounting standards to determine the expected financial impact, if any, that the adoption of each such standard will have. Based on our assessment, all new accounting pronouncements were determined to be either not applicable or are expected to have minimal impact on our consolidated financial statements or related disclosures.

**Certain Factors That May Affect Future Results of Operations**

The SEC encourages companies to disclose forward-looking information so that investors can better understand a company's future prospects and make informed investment decisions. This Quarterly Report on Form 10-Q contains such "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These statements involve known and unknown risks, uncertainties and other important factors which may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. Forward-looking statements include, but are not limited to, statements about: the accuracy of our estimates regarding expenses, revenues, uses of cash, cash equivalents and investment securities, capital requirements and the need for additional financing; our expectations regarding our commercialization of CAPLYTA; the duration and severity of the COVID-19 pandemic and its continued impact on our business; the supply and availability of and demand for our product; the initiation, cost, timing, progress and results of our development activities, pre-clinical 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, inflation 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; risks related to inflation and global supply chain disruptions on our business; 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, 2023, we had cash, cash equivalents, marketable securities and restricted cash of $540.5 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. Since early 2022, interest rates have risen which is increasing our interest income. Due to recent uncertainty in the banking industry, interest rates dropped in March 2023 causing a gain in investments held over various maturities. This gain resulted in a lower net unrealized loss balance of $2.7 million as of March 31, 2023.

*Inflation Risk*. Inflation generally may affect us by increasing our cost of labor, clinical trial costs, and costs of other outsourced activities. To date, inflation has not had a material impact on our business, but if the global inflationary trends continue, we expect appreciable increases in clinical trial, selling, labor, and other operating costs. If our costs were to become subject to significant inflationary pressures, we may not be able to fully offset such higher costs through price increases of our product. 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 assess the need for additional funding 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-month period ended March 31, 2023 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

On July 8, 2022, a purported shareholder derivative complaint was filed in the Supreme Court for the State of New York against the directors serving on the Company's board of directors and the Company as a nominal defendant alleging breach of fiduciary duty and unjust enrichment alleging that compensation awarded to the director defendants for service on the board of directors was excessive. On March 6, 2023, the parties filed a stipulation of settlement (the "Stipulation"). The Stipulation does not require any damages payments or disgorgement by defendants or the Company. The Stipulation provides that, going forward, the board of directors will amend its compensation policies for non-employee directors, including, inter alia, by capping annual equity compensation at the 75th percentile of the annual equity grants for a peer group of companies. Subject to the terms and conditions of the Stipulation and final approval of the Court, the Company and/or its insurance carriers have agreed to pay up to $375,000 in attorneys' fees to plaintiff's counsel. On April 12, 2023, the court granted preliminary approval of the settlement and set a hearing date of July 17, 2023 to consider final approval of the Stipulation.

### Item 1A. RISK FACTORS

There have been no material changes to the risk factors discussed in Item 1A. Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2022, filed with the Securities and Exchange Commission on March 1, 2023.

### 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 three-month period ended March 31, 2023.

### 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 the Registrant, as amended. | | 10-Q (Exhibit 3.1) | 8/9/2021 | 001-36274 |
| 10.1 | Supply Agreement dated as of January 5, 2023 by and between Siegfried AG and the Registrant.** | | 10-K (Exhibit 10.2) | 3/1/2023 | 001-36274 |
| 10.2 | 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, 2023, formatted in Inline XBRL (eXtensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets as of March 31, 2023 (unaudited) and December 31, 2022 (audited), (ii) Condensed Consolidated Statements of Operations (unaudited) for the three months ended March 31, 2023 and 2022, (iii) Condensed Consolidated Statements of Comprehensive Loss (unaudited) for the three months ended March 31, 2023 and 2022, (iv) Condensed Consolidated Statements of Stockholders' Equity (unaudited) for the three months ended March 31, 2023 and 2022, (v) Condensed Consolidated Statements of Cash Flows (unaudited) for the three months ended March 31, 2023 and 2022, 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.

** Certain confidential portions of this Exhibit were omitted by means of marking such portions with brackets ("[***]") because the identified confidential portions (i) are not material and (ii) are the type of information that the Company treats as private or confidential.

**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 4, 2023

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

Date: May 4, 2023

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, May 5, 2022 and April 27, 2023)**

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

**Applicable Persons**

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

**Compensation**

**A. General Compensation Limits**

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

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

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

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

**B. Equity Grants**

1. Annual Stock Option Grants

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

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

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

Subject to the Initial Equity Grant Limit set forth in Section A above, each new Outside Director shall be granted, under the Equity Plan, either (i) a non-qualified stock option to purchase the number of shares of Common Stock having an aggregate grant date fair value of $1,000,000, valued based on a Black-Scholes valuation method (rounded down to the nearest whole share) (an "Initial Option Grant"), (ii) a restricted stock unit for the number of shares of Common Stock, having an aggregate grant date fair value of $1,000,000, valued based on the closing price of the Common stock on The Nasdaq Global Select Market (or such other securities exchange on which the Common Stock is then traded) (rounded down to the nearest whole share) (an "Initial RSU Grant"), or (iii) a non-qualified stock option to purchase a number of shares of Common Stock and a restricted stock unit for a number of shares of Common Stock having a combined aggregate grant date fair value of $1,000,0000, with the non-qualified stock option valued in accordance with (i) above and the restricted stock unit valued in accordance with (ii) above (an "Initial Option and RSU Grant"), on or about the date that the Outside Director is first appointed or elected to the Board of Directors (the Initial Option Grant, the Initial RSU Grant or the Initial Option and RSU Grant, as the case may be, the "Initial Equity Grant"); provided that any Initial Equity Grant made on or after January 1, 2027 will be solely in the form of an Initial RSU Grant (and not an Initial Option Grant or an Initial Option and RSU Grant); and provided, further, that the total aggregate grant date fair value of the Initial Equity Grant, calculated in accordance with this paragraph, shall not exceed the Initial Equity Grant Limit.

3. Terms of Equity Grants

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

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

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

1. Annual Cash Fees

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

| Board of Directors or Committee of Board of Directors | Annual Retainer Amount for Chair (or Lead Independent Director, as applicable) | Annual Retainer Amount for Other Members |
|---|---|---|
| Board of Directors | $ 75,000 | $ 50,000 |
| Audit Committee | $ 25,000 | $ 12,000 |
| Compensation Committee | $ 20,000 | $ 10,000 |
| 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 4, 2023

/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 4, 2023

/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, 2023 (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 4, 2023

/s/ Sharon Mates, Ph.D.

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

Dated: May 4, 2023

/s/ Lawrence J. Hineline

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