UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the Quarterly Period Ended September 30, 2022

OR

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

For the Transition Period from _____ to _____

Commission File Number 001-33650

LISATA THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

| Delaware | 22-2343568 |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (I.R.S. Employer Identification No.) |
| 110 Allen Road, 2nd Floor, Basking Ridge, New Jersey | 07920 |
| (Address of principal executive offices) | (zip code) |

Registrant's telephone number, including area code: 908-842-0100

Caladrius Biosciences, Inc.
(Former name or former address, if changed since last report)

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, par value $0.001 per share | LSTA | The Nasdaq Capital 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 and post 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 definition 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 ☒

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

| Class | Outstanding as of November 10, 2022 |
|---|---|
| Common stock, $0.001 par value per share | 7,859,684 shares |

## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This quarterly report (this "Quarterly Report") contains "forward-looking" statements within the meaning of the Private Securities Litigation Reform Act of 1995, as well as historical information. When used in this Quarterly Report, statements that are not statements of current or historical fact may be deemed to be forward-looking statements, including, without limitation, all statements related to any expectations of revenues, expenses, cash flows, earnings or losses from operations, cash required to maintain current and planned operations, capital or other financial items; any statements of the plans, strategies and objectives of management for future operations; any plans or expectations with respect to product research, development and commercialization, including regulatory approvals; any other statements of expectations, plans, intentions or beliefs; and any statements of assumptions underlying any of the foregoing. Without limiting the foregoing, the words "plan," "project," "forecast," "outlook," "intend," "may," "will," "expect," "anticipate," "likely," "believe," "could," "anticipate," "estimate," "continue," "target" or similar expressions or other variations or comparable terminology are intended to identify such forward-looking statements, although some forward-looking statements are expressed differently. We remind readers that forward-looking statements are merely predictions and therefore inherently subject to uncertainties and other factors and involve known and unknown risks that could cause the actual results, performance, levels of activity or our achievements or industry results, to be materially different from any future results, performance, levels of activity or our achievements or industry results expressed or implied by such forward-looking statements. Factors that could cause our actual results to differ materially from anticipated results expressed or implied by forward-looking statements include, among others:

- our ability to obtain sufficient capital or strategic business arrangements to fund our operations and expansion plans, including meeting our financial obligations under various licensing and other strategic arrangements, the funding of our clinical trials for product candidates, and the commercialization of the relevant technology;
- our ability to build and maintain the management and human resources infrastructure necessary to support the growth of our business;
- whether a relevant market is established for our products and services and our ability to capture a meaningful share of this market;
- scientific, regulatory and medical developments beyond our control;
- our ability to obtain and maintain, as applicable, appropriate governmental licenses, accreditations or certifications or to comply with healthcare laws and regulations or any other adverse effect or limitations caused by government regulation of our business;
- whether any of our current or future patent applications result in issued patents, the scope of those patents and our ability to obtain and maintain other rights to technology required or desirable for the conduct of our business, and our ability to commercialize products without infringing upon the claims of third-party patents;
- whether any potential strategic or financial benefits of various licensing agreements will be realized;
- the long-term success of our recently completed merger with Cend Therapeutics, Inc. ("Cend"), including the ongoing integration of Cend's operations and the advancement of their development programs;
- the results of our development activities;
- our ability to complete our other planned clinical trials (or initiate other trials) in accordance with our estimated timelines due to delays associated with enrolling patients due to the novelty of the treatment, the size of the patient population, competition with other clinical trials for similar subjects and the need of patients to meet the inclusion criteria of the trial or otherwise;
- the extent to which the COVID-19 pandemic and/or its long-term effects may impact, directly or indirectly, our business, including our clinical trials and financial condition;
- our ability to maintain the listing of our common stock on The Nasdaq Capital Market; and
- other factors discussed in "Risk Factors" in our Annual Report on Form 10-K filed with the Securities and Exchange Commission (the "SEC") on March 22, 2022 (our "2021 Form 10-K"), in our Quarterly Reports on Form 10-Q for the periods ended March 31, 2022 and June 30, 2022 and in Exhibit 99.2 to our Amendment No. 1 to Current Report on Form 8-K/A filed on October 4, 2022.

The factors discussed herein, including those risks described in “Item 1A. Risk Factors” and elsewhere in our 2021 Form 10-K and in our other periodic filings with the SEC, which are available for review at *www.sec.gov,* could cause actual results and developments to be materially different from those expressed or implied by such statements. All forward-looking statements attributable to us are expressly qualified in their entirety by these and other factors. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date they were made. Except as required by law, we undertake no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

## TABLE OF CONTENTS

## PART I. FINANCIAL INFORMATION

## ITEM 1. FINANCIAL STATEMENTS

### LISATA THERAPEUTICS, INC. AND SUBSIDIARIES
### CONSOLIDATED BALANCE SHEETS
(In thousands, except share data)

| | September 30, 2022 | December 31, 2021 |
|---|---|---|
| **ASSETS** | **(Unaudited)** | |
| Cash and cash equivalents | $ 31,478 | $ 24,647 |
| Marketable securities | 44,052 | 70,323 |
| Prepaid and other current assets | 1,760 | 1,212 |
| Total current assets | 77,290 | 96,182 |
| Property and equipment, net | 299 | 62 |
| Acquired license - intangible | 352 | — |
| Other assets | 588 | 764 |
| Total assets | $ 78,529 | $ 97,008 |
| | | |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| **Liabilities** | | |
| Accounts payable | $ 974 | $ 1,934 |
| Accrued liabilities | 5,417 | 2,589 |
| Total current liabilities | 6,391 | 4,523 |
| Other long-term liabilities | 367 | 485 |
| Total liabilities | 6,758 | 5,008 |
| **Commitments and Contingencies (Note 13)** | | |
| | | |
| **Stockholders' Equity** | | |
| Preferred stock, authorized, 20,000,000 shares Series B convertible redeemable preferred stock liquidation value, 0.000067 share of common stock, $0.01 par value; 825,000 shares designated; issued and outstanding, 10,000 shares at September 30, 2022 and December 31, 2021, respectively | — | — |
| Common stock, $0.001 par value, authorized 33,333,333 shares; issued 7,863,340 and 3,986,719 shares at September 30, 2022 and December 31, 2021, respectively; and outstanding, 7,862,602 and 3,985,981 shares at September 30, 2022 and December 31, 2021, respectively | 8 | 4 |
| Additional paid-in capital | 574,066 | 546,044 |
| Treasury stock, at cost; 738 shares at September 30, 2022 and December 31, 2021 | (708) | (708) |
| Accumulated deficit | (501,251) | (453,016) |
| Accumulated other comprehensive loss | (90) | (70) |
| Total Lisata Therapeutics, Inc. stockholders' equity | 72,025 | 92,254 |
| **Non-controlling interests** | (254) | (254) |
| Total stockholders' equity | 71,771 | 92,000 |
| Total liabilities, non-controlling interests and stockholders' equity | $ 78,529 | $ 97,008 |

See accompanying notes to consolidated financial statements.

**LISATA THERAPEUTICS, INC. AND SUBSIDIARIES**
**CONSOLIDATED STATEMENTS OF OPERATIONS**
**(Unaudited)**
(In thousands, except per share data)

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | **2022** | **2021** | **2022** | **2021** |
| Operating Expenses: | | | | |
| Research and development | $ 3,380 | $ 4,125 | $ 9,898 | $ 13,530 |
| In-process research and development | 30,393 | — | 30,393 | — |
| General and administrative | 3,947 | 2,843 | 10,770 | 8,671 |
| Total operating expenses | 37,720 | 6,968 | 51,061 | 22,201 |
| Operating loss | (37,720) | (6,968) | (51,061) | (22,201) |
| Other income (expense): | | | | |
| Investment income, net | 337 | 41 | 496 | 111 |
| Other expense, net | — | — | (149) | (90) |
| Total other income (expense) | 337 | 41 | 347 | 21 |
| Net loss before benefit from income taxes and noncontrolling interests | (37,383) | (6,927) | (50,714) | (22,180) |
| Benefit from income taxes | — | — | (2,479) | (1,508) |
| Net loss attributable to Lisata Therapeutics, Inc. common stockholders | $ (37,383) | $ (6,927) | $ (48,235) | $ (20,672) |
| **Basic and diluted loss per share** | | | | |
| Lisata Therapeutics, Inc. common stockholders | $ (7.88) | $ (1.74) | $ (11.28) | $ (5.76) |
| **Weighted average common shares outstanding** | | | | |
| Basic and diluted shares | 4,747 | 3,974 | 4,276 | 3,587 |

See accompanying notes to consolidated financial statements.

**LISATA THERAPEUTICS, INC. AND SUBSIDIARIES**
**CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**
**(Unaudited)**
(In thousands)

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2022 | 2021 | 2022 | 2021 |
| Net loss | $ (37,383) | $ (6,927) | $ (48,235) | $ (20,672) |
| Other comprehensive loss: | | | | |
| Available for sale securities - net unrealized gain (loss) | 5 | (47) | 5 | (51) |
| Cumulative translation adjustment arising during the period | (25) | — | (25) | — |
| Total other comprehensive loss | (20) | (47) | (20) | (51) |
| Comprehensive loss attributable to Lisata Therapeutics, Inc. common stockholders | $ (37,403) | $ (6,974) | $ (48,255) | $ (20,723) |

See accompanying notes to consolidated financial statements.

**LISATA THERAPEUTICS, INC. AND SUBSIDIARIES**
**CONSOLIDATED STATEMENTS OF EQUITY**
**(Unaudited)**
(In thousands)

| | Series B Convertible Preferred Stock | | Common Stock | | Additional Paid-in Capital | Accumulated Other Comprehensive Loss | Accumulated Deficit | Treasury Stock | Total Lisata Therapeutics, Inc. Stockholders' Equity | Non-Controlling Interest in Subsidiary | Total Equity |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | | | | | | | |
| **Balance at June 30, 2022** | — | $ — | 4,038 | $ 4 | $ 547,032 | $ (70) | $ (463,868) | $ (708) | $ 82,391 | $ (254) | $ 82,137 |
| Net loss | — | — | — | — | — | — | (37,383) | — | (37,383) | — | (37,383) |
| Share-based compensation | — | — | 52 | — | 940 | — | — | — | 939 | — | 939 |
| Issuance of common stock in connection with merger | — | — | 3,773 | 4 | 26,094 | — | — | — | 26,098 | — | 26,098 |
| Unrealized gain on marketable securities | — | — | — | — | — | 5 | — | — | 5 | — | 5 |
| Foreign currency translation adjustment | — | — | — | — | — | (25) | — | — | (25) | — | (25) |
| **Balance at September 30, 2022** | — | $ — | 7,863 | $ 8 | $ 574,066 | $ (90) | $ (501,251) | $ (708) | $ 72,025 | $ (254) | $ 71,771 |

| | Series B Convertible Preferred Stock | | Common Stock | | Additional Paid-in Capital | Accumulated Other Comprehensive Loss | Accumulated Deficit | Treasury Stock | Total Lisata Therapeutics, Inc. Stockholders' Equity | Non-Controlling Interest in Subsidiary | Total Equity |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | | | | | | | |
| **Balance at December 31, 2021** | — | $ — | 3,986 | $ 4 | $ 546,044 | $ (70) | $ (453,016) | $ (708) | $ 92,254 | $ (254) | $ 92,000 |
| Net loss | — | — | — | — | — | — | (48,235) | — | (48,235) | — | (48,235) |
| Share-based compensation | — | — | 100 | — | 1,899 | — | — | — | 1,899 | — | 1,899 |
| Net proceeds from issuances of common stock | — | — | 4 | — | 29 | — | — | — | 29 | — | 29 |
| Issuance of common stock in connection with merger | — | — | 3,773 | 4 | 26,094 | — | — | — | 26,098 | — | 26,098 |
| Unrealized gain on marketable securities | — | — | — | — | — | 5 | — | — | 5 | — | 5 |
| Foreign currency translation adjustment | — | — | — | — | — | (25) | — | — | (25) | — | (25) |
| **Balance at September 30, 2022** | — | $ — | 7,863 | $ 8 | $ 574,066 | $ (90) | $ (501,251) | $ (708) | $ 72,025 | $ (254) | $ 71,771 |

| | Series B Convertible Preferred Stock | | Common Stock | | Additional Paid-in Capital | Accumulated Other Comprehensive Loss | Accumulated Deficit | Treasury Stock | Total Lisata Therapeutics, Inc. Stockholders' Equity | Non-Controlling Interest in Subsidiary | Total Equity |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | | | | | | | |
| **Balance at June 30, 2021** | — | $ — | 3,967 | $ 4 | $ 544,949 | $ (17) | $ (439,295) | $ (708) | $ 104,933 | $ (254) | $ 104,679 |
| Net loss | — | — | — | — | — | — | (6,927) | — | (6,927) | — | (6,927) |
| Share-based compensation | — | — | 19 | — | 708 | — | — | — | 708 | — | 708 |
| Unrealized loss on marketable securities | — | — | — | — | — | (47) | — | — | (47) | — | (47) |
| **Balance at September 30, 2021** | — | $ — | 3,986 | $ 4 | $ 545,657 | $ (64) | $ (446,222) | $ (708) | $ 98,667 | $ (254) | $ 98,413 |

| | Series B Convertible Preferred Stock | | Common Stock | | Additional Paid-in Capital | Accumulated Other Comprehensive Income (Loss) | Accumulated Deficit | Treasury Stock | Total Lisata Therapeutics, Inc. Stockholders' Equity | Non-Controlling Interest in Subsidiary | Total Equity |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | | | | | | | |
| **Balance at December 31, 2020** | — | $ — | 1,292 | $ 1 | $ 458,766 | $ (13) | $ (425,550) | $ (708) | $ 32,496 | $ (254) | $ 32,242 |
| Net loss | — | — | — | — | — | — | (20,672) | — | (20,672) | — | (20,672) |
| Share-based compensation | — | — | 36 | — | 1,391 | — | — | — | 1,391 | — | 1,391 |
| Net proceeds from issuances of common stock and warrants | — | — | 2,658 | 3 | 85,476 | — | — | — | 85,479 | — | 85,479 |
| Proceeds from option exercises | — | — | — | — | 24 | — | — | — | 24 | — | 24 |
| Unrealized loss on marketable securities | — | — | — | — | — | (51) | — | — | (51) | — | (51) |
| **Balance at September 30, 2021** | — | $ — | 3,986 | $ 4 | $ 545,657 | $ (64) | $ (446,222) | $ (708) | $ 98,667 | $ (254) | $ 98,413 |

See accompanying notes to consolidated financial statements.

**LISATA THERAPEUTICS, INC. AND SUBSIDIARIES**
**CONSOLIDATED STATEMENTS OF CASH FLOWS**
**(Unaudited)**
(In thousands)

| | Nine Months Ended September 30, | |
|---|---|---|
| | **2022** | **2021** |
| Cash flows from operating activities: | | |
| Net loss | $ (48,235) | $ (20,672) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Share-based compensation | 2,168 | 1,639 |
| Depreciation and amortization | 22 | 47 |
| In process research and development expenses | 30,393 | — |
| Accretion on marketable securities | 893 | 1,925 |
| Changes in operating assets and liabilities: | | |
| Prepaid and other current assets | 29 | (1,199) |
| Other assets | 178 | 252 |
| Accounts payable, accrued liabilities and other liabilities | (150) | 367 |
| Net cash used in operating activities | (14,702) | (17,641) |
| Cash flows from investing activities: | | |
| Purchase of marketable securities | (68,481) | (137,329) |
| Sale of marketable securities | 93,865 | 66,035 |
| Asset acquisition costs, net of cash acquired related to merger with Cend | (3,320) | — |
| Purchase of property and equipment | (259) | (60) |
| Net cash provided by (used in) investing activities | 21,805 | (71,354) |
| Cash flows from financing activities: | | |
| Proceeds from exercise of options | — | 24 |
| Tax withholding payments on net share settlement equity awards | (267) | (248) |
| Net proceeds from issuance of common stock | 29 | 85,479 |
| Net cash (used in) provided by financing activities | (238) | 85,255 |
| Effect of exchange rate changes on cash | (34) | — |
| Net increase (decrease) in cash and cash equivalents | 6,831 | (3,740) |
| Cash and cash equivalents at beginning of period | 24,647 | 16,512 |
| Cash and cash equivalents at end of period | $ 31,478 | $ 12,772 |
| | | |
| **Supplemental disclosure of noncash investing activities:** | | |
| Issuance of common stock in connection with merger | $ 23,580 | $ — |
| Incremental fair value of Cend's fully vested stock options assumed | $ 2,136 | $ — |

See accompanying notes to consolidated financial statements.

**LISATA THERAPEUTICS, INC. AND SUBSIDIARIES**

**NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS**

## Note 1 – The Business

***Overview***

Lisata Therapeutics, Inc. (together with its subsidiaries, "we," "us," "our," "Lisata" or the "Company") is a clinical-stage pharmaceutical company dedicated to the discovery, development and commercialization of innovative therapies for the treatment of solid tumors and other major diseases. Lisata's lead investigational product candidate, LSTA1 (formerly known as CEND-1), is designed to activate a novel uptake pathway that allows anti-cancer drugs to penetrate solid tumors more effectively. LSTA1 actuates this active transport system in a tumor-specific manner, resulting in systemically co-administered anti-cancer drugs more efficiently penetrating and accumulating in the tumor, while normal tissues are not affected. LSTA1 also has the potential to modify the tumor microenvironment ("TME"), making tumors more susceptible to immunotherapies. LSTA1 has demonstrated favorable safety, tolerability, and activity to date in completed and ongoing clinical trials to enhance delivery of standard-of-care chemotherapy for pancreatic cancer. Lisata and its collaborators have also amassed significant non-clinical data demonstrating enhanced delivery of a range of emerging anti-cancer therapies, including immunotherapies and RNA-based therapeutics. Lisata is exploring the potential of LSTA1 to enable a variety of treatment modalities to treat a range of solid tumors more effectively. In addition, Lisata also has clinical development programs based on its autologous CD34+ cell therapy technology platform.

The Company's leadership team has decades of collective biopharmaceutical and pharmaceutical product development experience across a variety of therapeutic categories and at all stages of development from preclinical through to product registration and launch. Its goal is to develop and commercialize products that address important unmet medical needs based on a broad and versatile portfolio of candidates. The Company's current product candidates include:

- LSTA1, the subject of phase 1b/2a and 2b clinical studies being conducted globally in a variety of solid tumor types, including metastatic pancreatic ductal adenocarcinoma (mPDAC), in combination with a variety of anti-cancer regimens;

- XOWNA® (LSTA16 formerly CLBS16), the subject of both a completed positive Phase 2a study (ESCaPE-CMD) and follow on Phase 2b study (FREEDOM Trial) in the United States for the treatment of coronary microvascular dysfunction ("CMD");

- HONEDRA® (LSTA12 formerly CLBS12), recipient of SAKIGAKE designation, pursuant to which early conditional approval in Japan for the treatment of critical limb ischemia ("CLI") and Buerger's disease is being sought based on the current results of a clinical trial executed in Japan. HONEDRA® was the recipient of orphan drug designation in March 2021 from the U.S. Food and Drug Administration ("FDA") for Buerger's disease; and

- LSTA201 (formerly CLBS201), the subject of a study designed to assess the safety and efficacy of CD34+ cell therapy as a regenerative treatment for patients with chronic kidney disease related to type 2 diabetes (diabetic kidney disease or "DKD").

***Merger with Cend Therapeutics, Inc. and Name Change***

On September 15, 2022, the Company, then operating as Caladrius Biosciences, Inc. ("Caladrius"), completed its acquisition of Cend Therapeutics, Inc. ("Cend"), a Delaware corporation (the "Merger"), in accordance with the terms of the Agreement and Plan of Merger and Reorganization (the "Merger Agreement"), dated as of April 26, 2022, by and among Caladrius, Cend and CS Cedar Merger Sub, Inc. ("Merger Sub").

Pursuant to the terms set forth in the Merger Agreement and effective September 15, 2022 (the "Effective Time"): (i) Merger Sub merged with and into Cend, with Cend surviving as a wholly owned subsidiary of Caladrius, (ii) Caladrius changed its name to Lisata Therapeutics, Inc. in connection with and immediately following to the Effective Time, and (iii) Caladrius effected a 1:15 reverse stock split of its common stock ("Reverse Stock Split") prior to the Effective Time. At the Effective Time, each share of Cend's common stock outstanding immediately prior to the Effective Time was converted into the right to receive shares of Lisata's common stock based on an exchange ratio of 0.5338 (the "Exchange Ratio"), after taking into account the Reverse Stock Split. In connection with the Merger close, the Company issued an aggregate of 3,772,768 shares of common stock, based on the Exchange Ratio, to holders of Cend, in exchange for all of the Cend capital stock outstanding immediately prior to the closing of the Merger.

Pursuant to the Merger Agreement, Lisata assumed all of the outstanding and unexercised options to purchase shares of Cend capital stock under the 2016 Equity Incentive Plan (the "Cend Plan"), and, in connection with the Merger, such options were converted into options to purchase shares of Lisata's common stock based on the Exchange Ratio. At the closing of the Merger at the Effective Time, the Company assumed Cend's stock options to purchase an aggregate of 1,227,776 shares of the Company's common stock.

Caladrius was considered to be the accounting acquirer based on the terms of the Merger Agreement and certain factors including: (i) Caladrius owned approximately 52% of the Company's outstanding shares of common stock immediately following the close of the Merger; (ii) although both entities contributed to the new management team of Lisata, the Caladrius team has more individuals on the management team and will hold the CEO, CMO and other senior management roles; (iii) Caladrius paid a premium to acquire Cend's assets; and (iv) Caladrius was significantly larger than Cend regarding total assets, operations, and research and development activities. The Merger was accounted for as an asset acquisition as substantially all of the fair value is concentrated in in-process research and development ("IPR&D"). Cend's assets (except for cash and working capital) were measured and recognized as an allocation of the transaction price based on their relative fair values as of the transaction date with any value associated with IPR&D with no alternative future use being expensed as reported in the consolidated statement of operations. The prior reported operating results prior to the Merger close are those of Caladrius alone.

***Coronavirus Considerations***

In December 2019, a novel strain of coronavirus (SARS-CoV-2), which causes COVID-19, was reported to have surfaced in China. In March 2020, the World Health Organization declared the outbreak of COVID-19 to be a pandemic, and the world's economies began to experience pronounced effects. Despite the FDA approval of multiple COVID-19 vaccines in late 2020, there remains uncertainty around the extent and duration of disruption and any future related financial impact cannot reasonably be estimated at this time. In response to the COVID-19 pandemic, the Company implemented a universal work from home policy as well as stringent social distancing and other hygiene policies for employees when they must be in the office. The Company's clinical study of HONEDRA® in Japan experienced significant delays in enrollment due to the States of Emergency in effect in Japan for most of 2020, 2021, and 2022 covering Tokyo and other regions in response to an increased number of COVID-19 infections. With the Company's expectation that COVID-19 in Japan will continue to impact negatively clinical site operations and enrollment of patients in the HONEDRA® clinical trial, it elected to suspend trial enrollment, seek a development partner and consult with the Japanese regulatory authorities regarding the submission of patient data already accrued. Caladrius' phase 2b FREEDOM Trial of XOWNA® in the U.S. has also experienced delays in enrolling patients as a result of COVID-19. While early enrollment proceeded to plan with the first patient treated in January 2021, the impact of the COVID-19 pandemic contributed to a general slowing of enrollment, including supply chain disruptions affecting the availability of qualified catheters used in the diagnosis of CMD and/or administration of XOWNA® as well as with a contrast agent typically used in many catheter laboratories. In May 2022, the Company announced that enrollment in the FREEDOM Trial had been suspended and that it intended to conduct an interim analysis of the data from not less than the first 20 patients enrolled using the 6-month follow-up data to evaluate the efficacy and safety of XOWNA® in subjects with CMD. Following the analysis of results of the FREEDOM Trial subjects completing 6-month follow-up along with Key Opinion Leaders' input, the Company's board of directors determined that execution of a redesigned FREEDOM-like trial would be the appropriate next step, but the cost of such a trial would be prohibitively expensive to undergo without a strategic partner. Accordingly, the Company's board of directors concluded that XOWNA® development will only be continued if a strategic partner that can contribute the necessary capital for a redesigned trial is identified and secured. There can be no assurance that we will be able to identify such a partner and enter into an agreement with such partner on acceptable terms or at all.

***Reverse Stock Split***

On September 14, 2022, in connection with the Merger, the Company implemented the Reverse Stock Split, as authorized at the annual meeting of stockholders on September 13, 2022. The Reverse Stock Split became effective on September 14, 2022 at 5:00 pm and the Company's common stock began trading on The Nasdaq Capital Market on a post-split basis at the open of business on September 15, 2022. As of September 14, 2022, every fifteen shares of the Company's issued and outstanding common stock (and such shares held in treasury) were automatically converted into one share of common stock, without any change in the par value per share. In addition, proportionate adjustments were made to the per share exercise price and the number of shares issuable upon the exercise of all outstanding stock options, stock appreciation rights, convertible notes and warrants to purchase shares of common stock, the number of shares issuable upon the vesting of all restricted stock awards, and the number of shares of common stock reserved for issuance pursuant to the Company's equity incentive compensation plans. Any stockholder who would otherwise be entitled to a fractional share of common stock created as a result of the Reverse Stock Split received a cash payment equal to the product of such resulting fractional interest in one share of common stock multiplied by the closing trading price of the common stock on September 15, 2022. The Reverse Stock Split was effectuated in order to

increase the per share trading price of our common stock to satisfy the $1.00 minimum bid price requirement for continued listing on The Nasdaq Capital Market.

All share and per share amounts of common stock, options and warrants in the accompanying financial statements have been restated for all periods presented to give retroactive effect to the Reverse Stock Split. Accordingly, the consolidated statements of equity reflect the impact of the Reverse Stock Split by reclassifying from “common stock” to “additional paid-in capital” in an amount equal to the par value of the decreased shares resulting from the Reverse Stock Split.

***Basis of Presentation***

The accompanying unaudited Consolidated Financial Statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“GAAP”) for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X of the SEC for interim financial information. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, the accompanying Consolidated Financial Statements of the Company and its subsidiaries, which are unaudited, include all normal and recurring adjustments considered necessary to present fairly the Company’s financial position as of September 30, 2022, and the results of its operations and its cash flows for the periods presented. The unaudited consolidated financial statements herein should be read together with the historical consolidated financial statements of the Company for the years ended December 31, 2021 and 2020 included in our 2021 Form 10-K. Operating results for the three and nine months ended September 30, 2022 are not necessarily indicative of the results that may be expected for the year ending December 31, 2022.

***Use of Estimates***

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements. Estimates also affect the reported amounts of expenses during the reporting period. The Company bases its estimates on historical experience and other assumptions believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. The Company makes critical estimates and assumptions in determining stock-based awards values and the valuation of the Merger which was accounted for as an asset acquisition as substantially all of the fair value is concentrated in in-process research and development (“IPR&D”). Accordingly, actual results could differ from those estimates and assumptions.

***Principles of Consolidation***

The Consolidated Financial Statements include the accounts of Lisata and its wholly owned and majority owned subsidiaries and affiliates. All intercompany activities have been eliminated in consolidation.

***Foreign Currency Remeasurement***

The Company’s reporting currency is the U.S. Dollar. The functional currency of DrugCendR Australia PTY Ltd. which is a foreign subsidiary of the Company is the Australian Dollar. The assets and liabilities of DrugCendR Australia PTY Ltd. are translated into U.S. Dollars at the exchange rates in effect at each balance sheet date, and the results of operations are translated using the average exchange rates prevailing throughout the reporting period. Adjustments resulting from translating foreign functional currency financial statements into U.S. Dollars are included in the foreign currency translation adjustment, a component of accumulated other comprehensive income (loss) in stockholders' equity.

## Note 2 – Summary of Significant Accounting Policies

***Cash and Cash Equivalents***

Cash and cash equivalents include short-term, highly liquid, investments with maturities of ninety days or less when purchased.

***Concentration of Risks***

The Company is subject to credit risk from its portfolio of cash, cash equivalents and marketable securities. Under its investment policy, the Company limits amounts invested in such securities by credit rating, maturity, industry group, investment type and issuer, except for securities issued by the U.S. government. Cash is held at major banks in the United States and Australia. Therefore, the Company is not exposed to any significant concentrations of credit risk from these financial instruments. The goals of the Company's investment policy, in order of priority, are as follows: safety and preservation

of principal and diversification of risk, liquidity of investments sufficient to meet cash flow requirements, and a competitive after-tax rate of return.

***Marketable Securities***

The Company determines the appropriate classification of its marketable securities at the time of purchase and reevaluates such designation at each balance sheet date. All of the Company's marketable securities are considered as available-for-sale and carried at estimated fair values and reported in cash equivalents and marketable securities. Unrealized gains and losses on available-for-sale securities are excluded from net income and reported in accumulated other comprehensive income (loss) as a separate component of stockholders' equity. Other income (expense), net includes interest, dividends, amortization of purchase premiums and discounts, realized gains and losses on sales of securities and other-than-temporary declines in the fair value of securities, if any. The cost of securities sold is based on the specific identification method. The Company regularly reviews all of its investments for other-than-temporary declines in fair value. The Company's review includes the consideration of the cause of the impairment, including the creditworthiness of the security issuers, the number of securities in an unrealized loss position, the severity and duration of the unrealized losses, whether the Company has the intent to sell the securities and whether it is more likely than not that it will be required to sell the securities before the recovery of their amortized cost basis. When the Company determines that the decline in fair value of an investment is below its accounting basis and this decline is other-than-temporary, it reduces the carrying value of the security it holds and records a loss for the amount of such decline.

***Property and Equipment***

The cost of property and equipment is depreciated over the estimated useful lives of the related assets. Depreciation is computed on the straight-line method. Repairs and maintenance expenditures that do not extend original asset lives are charged to expense as incurred. The estimated useful lives of property and equipment are as follows:

| | |
|---|---|
| Furniture and fixtures | 10 years |
| Computer equipment | 3 years |
| Software | 3 years |
| Leasehold improvements | Life of lease |

***Long-lived Assets***

Long-lived assets consist of property and equipment and intangibles. The assets are amortized on a straight line basis over their respective useful lives. The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset exceeds the fair value of the asset. If other events or changes in circumstances indicate that the carrying amount of an asset that the Company expects to hold and use may not be recoverable, the Company will estimate the undiscounted future cash flows expected to result from the use of the asset and/or its eventual disposition, and recognize an impairment loss, if any. The impairment loss, if determined to be necessary, would be measured as the amount by which the carrying amount of the assets exceeds the fair value of the assets.

***Share-Based Compensation***

The Company expenses all share-based payment awards to employees, directors, and consultants, including grants of stock options, warrants, and restricted stock, over the requisite service period based on the grant date fair value of the awards. Consultant awards are remeasured each reporting period through vesting. For awards with performance-based vesting criteria, the Company estimates the probability of achievement of the performance criteria and recognizes compensation expense related to those awards expected to vest. The Company determines the fair value of option awards using the Black-Scholes option-pricing model which uses both historical and current market data to estimate the fair value. This method incorporates various assumptions such as the risk-free interest rate, expected volatility, expected dividend yield and expected life of the options or warrants. Stock based compensation expense also includes an estimate, which is made at the time of the grant, of the number of awards that are expected to be forfeited. The fair value of the Company’s restricted stock and restricted stock units is based on the closing market price of the Company’s common stock on the date of grant.

***Loss Per Share***

Basic loss per share is based on the weighted effect of all common shares issued and outstanding and is calculated by dividing net loss attributable to common stockholders by the weighted average shares outstanding during the period. Diluted loss per share is calculated by dividing net loss attributable to common stockholders by the weighted average number of common shares used in the basic loss per share calculation plus the number of common shares that would be issued assuming conversion of all potentially dilutive securities outstanding. Diluted loss per share is not presented as such potentially dilutive securities are anti-dilutive to losses incurred in all periods presented.

***Treasury Stock***

Treasury stock purchases are accounted for under the cost method whereby the entire cost of the acquired stock is recorded as treasury stock. Gains or losses on the subsequent reissuance of shares are credited or charged to additional paid in capital.

***Research and Development Costs***

Research and development ("R&D") expenses include salaries, benefits, and other headcount related costs, clinical trial and related clinical manufacturing costs, contract and other outside service fees including sponsored research agreements, and facilities and overhead costs. The Company expenses the costs associated with research and development activities when incurred.

To further drive the Company's initiatives, the Company will continue targeting key governmental agencies, congressional committees and not-for-profit organizations to contribute funds for the Company's research and development programs. The Company accounts for such grants as a deduction to the related expense in research and development operating expenses when earned.

***In-process Research and Development Expense***

Upfront payments that relate to the acquisition of a new drug compound, as well as pre-commercial milestone payments, are immediately expensed as IPR&D in the period in which they are incurred, provided that the new drug compound did not also include processes or activities that would constitute a "business" as defined under GAAP, the drug has not achieved regulatory approval for marketing and, absent obtaining such approval, has no established alternative future use. The Company accounts for contingent consideration payable upon achievement of certain regulatory, development or sales milestones in such asset acquisitions when the underlying contingency is probable and estimable. Milestone payments made to third parties subsequent to regulatory approval will be capitalized as intangible assets and amortized over the estimated remaining useful life of the related product.

***Intangible Asset***

The Company's intangible asset consists of a single asset, Cend's license agreement with Qilu Pharmaceutical, Co., Ltd. ("Qilu") acquired in the Merger, with a value of $0.4 million. The intangible asset is stated at fair value and is amortized using the straight-line method over its estimated useful life of 5 years. Amortization expense was $3 thousand for the three and nine months ended September 30, 2022. The intangible asset is reviewed for potential impairment when events or circumstances indicate that carrying amounts may not be recoverable. The projected amortization expense is $71 thousand per year for the next five years.

***Revenue Recognition***

The Company evaluates license and collaboration arrangements to determine whether units of account within the arrangement exhibit the characteristics of a vendor and customer relationship. For arrangements and units of account where a customer relationship exists, the Company applies the revenue recognition guidance. The Company recognizes revenue upon the transfer of promised goods or services to customers in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services. To determine revenue recognition for contracts with customers the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies the performance obligations. At contract inception, the Company assesses the goods or services promised within each contract and assesses whether each promised good or service is distinct and determines those that are performance obligations. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. Taxes imposed by governmental authorities on the Company's revenue, such as sales taxes and withholding taxes, are excluded from net revenue.

If a license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from non-refundable, upfront fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. If licenses are bundled with other performance obligations, the Company would utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. There was no revenue recognized for the three and nine months ended September 30, 2022.

***Milestones***

At the inception of each arrangement that includes milestone payments (variable consideration), the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company or the Company's collaboration partner's control, such as regulatory approvals, are generally not considered probable of being achieved until those approvals are received. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of such milestones and any related constraint, and if necessary, adjusts the Company's estimate of the overall transaction price. Any such adjustments are allocated on a cumulative catch-up basis to satisfied and partially satisfied performance obligations, with the consideration allocated to an ongoing performance obligation being recognized over the period of performance.

***Royalties***

For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and for which the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, the Company has not recognized any royalty revenue from any collaborative arrangement.

## Note 3 – Merger

The Merger was accounted for as an asset acquisition as substantially all of the fair value was concentrated in IPR&D. Cend's assets (except for cash and working capital) were measured and recognized as an allocation of the transaction price based on their relative fair values as of the transaction date with any value associated with IPR&D being expensed. The fair value of total consideration was $36.1 million. The following table is a summary of the purchase price calculation (in thousands except per share data).

| | |
|---|---|
| Number of common shares of the combined company owned by Cend stockholders | 3,772,768 |
| Multiplied by the fair value per share of Lisata common stock on September 15, 2022 | $6.25 |
| Total | $23,580 |
| Carrying value of Lisata's cost method investment in Cend | 10,000 |
| Incremental fair value of Cend's fully vested stock options | 2,136 |
| Lisata transaction costs | 382 |
| Total purchase price | $36,098 |

The allocation of the purchase price was as follows (amounts in thousands):

| | |
|---|---|
| Cash and cash equivalents | $7,062 |
| Net working capital (excluding cash) | (1,690) |
| Other liabilities | (22) |
| Acquired in-process research and development | 30,393 |
| License | 355 |
| Net assets acquired | $36,098 |

## Note 4 – Available-for-Sale-Securities

The following table is a summary of available-for-sale securities recorded in cash and cash equivalents or marketable securities in our Consolidated Balance Sheets (in thousands):

| | September 30, 2022 | | | | December 31, 2021 | | | |
|---|---|---|---|---|---|---|---|---|
| | Cost | Gross Unrealized Gains | Gross Unrealized Losses | Estimated Fair Value | Cost | Gross Unrealized Gains | Gross Unrealized Losses | Estimated Fair Value |
| Corporate debt securities | $ 39,311 | $ — | $ (65) | $ 39,246 | $ 53,135 | $ — | $ (65) | $ 53,070 |
| Commercial paper | 14,459 | — | — | 14,459 | — | — | — | — |
| Money market funds | 13,457 | — | — | 13,457 | 18,124 | — | — | 18,124 |
| Municipal debt securities | 170 | — | — | 170 | 20,263 | — | (5) | 20,258 |
| Total | $ 67,397 | $ — | $ (65) | $ 67,332 | $ 91,522 | $ — | $ (70) | $ 91,452 |

Estimated fair values of available-for-sale securities are generally based on prices obtained from commercial pricing services. The following table summarizes the classification of the available-for-sale securities in our Consolidated Balance Sheets (in thousands):

| | September 30, 2022 | December 31, 2021 |
|---|---|---|
| Cash equivalents | $ 23,280 | $ 21,129 |
| Marketable securities | 44,052 | 70,323 |
| Total | $ 67,332 | $ 91,452 |

The following table summarizes our portfolio of available-for-sale securities by contractual maturity (in thousands):

| | September 30, 2022 | |
|---|---|---|
| | Amortized Cost | Estimated Fair Value |
| Less than one year | $ 67,397 | $ 67,332 |
| Greater than one year | — | — |
| Total | $ 67,397 | $ 67,332 |

## Note 5 – Income (Loss) Per Share

For the nine months ended September 30, 2022 and 2021, the Company incurred net losses and therefore no common stock equivalents were utilized in the calculation of diluted loss per share as they are anti-dilutive. At September 30, 2022 and 2021, the Company excluded the following potentially dilutive securities (in thousands):

| | September 30, | |
|---|---|---|
| | 2022 | 2021 |
| Stock Options | 1,399 | 142 |
| Warrants | 1,424 | 1,424 |
| Restricted Stock Units | 48 | 53 |

## Note 6 – Fair Value Measurements

The fair value of financial assets and liabilities that are being measured and reported are defined as the exchange price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants in the principal market at the measurement date (exit price). The Company is required to classify fair value measurements in one of the following categories:

Level 1 inputs are defined as quoted prices (unadjusted) in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date.

Level 2 inputs are defined as inputs other than quoted prices included within Level 1 that are observable for the assets or liabilities, either directly or indirectly.

Level 3 inputs are defined as unobservable inputs for the assets or liabilities. Financial assets and liabilities are classified based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement requires judgment and may affect the valuation of the fair value of assets and liabilities and their placement within the fair value hierarchy levels.

The following table sets forth by level within the fair value hierarchy the Company's financial assets that were accounted for at fair value on a recurring basis as of September 30, 2022 and December 31, 2021 (in thousands).

| | September 30, 2022 | | | | December 31, 2021 | | | |
|---|---|---|---|---|---|---|---|---|
| | Level 1 | Level 2 | Level 3 | Total | Level 1 | Level 2 | Level 3 | Total |
| Assets: | | | | | | | | |
| Marketable securities - available for sale | $ — | $ 44,052 | $ — | $ 44,052 | $ — | $ 70,323 | $ — | $ 70,323 |
| | $ — | $ 44,052 | $ — | $ 44,052 | $ — | $ 70,323 | $ — | $ 70,323 |

## Note 7 – Accrued Liabilities

Accrued liabilities as of September 30, 2022 and December 31, 2021 were as follows (in thousands):

| | September 30, 2022 | December 31, 2021 |
|---|---|---|
| Salaries, employee benefits and related taxes | $ 2,147 | $ 2,034 |
| Operating lease liabilities — current | 203 | 229 |
| Clinical and R&D related liabilities | 2,338 | — |
| Other | 729 | 326 |
| Total | $ 5,417 | $ 2,589 |

## Note 8 – Operating Leases

The Company has operating leases for two offices with terms that expire in 2023 and 2025, respectively. The Company estimates its incremental borrowing rate at lease commencement to determine the present value of lease payments as most of the Company's leases do not provide an implicit rate of return. The Company recognizes lease expense on a straight-line basis over the lease term. For lease agreements entered into or reassessed after the adoption of Topic 842, the Company elected to account for non-lease components associated with its leases and lease components as a single lease component. Each of the Company's leases includes options for the Company to extend the lease term and/or sub-lease space in whole or in part.

Operating lease liabilities and right-of-use assets were recorded in the following captions of our balance sheet were as follows (in thousands):

| | September 30, 2022 | December 31, 2021 |
|---|---|---|
| Right-of Use Assets: | | |
| Other assets | $ 548 | $ 724 |
| Total Right-of-Use Asset | $ 548 | $ 724 |
| | | |
| Operating Lease Liabilities: | | |
| Accrued liabilities | $ 203 | $ 229 |
| Other long-term liabilities | 345 | 485 |
| Total Operating Lease Liabilities | $ 548 | $ 714 |

As of September 30, 2022, the weighted average remaining lease term for our operating leases was 1.8 years, and the weighted average discount rate for our operating leases was 9.625%. Future minimum lease payments under the lease agreements as of September 30, 2022 were as follows (in thousands):

| Years ended | Operating Leases |
|---|---|
| 2022 | 75 |
| 2023 | 217 |
| 2024 | 190 |
| 2025 | 143 |
| Total lease payments | 625 |
| Less: Amounts representing interest | (77) |
| Present value of lease liabilities | $ 548 |

**Note 9 – Stockholders' Equity**

***Reverse Stock Split***

On September 14, 2022, in connection with the merger, we implemented the Reverse Stock Split, as described in Note 1. All share and per share amounts of common stock, options and warrants in the accompanying financial statements have been restated for all periods presented to give retroactive effect to the Reverse Stock Split. Accordingly, the consolidated statements of equity reflect the impact of the Reverse Stock Split by reclassifying from “common stock” to “additional paid-in capital” in an amount equal to the par value of the decreased shares resulting from the Reverse Stock Split.

***Equity Issuances***

Purchase Agreement

In March 2019, the Company and Lincoln Park Capital Fund, LLC (“Lincoln Park”) entered into a purchase agreement (the “Purchase Agreement”) and a registration rights agreement (the “Registration Rights Agreement”), pursuant to which the Company has the right to sell to Lincoln Park shares of the Company’s common stock having an aggregate value of up to $26.0 million, subject to certain limitations and conditions set forth in the Purchase Agreement (the “Offering”). As consideration for entering into the Purchase Agreement, the Company issued to Lincoln Park an additional 181,510 shares of common stock as commitment shares.

Pursuant to the Purchase Agreement, Lincoln Park purchased 250,000 shares of common stock, at a price of $4.00 per share, for a total gross purchase price of $1.0 million (the “Initial Purchase”) upon commencement. Thereafter, as often as every business day from and after one business day following the date of the Initial Purchase and over the 36-month term of the Purchase Agreement, the Company has the right, from time to time, at its sole discretion and subject to certain conditions, to direct Lincoln Park to purchase up to 100,000 shares of common stock, with such amount increasing as the closing sale price of the common stock increases; provided Lincoln Park’s obligation under any single such purchase will not exceed $2.5 million, unless the Company and Lincoln Park mutually agree to increase the maximum amount of such single purchase (each, a “Regular Purchase”). If the Company directs Lincoln Park to purchase the maximum number of shares of common stock it then may sell in a Regular Purchase, then in addition to such Regular Purchase, and subject to certain conditions and limitations in the Purchase Agreement, the Company may direct Lincoln Park in an “accelerated purchase” to purchase an additional amount

of common stock that may not exceed the lesser of (i) 300% the number of shares purchased pursuant to the corresponding Regular Purchase or (ii) 30% of the total number of shares of the Company's common stock traded during a specified period on the applicable purchase date as set forth in the Purchase Agreement. Under certain circumstances and in accordance with the Purchase Agreement, the Company may direct Lincoln Park to purchase shares in multiple accelerated purchases on the same trading day.

The Company controls the timing and amount of any sales of its common stock to Lincoln Park. There is no upper limit on the price per share that Lincoln Park must pay for its common stock under the Purchase Agreement, but in no event will shares be sold to Lincoln Park on a day the closing price is less than the floor price specified in the Purchase Agreement. In all instances, the Company may not sell shares of its common stock to Lincoln Park under the purchase agreement if it would result in Lincoln Park beneficially owning more than 9.99% of its common stock.

The Purchase Agreement does not limit the Company's ability to raise capital from other sources at the Company's sole discretion, except that (subject to certain exceptions) the Company may not enter into any Variable Rate Transaction (as defined in the Purchase Agreement, including the issuance of any floating conversion rate or variable priced equity-like securities) during the 36 months after the date of the Purchase Agreement. The Company has the right to terminate the Purchase Agreement at any time, at no cost to the Company.

As of September 30, 2022, the Company had not made any sales of common stock to Lincoln Park under the Purchase Agreement other than the Initial Purchase. The agreement expired on April 1, 2022.

At The Market Offering Agreement

On June 4, 2021, the Company entered into an At The Market Offering Agreement (the "ATM Agreement") with H.C. Wainwright & Co., LLC, as sales agent, in connection with an "at the market offering" under which the Company from time to time may offer and sell shares of its common stock, having an aggregate offering price of up to $50.0 million. During the nine months ended September 30, 2022 and since inception, the Company has not issued any shares under the ATM Agreement.

Common Stock

In connection with the Merger close, the Company issued an aggregate of 3,772,768 shares of common stock, based on the Exchange Ratio, to holders of Cend, in exchange for all of the Cend capital stock outstanding immediately prior to the closing of the Merger.

***Stock Options and Warrants***

In connection with the Merger and after giving effect to the Reverse Stock Split, the Company assumed 1,227,776 options outstanding from Cend. The options granted from the Cend Plan are exercisable at various dates as determined upon grant and will expire no more than ten years from their original date of grant. The Cend Plan stock options generally vest over a four-year term. The following table summarizes the activity for stock options and warrants for the nine months ended September 30, 2022:

| | Stock Options | | | | Warrants | | | |
|---|---|---|---|---|---|---|---|---|
| | Shares | Weighted Average Exercise Price | Weighted Average Remaining Contractual Term (Years) | Aggregate Intrinsic Value (In Thousands) | Shares | Weighted Average Exercise Price | Weighted Average Remaining Contractual Term (Years) | Aggregate Intrinsic Value (In Thousands) |
| Outstanding at December 31, 2021 | 142,041 | $ 84.60 | 7.97 | $ — | 1,423,774 | $ 42.57 | 4.37 | $ — |
| Changes during the period: | | | | | | | | |
| Granted | 37,458 | 13.49 | | | — | — | | |
| Assumed through merger | 1,227,776 | 3.77 | | | — | — | | |
| Exercised | — | — | | | — | — | | |
| Forfeited | (2,910) | 19.96 | | | — | — | | |
| Expired | (5,388) | 352.31 | | | — | — | | |
| Outstanding at September 30, 2022 | 1,398,977 | $ 10.83 | 7.30 | $ — | 1,423,774 | $ 42.57 | 3.63 | $ — |
| Vested at September 30, 2022 or expected to vest in the future | 1,396,921 | $ 10.83 | 7.30 | $ — | 1,423,774 | $ 42.57 | 3.63 | $ — |
| Vested at September 30, 2022 | 1,110,635 | $ 11.82 | 6.97 | $ — | 1,423,774 | $ 42.57 | 3.63 | $ — |

***Restricted Stock***

During the nine months ended September 30, 2022 and 2021, the Company issued restricted stock for services as follows ($ in thousands):

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2022 | 2021 |
| Number of restricted stock issued | 70,740 | 40,863 |
| Value of restricted stock issued | $ 973 | $ 878 |

The vesting terms of restricted stock issuances are generally between one and four years.

***Restricted Stock Units***

During the nine months ended September 30, 2022 and 2021, the Company issued restricted stock units for services as follows ($ in thousands, except share data):

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2022 | 2021 |
| Number of restricted stock units issued | 111,170 | 30,549 |
| Value of restricted stock units issued | $ 1,386 | $ 729 |

The weighted average estimated fair value of restricted stock issued for services in the nine months ended September 30, 2022 and 2021 was $12.46 and $23.85 per share, respectively. The fair value of the restricted stock units was determined using the Company's closing stock price on the date of issuance. The vesting terms of restricted stock unit issuances are generally one year, or upon the achievement of performance-based milestones.

## Note 10 – Share-Based Compensation

***Share-Based Compensation***

We utilize share-based compensation in the form of stock options, restricted stock, and restricted stock units. The following table summarizes the components of share-based compensation expense for the three and nine months ended September 30, 2022 and 2021 (in thousands):

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2022 | 2021 | 2022 | 2021 |
| Research and development | $ 271 | $ 523 | $ 631 | $ 64 |
| General and administrative | 769 | 250 | 1,537 | 99 |
| Total share-based compensation expense | $ 1,040 | $ 773 | $ 2,168 | $ 1,63 |

Total compensation cost related to non-vested awards not yet recognized and the weighted-average periods over which the awards were expected to be recognized at September 30, 2022 were as follows (in thousands):

| | Stock Options | Restricted Stock Units | Restricted Stock |
|---|---|---|---|
| Unrecognized compensation cost | $ 1,577 | $ 168 | $ 722 |
| Expected weighted-average period in years of compensation cost to be recognized | 1.66 | 2.16 | 1.83 |

Total fair value of shares vested and the weighted average estimated fair values of shares granted for the nine months ended September 30, 2022 and 2021 were as follows (in thousands):

| | Stock Options | |
|---|---|---|
| | Nine Months Ended September 30, | |
| | 2022 | 2021 |
| Total fair value of shares vested | $ 853 | $ 757 |
| Weighted average estimated fair value of shares granted | $ 1.23 | $ 13.59 |

***Valuation Assumptions***

The fair value of stock options and warrants at the date of grant was estimated using the Black-Scholes option pricing model. The expected volatility is based upon historical volatility of the Company's common stock. The expected term for the options is based upon observation of actual time elapsed between date of grant and exercise of options for all employees. The expected term for the warrants is based upon the contractual term of the warrants.

## Note 11 – Income Taxes

In assessing the realizability of deferred tax assets, including the net operating loss carryforwards ("NOLs"), the Company assesses the available positive and negative evidence to estimate if sufficient future taxable income will be generated to utilize its existing deferred tax assets. Based on its assessment, the Company has provided a full valuation allowance against its net deferred tax assets as their future utilization remains uncertain at this time.

As of December 31, 2021 and 2020, the Company had approximately $281 million and $264 million, respectively, of federal NOLs available to offset future taxable income expiring from 2030 through 2036. The Company performed an analysis and determined that it had an ownership change of greater than 50% over a 3-year testing period on January 25, 2021. As a result, $169 million of the $281 million of federal NOLs will expire unutilized. The Company wrote off that portion of the deferred tax asset and reduced the corresponding valuation allowance resulting in $112 million of remaining federal NOL. The write off of the deferred tax asset and the corresponding reduction in valuation allowance has no impact to the balance sheet or income statement. Losses incurred before the ownership change on January 25, 2021 will be subject to an annual limitation of $173 thousand under Internal Revenue Code Section 382, while losses incurred after January 25, 2021 will not be subject to limitations. The Company may be able to utilize additional NOLs of approximately $1.1 million per year for the first five years after this ownership change as a result of the application of the Net Unrealized Built-in Gain rules.

As of December 31, 2021 and 2020, the Company had state NOLs available in New Jersey of $97 million and $99 million, respectively, California of $70 million and $70 million, respectively, and New York City of $13 million and $13 million, respectively, to offset future taxable income expiring from 2031 through 2041. In accordance with Section 382 of the Internal Revenue code, the usage of the Company's NOLs would be limited given the change in ownership. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the period when those temporary differences become deductible.

The Company applies the FASB's provisions for uncertain tax positions. The Company utilizes the two-step process to determine the amount of recognized tax benefit. For tax positions meeting the more-likely-than-not threshold, the amount recognized in the consolidated financial statements is the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement with the relevant tax authority. The Company recognizes interest and penalties associated with uncertain tax positions as a component of income tax expense.

As of September 30, 2022, management does not believe the Company has any material uncertain tax positions that would require it to measure and reflect the potential lack of sustainability of a position on audit in its financial statements. The Company will continue to evaluate its uncertain tax positions in future periods to determine if measurement and recognition in its financial statements is necessary. The Company does not believe there will be any material changes in its unrecognized tax positions over the next year.

For years prior to 2018, the federal statute of limitations is closed for assessing tax. The Company's state tax returns remain open to examination for a period of three to four years from date of filing.

In December 2021, the Company received preliminary approval from the New Jersey Economic Development Authority ("NJEDA") to participate in the Technology Business Tax Certificate Transfer Program (the "Program"). The Program permits qualified companies to sell a percentage of their New Jersey net operating losses ("NJ NOLs") to unrelated profitable corporations. On February 22, 2022, the Company received final approval from NJEDA to sell $2.5 million of its NJ NOLs related tax benefits ("NJ NOL Tax Benefits"), which was subsequently sold to a qualifying and approved buyer pursuant to the Program for net proceeds of $2.3 million. The gross proceeds of $2.5 million have been recorded as a benefit from income taxes and the loss on sale of NJ NOLs of $0.1 million recorded in other income (expense) in the consolidated financial statements.

As a result of the merger with Cend Therapeutics, Inc. ("Cend") on September 15, 2022, federal and state NOLs of Cend may be subject to certain annual limitations under the ownership change rules of Section 382 of the IRC. As of December 31, 2021, Cend had state and foreign NOLs of approximately $4.3 million and $1.3 million, respectively. The state NOLs will begin to expire in 2036 unless previously utilized. The foreign NOLs will carry forward indefinitely.

As of December 31, 2021, Cend had state research credit carryforwards of approximately $48 thousand that will carry forward indefinitely.

## Note 12 – Australia Research and Development Tax Incentive

The Company's Australian subsidiary, which conducts core research and development activities, is eligible to receive a 43.5% refundable tax incentive for qualified research and development activities. As of the nine months ended September 30, 2022, $0.4 million was recorded as an income tax incentive receivable in the consolidated balance sheets, as the Company determined that the expenses met the eligibility criteria and the amounts claimed are expected to be received shortly after the related tax returns are filed.

## Note 13 – Contingencies

***Contingencies***

From time to time, the Company is subject to legal proceedings and claims, either asserted or unasserted, that arise in the ordinary course of business. While the outcome of pending claims cannot be predicted with certainty, the Company does not believe that the outcome of any pending claims will have a material adverse effect on the Company's financial condition or operating results.

In May 2021, Cend received a written threat of litigation on behalf of a Chinese entity called Lingmed Limited ("Lingmed") claiming Lingmed was entitled to a success fee based on Cend's Collaboration and License Agreement with Qilu Pharmaceuticals. Cend responded by denying that Lingmed is entitled to a success fee under the terms of their agreement. In May 2022, Cend was served with a complaint filed by Lingmed in the San Diego County Superior Court, alleging claims for breach of contract, fraud and declaratory relief. Cend's response to the complaint was filed on June 6, 2022. Lingmed filed an

answer to Cend's response on July 11, 2022. The court held a case management conference on October 7, 2022, which resulted in a continuance until December 16, 2022.

## Note 14 – License Agreements

***Sanford Burnham Prebys***

In December 2015, Cend entered into a license agreement with Sanford Burnham Prebys ("SBP") under which Cend was granted an exclusive, worldwide, royalty-bearing license to certain patent rights and know-how controlled by SBP related to the development of CEND-1. At the time the license agreement was entered into, Cend's founding shareholder, now a Lisata board member, was an executive at SBP. The agreement provides the Company with the rights to grant and authorize sublicenses to use, sell, and otherwise exploit the patent rights. As consideration for the license, Cend issued a total of 382,030 shares of common stock, as adjusted for the Reverse Stock Split and Exchange Ratio. The Company is required to pay an annual license maintenance fee of $10,000 increasing to $20,000 on year seven of the agreement. The Company could also be required to make milestone payments to SBP upon completion of certain regulatory and commercial milestones. The aggregate potential milestone payments are approximately $10.6 million. The Company has also agreed to pay SBP royalties of 4% of net sales of products sold by the Company, or through a sublicense, subject to certain reductions. Additionally, the Company is obligated to pay SBP 25% of any sublicensing income.

In October 2021, Cend entered into a license agreement with SBP under which Cend was granted an exclusive, royalty-bearing license to certain patent rights and know-how controlled by SBP. The agreement provides Cend with the rights to grant and authorize sublicenses to use, sell, and otherwise exploit the patent rights. The Company is required to pay an annual license maintenance fee of $20,000, increasing to $30,000 on year four of the agreement. Further, the Company could be required to make milestone payments to SBP upon completion of certain regulatory and commercial milestones. The aggregate potential milestone payments are approximately $23.2 million. The Company is obligated to pay SBP royalties of 4% of net sales of products sold by the Company or through a sublicense, subject to certain reductions. Additionally, the Company is obligated to pay SBP varying sublicense fees, ranging from 10% to 25%, dependent on when the related milestones are reached.

The agreements will expire upon the later of (i) the final abandonment of all pending patent applications within the licensed patents or (ii) the expiration of the last to expire patent within the licensed patents. The agreements may be terminated in their entirety by the Company at any time by giving SBP sixty days' prior written notice. The agreements may be terminated in their entirety by SBP if the Company, at any time, defaults in the payment of any sum when due and fails to make such payment within thirty days after receipt of written notice. The agreements may be terminated in their entirety by SBP or the Company (i) in the event of an uncured material breach by the other party, or (ii) in the event the other party (a) files for, or is involuntarily petitioned with, bankruptcy (other than dissolution or winding up for the purposes of reconstruction or amalgamation), (b) makes an assignment of all or substantially all of its assets for the benefit of creditors, or (c) has a receiver or trustee is appointed and is unable to secure a dismissal, stay or other suspension of such proceedings within thirty days. Upon termination of the agreements for any reason, all rights and obligations of the Company with respect to the patents and patent applications shall terminate and revert to SBP.

SBP owned 382,030 shares of the Company's common stock as of September 30, 2022 and is a related party.

***University of California at San Diego***

In March 2021, Cend entered into a license agreement with the University of California at San Diego ("UCSD") under which Cend was granted an exclusive, royalty-bearing license to certain patent rights related to the development of nano-particles to modulate immune response. The agreement provides the Company with the rights to grant and authorize sublicenses to use, sell and otherwise exploit the patent rights. The Company could be required to make milestone payments to UCSD upon completion of certain regulatory and commercial milestones. The aggregate potential milestone payments are approximately $1.2 million. The Company has also agreed to pay UCSD royalties of 1.5% of net sales of products sold by the Company or through a sublicense, subject to certain reductions. Additionally, the Company agreed to pay UCSD varying sublicense fees, ranging from 10% to 20%, dependent on when the related milestones are reached.

The agreement will expire upon the expiration of the longest-lived patent rights. The agreement may be terminated in its entirety by the Company at any time by giving UCSD ninety days' prior written notice. The agreement may be terminated in its entirety by UCSD if the Company, at any time, (i) fails to perform or violates any term of the agreement and fails to cure the default within sixty days. Upon termination of the agreement for any reason, UCSD may terminate a sublicensee but will allow

the Company to assign any sublicenses to UCSD provided a) that the sublicensee is in good standing upon termination of the agreement with the Company; and b) the sublicensee is not currently involved in litigation as an adverse party to UCSD.

***Massachusetts Institute of Technology***

In October 2021, Cend entered into a license agreement with the Massachusetts Institute of Technology ("MIT") under which Cend was granted an exclusive, royalty-bearing license to certain patent rights related to the development of tissue specific delivery of interfering RNA. The agreement provides the Company with the rights to grant and authorize sublicenses to use, sell, and otherwise exploit the patent rights. The Company is required to pay an annual license maintenance fee of $20,000, increasing to $25,000 for year two and three of the agreement, increasing to $50,000 on year four of the agreement and thereafter until the first commercial sale, and increasing to $150,000 each year of the agreement after the first sale. Further, the Company could be required to make milestone payments to MIT upon completion of certain regulatory and commercial milestones. The aggregate potential milestone payments are approximately $5.0 million. The Company has also agreed to pay MIT royalties of 2% of net sales of products sold by the Company or through a sublicense, subject to certain reductions. Additionally, the Company is obligated to pay MIT varying sublicense fees, ranging from 3% to 20%, dependent on when the related milestones are reached. In connection with the close of the Merger,, the Company was required to pay MIT a change of control fee of $0.3 million, which is included in accrued liabilities within the condensed consolidated balance sheets as of September 30, 2022.

The agreement will expire upon the expiration or abandonment of all valid claims. The agreement may be terminated in its entirety by the Company at any time by giving MIT six months prior written notice. The agreement may be terminated in its entirety by MIT if the Company, at any time, (i) defaults in the payment of any sum when due and fails to make such payment within thirty days after receipt of written notice, or (ii) commits a material breach of its obligations under the agreement (aside from item (i)) and fails to cure that breach within sixty days after receipt of written notice. Upon termination of the agreement for any reason, the rights and licenses granted to the Company shall terminate and revert to MIT. Upon termination of the agreement for any reason, MIT may terminate a sublicensee but will allow the Company to assign any sublicenses to MIT provided that the sublicensee is in good standing upon termination of the agreement with the Company.

## Note 15 – Research Collaboration and License Agreement

***Exclusive License and Collaboration Agreement***

In February 2021, Cend entered into an Exclusive License and Collaboration Agreement (the “Qilu Agreement”) in which Cend granted an exclusive license to Qilu for the development and commercialization of CEND-1 in the Territory (defined as the Greater Area of China including China, Macau, Hong Kong, and Taiwan). Under the terms of the agreement, Qilu is solely responsible for the development of CEND-1 in its Territory. In consideration for the license, Qilu made an upfront payment of $10 million to Cend, which was recognized as revenue by Cend prior to the Merger. In addition, Cend received and recognized as revenue a $5 million development milestone prior to the Merger. The Company is eligible to receive additional developmental and commercial milestone payments up to $100 million and $125 million, respectively, tiered royalties on net sales ranging from 10% to 15%, and tiered sublicensing revenues ranging from 12% to 35%.

Unless terminated early, the Qilu Agreement will continue in effect until the expiration of all Qilu payment obligations. Either party may terminate the Qilu Agreement if an undisputed material breach by the other party is not cured within a defined period of time, or upon notice for insolvency-related events of the other party that are not discharged within a defined time period. Qilu may terminate the Qilu Agreement in its entirety, at any time with at least sixty days written notice. All right and obligations of Qilu with respect to such licensed patents and patent applications would terminate.

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

The following Management's Discussion and Analysis of Financial Condition and Results of Operations contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under "Cautionary Note Regarding Forward-Looking Statements" herein and under "Risk Factors" in our 2021 Form 10-K. The following discussion should be read in conjunction with our consolidated financial statements and related notes thereto included elsewhere in this Quarterly Report and in our 2021 Form 10-K.

***Overview***

We are a clinical-stage pharmaceutical company dedicated to the discovery, development and commercialization of innovative therapies for the treatment of solid tumors and other major diseases. Lisata's lead investigational product candidate, LSTA1 (formerly known as CEND-1), is designed to activate a novel uptake pathway that allows anti-cancer drugs to penetrate solid tumors more effectively. LSTA1 actuates this active transport system in a tumor-specific manner, resulting in systemically co-administered anti-cancer drugs more efficiently penetrating and accumulating in the tumor, while normal tissues are not affected. LSTA1 also has the potential to modify the tumor microenvironment ("TME"), making tumors more susceptible to immunotherapies. LSTA1 has demonstrated favorable safety, tolerability, and activity to date in completed and ongoing clinical trials to enhance delivery of standard-of-care chemotherapy for pancreatic cancer. Lisata and its collaborators have also amassed significant non-clinical data demonstrating enhanced delivery of a range of emerging anti-cancer therapies, including immunotherapies and RNA-based therapeutics. We are exploring the potential of LSTA1 to enable a variety of treatment modalities to treat a range of solid tumors more effectively. In addition, Lisata also has clinical development programs based on its autologous CD34+ cell therapy technology platform.

Our leadership team has decades of collective biopharmaceutical and pharmaceutical product development experience across a variety of therapeutic categories and at all stages of development from preclinical through to product registration and launch. Our goal is to develop and commercialize products that address important unmet medical needs based on a broad and versatile portfolio of candidates. Our current product candidates include:

- LSTA1, the subject of phase 1b/2a and 2b clinical studies being conducted globally in a variety of solid tumor types, including metastatic pancreatic ductal adenocarcinoma (mPDAC), in combination with a variety of anti-cancer regimens;

- XOWNA® (LSTA16 formerly CLBS16), the subject of both a completed positive Phase 2a study (ESCaPE-CMD) and follow on Phase 2b study (FREEDOM Trial) in the United States for the treatment of coronary microvascular dysfunction ("CMD");

- HONEDRA® (LSTA12 formerly CLBS12), recipient of SAKIGAKE designation and eligible for early conditional approval in Japan for the treatment of critical limb ischemia ("CLI") and Buerger's disease is being sought based on the current results of a clinical trial executed in Japan. CLBS12 was the recipient of orphan drug designation in March 2021 from the U.S. Food and Drug Administration ("FDA") for Buerger's disease; and

- LSTA201 (formerly CLBS201), the subject of a study designed to assess the safety and efficacy of CD34+ cell therapy as a regenerative treatment for patients with chronic kidney disease related to type 2 diabetes (diabetic kidney disease or "DKD").

***Targeted Solid Tumor Penetration via CendR Active Transport***

Many solid tumor cancers, including pancreatic ductal adenocarcinoma ("PDAC"), gastric cancers and many other solid tumor cancers are surrounded by dense fibrotic tissue, or stroma. This limits the efficacy of current chemotherapies for these cancers. Emerging immunotherapy treatments, including checkpoint inhibitors, adoptive cell therapies such as chimeric antigen receptor T ("CAR-T") cells, as well as nucleic acid-based therapies, such as short interfering RNA ("siRNA"), antisense oligonucleotides ("ASO"), and messenger RNAs ("mRNAs") face particular challenges in penetrating solid tumors. Many tumors also exhibit an immunosuppressive tumor microenvironment ("TME"), which suppresses patients' immune systems' ability to fight their cancer and can limit effectiveness of immunotherapies. These factors negatively impact the ability of many therapeutic agents and immunotherapies to effectively treat these cancers.

To address the tumor stroma's role as a primary impediment to effective treatment, Lisata's approach is to activate the C-end rule ("CendR") natural transport system that normally brings nutrients into a tissue under emergency situations such as an injury. Cancers highjack this system to promote their own growth. Lisata's lead investigational drug, LSTA1 (a specific internalizing R-G-D or iRGD peptide) activates this transport system in a tumor-specific manner (Sugahara, Science, 2010).

This results in tumors taking up systemically administered anticancer drugs as if they were nutrients. As a result, more drug accumulates in the tumor than would accumulate without LSTA1, while normal tissues are not affected. Moreover, the drugs penetrate tumor cells farther away from blood vessels with LSTA1 than without. The overall result is enhanced anticancer activity without an increase in side effects. Anticancer drugs can be coupled/tethered or conjugated to LSTA1 or other CendR peptides in Lisata's portfolio, but can be also simply given together with LSTA1. Lisata believes that the co-administration option is an advantage because it is not necessary to create a new chemical entity with its attendant development and regulatory hurdles, providing a potentially faster-to-clinic and potentially faster-to-market product opportunity for a range of solid tumor cancers and for co-administration with a range of therapies.

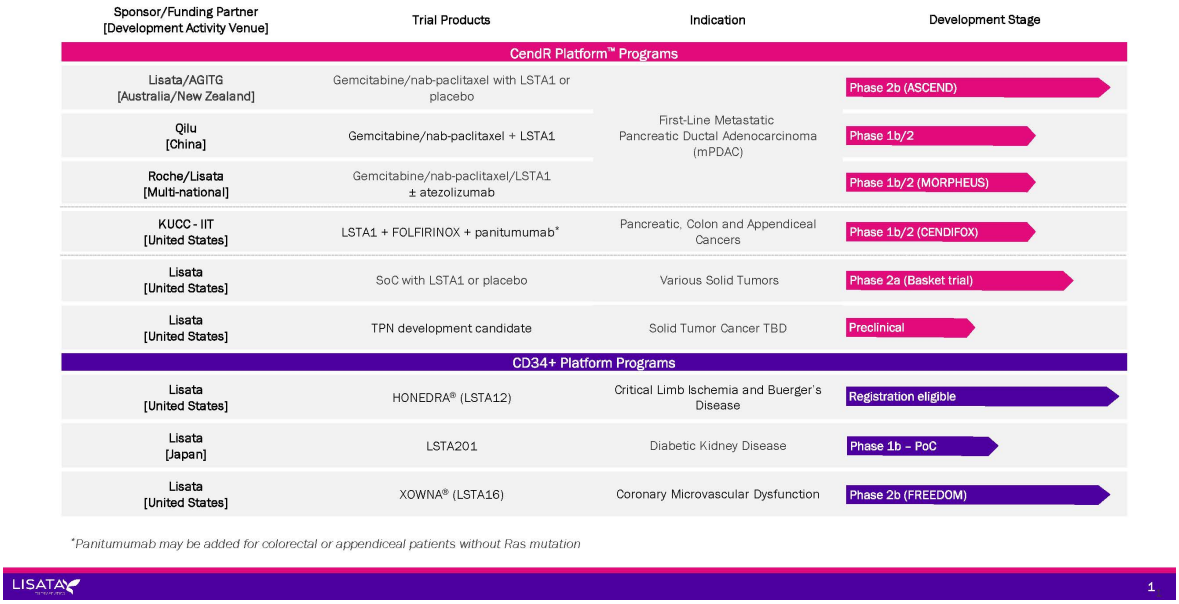
Clinical progress with other approaches to address delivery to highly fibrotic tumors, such as PEGylated hyaluronidase and hedgehog inhibitors, has been limited by toxicity and side effects. LSTA1 has demonstrated favorable safety/tolerability and activity in clinical trials to enhance delivery of standard-of-care chemotherapy for PDAC. Lisata and its collaborators have also amassed non-clinical data demonstrating enhanced delivery of a range of emerging anticancer therapies, including immunotherapies, and RNA-based therapeutics. LSTA1's cancer-targeted delivery may enable such emerging treatment modalities to potentially more effectively treat a range of solid tumors.

***LSTA1 as a treatment for solid tumor cancers in combination with other anti-cancer agents***

LSTA1 is an investigational drug that actuates the CendR active transport mechanism while also having the potential to modify the TME and make it less immunosuppresive. It is targeted to tumor vasculature by its affinity for alpha-v, beta-3 and beta-5 integrins that are selectively expressed in tumor vasculature, but not healthy tissue vasculature. LSTA1 is a specific cyclic internalizing RGD ("iRGD") peptide that, once bound to these integrins, is cleaved by proteases expressed in tumors to release a peptide fragment, called a CendR fragment, which binds to a second receptor, called neuropilin-1, to activate a novel uptake pathway that allows anticancer drugs to more selectively penetrate solid tumors. The ability of LSTA1 and iRGD peptides to modify the TME to enhance delivery and efficacy of co-administered drugs has been demonstrated in models of a range of solid tumors with the results from Lisata, collaborators and research groups around the world having been the subject of over 200 scientific publications.

With regard to clinical development, LSTA1 is the subject of a completed Phase 1b clinical trial of 31 first-line metastatic pancreatic ductal adenocarcinoma patients, of which 29 were evaluable. Results from the trial showed that the safety profile of the LSTA1 combination regimen was similar to standard of care ("SoC") alone with LSTA1 being well-tolerated with no-dose limiting toxicities. An Objective Response Rate ("ORR") of fifty nine percent was observed, including a rare complete response, which compares favorably to the twenty three percent ORR observed in the "MPACT" clinical trial that served as the basis for approval of nab-paclitaxel for use in combination with gemcitabine for the treatment of first line, metastatic pancreatic ductal adenocarcinoma. A Disease Control Rate ("DCR"); (partial and complete responses plus stable disease) of over seventy nine percent was observed in comparison to a DCR of forty eight percent observed in the MPACT trial. Reduction in the level of circulating tumor biomarker CA19-1 was observed in ninety six percent of patients versus sixty one percent in the MPACT trial. Importantly, median progression-free survival and median overall survival of nearly ten months and over thirteen months was observed, respectively, vs. less than six months and less than nine months, respectively, in the MPACT trial. These results have been published in The Lancet Gastroenterology and Hepatology (Dean, et al. 2022).

Additionally, LSTA1 is the subject of multiple ongoing and planned clinical trials being conducted globally in a variety of solid tumor types and in combination with several chemotherapy and immunotherapy anti-cancer regimens. The following diagram summarizes these studies.




***Ischemic Repair (CD34+ Cell Technology)***

The CD34+ cell was discovered as a result of the deliberate search for a cell capable of stimulating the development and/or repair of blood vessels. All tissues in the body maintain their function by replacing cells over time. In addition to the maintenance function, the body must also be capable of building new blood vessels after injury. A CD34+ cell is an endothelial progenitor cell that has the ability to stimulate new blood vessel formation at the level of the microvasculature. No other native cell discovered to date has demonstrated this same capability.

Our proprietary cell technology using autologous (a patient's own naturally occurring) CD34+ cells has led to the development of therapeutic product candidates designed to address diseases and conditions caused by ischemia. Ischemia occurs when the supply of oxygenated blood to healthy tissue is restricted or reduced. Through the administration of CD34+ cells, we seek to promote the development and formation of new microvasculature and thereby increase blood flow to the impacted area. We believe that a number of conditions caused by underlying ischemic injury can be improved through our CD34+ cell technology, including, but not limited to, Buerger's disease, CLI, CMD, and DKD.

***XOWNA® for Treatment of Coronary Microvascular Dysfunction***

In 2017, with the assistance of a $1.9 million grant from the National Institutes of Health (Award Number R44HL135889), we initiated our program for XOWNA® for the treatment of CMD, a disease that afflicts as many as 1.6 million patients in the United States alone, with no current targeted treatment options. That study, the ESCaPE-CMD Trial, was a Phase 2a proof-of-concept, open label study that enrolled patients at the Mayo Clinic in Rochester, MN and Cedars-Sinai Medical Center in Los Angeles, CA. Those data showed a positive therapeutic effect with a statistically significant improvement in angina frequency, coronary flow reserve, Canadian Cardiovascular Society Angina Class and Seattle Angina Questionnaire scores, as well as an acceptable safety profile. The full data set from that study was presented at the SCAI 2020 Scientific Sessions Virtual Conference on May 14, 2020 by Dr. Timothy Henry, FACC, of the Christ Hospital in Cincinnati, Ohio.

In December 2020, we commenced enrollment in our Phase 2b FREEDOM Trial of XOWNA®, a double-blind, randomized, placebo-controlled clinical trial designed to further evaluate the efficacy and safety of intracoronary artery delivery of autologous CD34+ cells in subjects with Coronary Microvascular Dysfunction (CMD) and without obstructive coronary artery disease and was expected to complete enrollment in approximately 12 months. While early enrollment proceeded to plan with the first patient treated in January 2021, the COVID-19 pandemic resulted in insurmountable enrollment rate challenges and population heterogenicity. As a result, in May 2022, we announced that enrollment in the FREEDOM Trial had been suspended and that we intended to conduct an interim analysis of the data from not less than the first 20 patients enrolled using the 6-month follow-up data to evaluate the efficacy and safety of XOWNA® in subjects with CMD. Following the analysis of results of the FREEDOM Trial subjects completing 6-month follow-up along with Key Opinion Leaders' input, our board of directors determined that execution of a redesigned FREEDOM-like trial would be the appropriate next step, but the cost of

such a trial would be prohibitively expensive to undergo without a strategic partner. Accordingly, our board of directors concluded that XOWNA® development will only be continued if a strategic partner that can contribute the necessary capital for a redesigned trial is identified and secured. There can be no assurance that we will be able to identify such a partner and enter into an agreement with such partner on acceptable terms or at all.

***HONEDRA® for Treatment of Critical Limb Ischemia***

Our randomized, open-label, registration-eligible study of HONEDRA® in Japan for the treatment of CLI and Buerger's disease has, to date, demonstrated positive trends in both safety and efficacy. The HONEDRA® study's enrollment, however, has been significantly curtailed by the COVID-19 pandemic's impact in Japan, including the States of Emergency in Japan that have persisted for much of 2020, 2021, and 2022. Due to the significant and continued operational and financial burden incurred as a result of these COVID-19 delays, coupled with the unpredictability of the timing of site enrollment re-initiation, we suspended further enrollment in the fourth quarter of 2021. Following study suspension, we completed all protocol-defined patient observations and are preparing the clinical study report. HONEDRA® is now in the pre-consultation phase of the registration process with the Pharmaceuticals and Medical Devices Agency (“PMDA”) in Japan. Data from the follow-up of all patients completed in the registration-eligible clinical trial in Japan has been compiled and are being reviewed by the PMDA after which the PMDA is expected to provide important perspective to be considered in preparation for the formal consultation meetings which precede the Japanese new drug application. If successful in the pre-consultation process, we expect formal clinical consultation to occur by mid-year 2023. In the meantime, we are focusing our efforts on consummating a partnership for the product in Japan. Such a partnership may become the basis for the completion of development and registration of HONEDRA® in Japan. This may include the completion of enrollment of the four remaining no-option CLI subjects stipulated in the original protocol, if necessary, and/or exploration of submitting the existing data to Japan's PMDA under Japan's regenerative medicine regulations, which allow for conditional approval of innovative regenerative medicine products. Despite receipt of orphan designation from the FDA in March 2021 in the United States for LSTA12 as a potential treatment for Buerger's disease, based on a response from the FDA in October 2021 regarding a development plan for U.S. registration, we have decided not to pursue U.S. development in Buerger's disease at this time.

***LSTA201 for Treatment of Diabetic Kidney Disease***

Progressive kidney failure is associated with attrition of the microcirculation of the kidney. Pre-clinical studies in kidney disease and injury models have demonstrated that protection or replenishment of the microcirculation results in improved kidney function. Based on these observations, we have elected to move forward with a Phase 1b, open-label, proof-of-concept trial evaluating LSTA201 dosed via intra-renal artery injections in subjects with DKD. This protocol includes six subjects in total with the first two subjects sequentially dosed and followed for a two-week safety observation period. Clearance by an independent Data Safety Monitoring Board (“DSMB”) overseeing the study then permitted the treatment of the next four patients, with all patients being followed for safety and therapeutic effect. A read-out of data will occur after the six-month follow-up visit for all patients. A key criterion for continued development of LSTA201 will be our ability to demonstrate a therapeutic effect that will make it competitive in the field of DKD treatment, i.e., kidney function regeneration, as indicated by increased glomerular filtration rate. The Company treated the first patient in the LSTA201 proof-of-concept study in April 2022 and completed treatment for all six subjects during the third quarter of 2022. Top-line data is anticipated from all subjects in the first quarter of 2023.

***Additional Out-licensing Opportunities***

Our broad intellectual property portfolio of assets includes notable programs available for out-licensing in order to augment or continue their clinical development. Our current long-term strategy focuses on advancing our therapies through development with the ultimate objective of obtaining market authorizations and entering commercialization, either alone or with partners, to provide treatment options to patients suffering from life-threatening medical conditions. We believe that we are well-positioned to realize potentially meaningful value increases within our own proprietary pipeline if we are successful in advancing our product candidates to their next significant development milestones.

***Merger with Cend Therapeutics, Inc. and Name Change***

On September 15, 2022, the Company, then operating as Caladrius Biosciences, Inc. (“Caladrius"), completed its acquisition of Cend Therapeutics, Inc. (“Cend”), a Delaware corporation (the “Merger”), in accordance with the terms of the Agreement and Plan of Merger and Reorganization (the “Merger Agreement”), dated as of April 26, 2022, by and among Caladrius, Cend and CS Cedar Merger Sub, Inc. (“Merger Sub”).

Pursuant to the terms set forth in the Merger Agreement and effective September 15, 2022 (the “Effective Time”): (i) Merger Sub merged with and into Cend, with Cend surviving as a wholly owned subsidiary of Caladrius, (ii) Caladrius changed its name to Lisata Therapeutics, Inc. in connection with and immediately following to the Effective Time, and (iii) Caladrius

effected a 1:15 reverse stock split of its common stock ("Reverse Stock Split") prior to the Effective Time. At the Effective Time, each share of Cend's common stock outstanding immediately prior to the Effective Time was converted into the right to receive shares of Lisata's common stock based on an exchange ratio of 0.5338 (the "Exchange Ratio"), after taking into account the Reverse Stock Split. In connection with the Merger close, the Company issued an aggregate of 3,772,768 shares of common stock, based on the Exchange Ratio, to holders of Cend, in exchange for all of the Cend capital stock outstanding immediately prior to the closing of the Merger.

Pursuant to the Merger Agreement, we assumed all of the outstanding and unexercised options to purchase shares of Cend capital stock under the 2016 Equity Incentive Plan (the "Cend Plan"), and, in connection with the Merger, such options were converted into options to purchase shares of Lisata's common stock based on the Exchange Ratio. At the closing of the Merger at the Effective Time, we assumed Cend's stock options to purchase an aggregate of 1,227,776 shares of the Company's common stock.

Caladrius was considered to be the accounting acquirer based on the terms of the Merger Agreement and certain factors including: (i) Caladrius owned approximately 52% of the Company's outstanding shares of common stock immediately following the close of the Merger; (ii) although both entities contributed to the new management team of Lisata, the Caladrius team has more individuals on the management team and will hold the CEO, CMO and other senior management roles; (iii) Caladrius paid a premium to acquire Cend's assets; and (iv) Caladrius was significantly larger than Cend regarding total assets, operations, and research and development activities. The Merger was accounted for as an asset acquisition as substantially all of the fair value is concentrated in in-process research and development ("IPR&D"). Cend's assets (except for cash and working capital) were measured and recognized as an allocation of the transaction price based on their relative fair values as of the transaction date with any value associated with IPR&D with no alternative future use being expensed. The prior reported operating results prior to the Merger close are those of Caladrius.

***Impact of the COVID-19 Pandemic***

The COVID-19 pandemic continues to present substantial public health and economic challenges around the world, and to date has led to the implementation of various responses, including government-imposed quarantines, stay-at-home orders, travel restrictions, mandated business closures and other public health safety measures.

We continue to closely monitor the impact of the COVID-19 pandemic on all aspects of our business, including how it has and will continue to impact our operations and the operations of our suppliers, vendors and business partners, and may take further precautionary and preemptive actions as may be required by federal, state or local authorities. In addition, we have taken steps to minimize the current environment's impact on our business and strategy, including devising contingency plans and securing additional resources from third party service providers. For the safety of our employees and families, we implemented a universal work from home policy as well as stringent social distancing and other hygiene policies for employees when they must be in the office. Our clinical study of HONEDRA® in Japan experienced significant delays in enrollment due to the States of Emergency in effect in Japan for most of 2020, 2021, and 2022 covering Tokyo and other regions in response to an increased number of COVID-19 infections. With our expectation that COVID-19 in Japan would continue to impact negatively enrollment of patients in the HONEDRA® clinical trial, we elected to suspend trial enrollment, seek a development partner and consult with the Japanese regulatory authorities regarding the submission of patient data already accrued. In addition, our phase 2b trial of XOWNA® in the United States has also experienced delays in enrolling patients as a result of COVID-19, as described above. In May 2022, we announced that enrollment in the FREEDOM Trial had been suspended and that we intend to conduct an interim analysis of the data from not less than the first 20 patients enrolled using the 6-month follow-up data to evaluate the efficacy and safety of XOWNA® in subjects with CMD. Following the analysis of results of the FREEDOM Trial subjects completing 6-month follow-up along with Key Opinion Leaders' input, the Company's board of directors determined that execution of a redesigned FREEDOM-like trial would be the appropriate next step, but the cost of such a trial would be prohibitively expensive to undergo without a strategic partner. Accordingly, the Company's board of directors concluded that XOWNA® development will only be continued if a strategic partner that can contribute the necessary capital for a redesigned trial is identified and secured. There can be no assurance that we will be able to identify such a partner and enter into an agreement with such partner on acceptable terms or at all.

Beyond its impact on our development pipeline described above, the extent to which COVID-19 ultimately impacts our business, results of operations and financial condition will depend on future developments, which remain highly uncertain and cannot be predicted with confidence, such as the duration of the outbreak, the emergence of new variants, new information that may emerge concerning the severity of COVID-19 or the effectiveness of actions taken to contain COVID-19 or treat its impact, including vaccination campaigns, among others. If we or any of the third parties with whom we engage, however, were to experience any additional shutdowns or other prolonged business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially or negatively affected, which could have a material adverse impact on our business, financial condition and results of operations. It is possible that our clinical development timelines could

continue to be negatively affected by COVID-19, which could materially and adversely affect our business, financial condition and results of operations. See "Risk Factors" in our 2021 Form 10-K for additional discussion of the potential adverse impact of the COVID-19 pandemic on our business, financial condition and results of operations.

**Results of Operations**

**Three Months Ended September 30, 2022 Compared to Three Months Ended September 30, 2021**

The following table summarizes our results of operations for the three months ended September 30, 2022 and September 30, 2021:

| | Three Months Ended September 30, | | |
|---|---|---|---|
| | 2022 | 2021 | Change |
| **Operating Expenses:** | | | |
| Research and development | $ 3,380 | $ 4,125 | $ (745) |
| In-process research and development | 30,393 | — | 30,393 |
| General and administrative | 3,947 | 2,843 | 1,104 |
| Total operating expenses | 37,720 | 6,968 | 30,752 |
| Loss from operations | (37,720) | (6,968) | (30,752) |
| Total other income | 337 | 41 | 296 |
| Net loss | $ (37,383) | $ (6,927) | $ (30,456) |

Overall, net losses were $37.4 million for the three months ended September 30, 2022, compared to $6.9 million for the three months ended September 30, 2021.

**Operating Expenses**

For the three months ended September 30, 2022, operating expenses totaled $37.7 million compared to $7.0 million for the three months ended September 30, 2021, representing an increase of 441.3%. Excluding the in-process research and development expense of $30.4 million relating to the Merger, operating expenses increased by $0.4 million, or 5.2% compared to the three months ended September 30, 2021 . Operating expenses comprised the following:

- Research and development expenses were approximately $3.4 million for the three months ended September 30, 2022, compared to $4.1 million for the three months ended September 30, 2021, representing a decrease of $0.7 million or 18.1%. This was primarily due to a decrease in expenses associated with our XOWNA® Phase 2b study (the FREEDOM Trial) as a result of the suspension in enrollment which commenced in the second quarter of 2022 and study close out activities in the third quarter of 2022, a decrease in expenses associated with HONEDRA® in Japan related to study close out costs partially offset by the addition of Chemistry, Manufacturing, and Controls ("CMC") activities for LSTA1 and enrollment activities for Australasian Gastrointestinal Trials Group ("AGITG") ASCEND study. Research and development in both periods related to:
    - expenses associated with our XOWNA® Phase 2b study (the FREEDOM Trial);
    - expenses associated with our registration-eligible study for HONEDRA® in critical limb ischemia in Japan as well as corresponding regulatory discussions support expenses;
    - expenses associated with the preparation of our filing of an Investigational New Drug Application ("IND"), as well as study execution expenses for the clinical study of LSTA201 for treatment of DKD, A Phase 1b, open-label, proof-of-concept trial which includes six subjects in total;
    - expenses associated with the addition of CMC activities for LSTA1, enrollment activities for the LSTA1 Phase 2b ASCEND study and preparatory activities associated with the design of a planned LSTA1 proof-of-concept basket trial in various solid tumors and in combination with the corresponding standards of care.
- General and administrative expenses were approximately $3.9 million for the three months ended September 30, 2022, compared to $2.8 million for the three months ended September 30, 2021, representing an increase of 39.0%. This increase was primarily due to an increase in equity expense as a result of performance stock unit vesting, Merger option assumption expense and departing board member restricted stock unit vesting in addition to an increase in

expenses associated with our annual stockholder meeting. Our general and administrative expenses focus on general corporate-related activities.

Historically, to minimize our use of cash, we have used a variety of equity and equity-linked instruments to compensate employees, consultants and other service providers. The use of these instruments has resulted in charges to the results of operations, which have been significant in the past.

**Other Income**

Total other income is comprised of investment income on cash, cash equivalents and marketable securities.

**Nine Months Ended September 30, 2022 Compared to Nine Months Ended September 30, 2021**

The following table summarizes our results of operations for the nine months ended September 30, 2022 and September 30, 2021:

| | Nine Months Ended September 30, | | |
|---|---|---|---|
| | 2022 | 2021 | Change |
| **Operating Expenses:** | | | |
| Research and development | $ 9,898 | $ 13,530 | $ (3,632) |
| In-process research and development | 30,393 | — | 30,393 |
| General and administrative | 10,770 | 8,671 | 2,099 |
| Total operating expenses | 51,061 | 22,201 | 28,860 |
| Loss from operations | (51,061) | (22,201) | (28,860) |
| Total other income (expense) | 347 | 21 | 326 |
| Benefit from income taxes | (2,479) | (1,508) | 971 |
| Net loss | $ (48,235) | $ (20,672) | $ (27,563) |

Overall, net losses were $48.2 million for the nine months ended September 30, 2022, compared to $20.7 million for the nine months ended September 30, 2021.

For the nine months ended September 30, 2022, operating expenses totaled $51.1 million compared to $22.2 million for the nine months ended September 30, 2021, representing an increase of 130.0%. Excluding the one-off in-process research and development expense of $30.4 million, operating expenses decreased by $1.5 million or 6.9% compared to the nine months ended September 30, 2021. Operating expenses comprised the following:

- Research and development expenses were approximately $9.9 million for the nine months ended September 30, 2022, compared to $13.5 million for the nine months ended September 30, 2021, representing a decrease of $3.6 million or 26.8%. This was primarily due to a decrease in expenses associated with our XOWNA® Phase 2b study (the FREEDOM Trial) as a result of the suspension in enrollment which commenced in the second quarter of 2022 and study close out activities in the third quarter of 2022, a decrease in expenses associated with HONEDRA® in Japan related to study close out costs and one off recruiting expenses and interim CMO consulting expenses in the prior year partially offset by the addition of CMC activities for LSTA1 and enrollment activities for AGITG ASCEND study. Research and development in both periods related to:
    - expenses associated with our XOWNA® Phase 2b study (the FREEDOM Trial);
    - expenses associated with our registration-eligible study for HONEDRA® in critical limb ischemia in Japan as well as corresponding regulatory discussions support expenses;
    - expenses associated with the preparation of our filing of an Investigational New Drug Application (“IND”), as well as study execution expenses for the clinical study of LSTA201 for treatment of DKD, a Phase 1b, open-label, proof-of-concept trial which includes six subjects in total;
    - expenses associated with the addition of CMC activities for LSTA1, enrollment activities for the LSTA1 Phase 2b ASCEND study and preparatory activities associated with the design of a planned LSTA1 proof-of-concept basket trial in various solid tumors and in combination with the corresponding standards of care.

- General and administrative expenses were approximately $10.8 million for the nine months ended September 30, 2022, compared to $8.7 million for the nine months ended September 30, 2021, representing an increase of 24.0%. This was primarily due to a one-time increase in fees associated with the review of potential strategic transactions and Merger related costs, an increase in equity expense as a result of performance stock unit vesting, Merger option assumption expense and departing board member restricted stock unit vesting in addition to an increase in expenses associated with our annual stockholder meeting. Our general and administrative expenses focus on general corporate-related activities.

Historically, to minimize our use of cash, we have used a variety of equity and equity-linked instruments to compensate employees, consultants and other service providers. The use of these instruments has resulted in charges to the results of operations, which have been significant in the past.

**Other Income (Expense)**

Total other income (expense) is comprised of investment income on cash, cash equivalents and marketable securities and a loss on sale related to the sale of our NJ NOLs.

**Income Tax Benefit**

In February 2022, we received final approval from the New Jersey Economic Development Authority (“NJEDA”) under the Technology Business Tax Certificate Transfer Program (“Program”) to sell a percentage of our NJ NOLs, which were subsequently sold to a qualifying and approved buyer pursuant to the Program for net proceeds of $2.3 million. The $2.5 million of our NJ NOL Tax Benefits have been recorded as a benefit from income taxes and the loss on sale of $0.1 million recorded in other income (expense).

**Analysis of Liquidity and Capital Resources**

As of September 30, 2022, we had cash, cash equivalents and marketable securities of approximately $75.5 million, working capital of approximately $70.9 million, and stockholders' equity of approximately $72.0 million.

During the nine months ended September 30, 2022, we met our immediate cash requirements through existing cash balances. Additionally, we used equity and equity-linked instruments to pay for services and compensation.

Net cash used in or provided by, operating, investing and financing activities were as follows (in thousands):

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2022 | 2021 |
| Net cash used in operating activities | $ (14,702) | $ (17,641) |
| Net cash provided by (used in) investing activities | 21,805 | (71,354) |
| Net cash (used in) provided by financing activities | (238) | 85,255 |

*Operating Activities*

Our cash used in operating activities during the nine months ended September 30, 2022 was $14.7 million, which is comprised of (i) our net loss of $48.2 million, adjusted for non-cash expenses totaling $33.5 million (which includes adjustments for equity-based compensation, depreciation and amortization, in process research and development expenses, and amortization/accretion of marketable securities), and (ii) changes in operating assets and liabilities providing approximately $0.1 million.

Our cash used in operating activities during the nine months ended September 30, 2021 was $17.6 million, which is comprised of (i) our net loss of $20.7 million, adjusted for non-cash expenses totaling $3.6 million (which includes adjustments for equity-based compensation, depreciation and amortization, and amortization/accretion of marketable securities) and (ii) changes in operating assets and liabilities using approximately $0.6 million.

*Investing Activities*

Our cash provided by investing activities during the nine months ended September 30, 2022 totaled $21.8 million and was primarily due to net sales of marketable securities (net of purchases of marketable securities) partially offset by the asset acquisition costs, net of cash acquired related to the Merger with Cend.

Our cash used in investing activities during the nine months ended September 30, 2021 totaled $71.4 million and was primarily due to net purchases of marketable securities (net of sales of marketable securities).

*Financing Activities*

Our cash used in financing activities during the nine months ended September 30, 2022 totaled $0.2 million, consisted primarily of tax withholding-related payments on net share settlement equity awards to employees.

Our cash provided by financing activities during the nine months ended September 30, 2021 totaled $85.3 million, primarily consisted of (i) net proceeds of $23.1 million through the issuance of common shares and warrants in our January 2021 private placement, (ii) net proceeds of $1.8 million in connection with warrant exercises, (iii) net proceeds of $60.6 million through the issuance of common shares and warrants in both of our February 2021 registered direct offerings, which was partially offset by tax withholding-related payments on net share settlement equity awards to employees.

**Liquidity and Capital Requirements Outlook**

To meet our short and long-term liquidity needs, we expect to use existing cash balances and a variety of other means. Other sources of liquidity could include additional potential issuances of debt or equity securities in public or private financings, partnerships and/or collaborations and/or sale of assets. Our history of operating losses and liquidity challenges may make it difficult for us to raise capital on acceptable terms or at all. The demand for the equity and debt of pharmaceutical companies like ours is dependent upon many factors, including the general state of the financial markets. During times of extreme market volatility, capital may not be available on favorable terms, if at all. Our inability to obtain such additional capital could materially and adversely affect our business operations. We will also continue to seek, as appropriate, grants for scientific and clinical studies from various governmental agencies and foundations, and other sources of non-dilutive funding. We believe that our cash on hand will enable us to fund operating expenses for at least the next 12 months following the issuance of our financial statements. Our future capital requirements are difficult to forecast and will depend on many factors

including the timing and nature of any other strategic transactions that we undertake; and our ability to establish and maintain collaboration partnerships, in-license/out-license or other similar arrangements and the financial terms of such agreements.

On June 4, 2021, we entered into an At The Market Offering Agreement (the "ATM Agreement") with H.C. Wainwright & Co., LLC as sales agent, in connection with an "at the market offering" under which we from time to time may offer and sell shares of our common stock, having an aggregate offering price of up to $50.0 million. As of September 30, 2022, we had not issued any shares under the ATM Agreement.

While we continue to seek capital through a number of means, there can be no assurance that additional financing will be available on acceptable terms, if at all, and our negotiating position in capital generating efforts may worsen as existing resources are used. Additional equity financing may be dilutive to our stockholders; debt financing, if available, may involve significant cash payment obligations and covenants that restrict our ability to operate as a business; our stock price may not reach levels necessary to induce option or warrant exercises; and asset sales may not be possible on terms we consider acceptable. If we are unable to access capital necessary to meet our long-term liquidity needs, we may have to delay the expansion of our business or raise funds on terms that we currently consider unfavorable.

**Seasonality**

We do not believe that our operations are seasonal in nature.

**Off-Balance Sheet Arrangements**

We do not have any off-balance sheet arrangements.

**Critical Accounting Policies and Estimates**

There have been no material changes in our critical accounting policies and estimates during the three and nine months ended September 30, 2022, compared to those reported in our 2021 Form 10-K with the exception of the valuation of the Merger which was accounted for as an asset acquisition as substantially all of the fair value is concentrated in in-process research and development ("IPR&D").

## ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

## ITEM 4. CONTROLS AND PROCEDURES

### (a) Disclosure Controls and Procedures

Disclosure controls and procedures are the controls and other procedures we have designed to ensure that information required to be disclosed in the reports that we file or submit under the Securities Exchange Act of 1934, as amended (the "Exchange Act") is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in the reports that we file under the Exchange Act is accumulated and communicated to management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well-designed and operated, can provide only reasonable assurance of achieving the desired control objectives. Due to the inherent limitations of control systems, not all misstatements may be detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. Controls and procedures can only provide reasonable, not absolute, assurance that the above objectives have been met.

As of September 30, 2022, we carried out an evaluation, with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of our disclosure controls and procedures pursuant to Rule 13a-15(e) and 15d-15(e) of the Exchange Act. Based on that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective, at the reasonable assurance level, in ensuring 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 management, including the principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

**(b) Changes in Internal Control over Financial Reporting**

Other than the internal control over financial reporting in conjunction with the Merger, there were no changes in our internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15, that occurred during our last quarter to which this Quarterly Report relates 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

Other than as disclosed in “Note 13 – Contingencies” set forth in the Notes to Unaudited Consolidated Financial Statements, which are included herein, there are no material changes to the disclosures previously reported in our 2021 Form 10-K.

### ITEM 1A. RISK FACTORS

There have been no material changes to the risk factors previously reported in our 2021 Form 10-K, in our Quarterly Reports on Form 10-Q for the periods ended March 31, 2022 and June 30, 2022 and in Exhibit 99.2 to our Amendment No. 1 to Current Report on Form 8-K/A filed on October 4, 2022. See the risk factors set forth in our 2021 Annual Report on Form 10-K under the caption “Item 1 A - Risk Factors.”

### ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None.

### ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

### ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

### ITEM 5. OTHER INFORMATION

None.

### ITEM 6. EXHIBITS

The Exhibit Index appearing immediately after the signature page to this Form 10-Q is incorporated herein by reference.

**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.

November 10, 2022

**LISATA THERAPEUTICS, INC.**
By: /s/ David J. Mazzo, PhD
Name: David J. Mazzo, PhD
Title: Chief Executive Officer
(Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer)

**LISATA THERAPEUTICS, INC.**
**FORM 10-Q**

**Exhibit Index**

| | | |
|---|---|---|
| 2.1 | | Agreement and Plan of Merger and Reorganization, dated April 26, 2022, among Caladrius Biosciences, Inc., CS Cedar Merger Sub, Inc., and Cend Therapeutics, Inc. (filed as Exhibit 2.1 to the Company's Current Report on Form 8-K, filed with the SEC on April 27, 2022). |
| 2.2 | | Form of Support Agreement, by and between Caladrius Biosciences, Inc. and certain securityholders of Cend Therapeutics, Inc. (filed as Exhibit 2.2 to the Company's Current Report on Form 8-K, filed with the SEC on April 27, 2022). |
| 2.3 | | Form of Support Agreement, by and between Cend Therapeutics, Inc. and certain securityholders of Caladrius Biosciences, Inc. (filed as Exhibit 2.3 to the Company's Current Report on Form 8-K, filed with the SEC on April 27, 2022). |
| 2.4 | | Form of Lock-Up Agreement, by and between Caladrius Biosciences, Inc. and certain securityholders of Caladrius Biosciences, Inc. and Cend Therapeutics, Inc. (filed as Exhibit 2.4 to the Company's Current Report on Form 8-K, filed with the SEC on April 27, 2022). |
| 3.1 | | Certificate of Amendment (Reverse Stock Split) to the Amended and Restated Certificate of Incorporation, dated September 14, 2022 (filed as Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the SEC on September 15, 2022). |
| 3.2 | | Certificate of Amendment (Name Change) to the Amended and Restated Certificate of Incorporation, dated September 15, 2022 (filed as Exhibit 3.2 of the Company's Current Report on Form 8-K, filed with the SEC on September 15, 2022). |
| 10.1 | | Series D Preferred Stock Purchase Agreement, dated April 26, 2022, among Caladrius Biosciences, Inc. and Cend Therapeutics, Inc. (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on April 27, 2022). |
| 10.2 | | Collaboration Agreement, dated April 26, 2022, between Caladrius Biosciences, Inc. and Cend Therapeutics, Inc. (filed as Exhibit 10.2 to the Company's Current Report on Form 8-K, filed with the SEC on April 27, 2022). |
| 10.3 | # | Employment Agreement, dated as of September 15, 2022, by and between the Company and David Slack (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on September 15, 2022). |
| 10.4 | # | Form of Indemnification Agreement between the Company and each of its directors and officers (filed as Exhibit 10.2 to the Company's Current Report on Form 8-K, filed with the SEC on September 15, 2022). |
| 10.5 | # | Cend 2016 Equity Incentive Plan, including all amendments thereto (filed as Exhibit 99.1 to the Company's Registration Statement on Form S-8, filed with the SEC on October 17, 2022). |
| 31.1 | * | Certification of Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 |
| 32 | ** | Certification of Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 |
| 101.INS | | Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document |
| 101.SCH | | Inline XBRL Taxonomy Extension Schema |
| 101.CAL | | Inline XBRL Taxonomy Extension Calculation Linkbase |
| 101.DEF | | Inline XBRL Taxonomy Extension Definition Linkbase |
| 101.LAB | | Inline XBRL Taxonomy Extension Label Linkbase |
| 101.PRE | | Inline XBRL Taxonomy Extension Presentation Linkbase |
| 104 | | Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101) |

* Filed herewith.

** Furnished herewith.

\# Management contract or compensatory plans or arrangements.

**Exhibit 31.1**

**CERTIFICATIONS UNDER SECTION 302**

I, David J. Mazzo, PhD, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Lisata Therapeutics, 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. I am 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 my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me 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 my 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 my 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. I have disclosed, based on my most recent evaluation of internal control over financial reporting to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

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

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

Date: November 10, 2022

/s/ David J. Mazzo, PhD
Name: David J. Mazzo, PhD
Title: Chief Executive Officer
(Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer)

**Exhibit 32**

**CERTIFICATION PURSUANT TO**
**18 U.S.C. SECTION 1350,**
**AS ADOPTED PURSUANT TO**
**SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of Lisata Therapeutics, Inc. (the "Company") for the quarter ended September 30, 2022 filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, David J. Mazzo, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to my knowledge that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition of the Company as of the dates presented and the results of operations of the Company for the periods presented.

Dated: November 10, 2022

/s/ David J. Mazzo, PhD
David J. Mazzo, PhD
Chief Executive Officer (Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer)

The foregoing certification is being furnished solely 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) and is not being filed as part of the Form 10-Q or as a separate disclosure document.