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 June 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

CALADRIUS BIOSCIENCES, 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

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	CLBS	The Nasdaq Capital Market

Securities registered pursuant to Section 12(g) of the Act: **None**

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 August 4, 2022**
Common stock, $0.001 par value per share	60,583,249 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," "likely," "believe," "could," "anticipate," "estimate," "continue" 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 complete the proposed merger with Cend Therapeutics, Inc. ("Cend");
- 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 market is established for our cell-based 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;
- our ability to diversify our pipeline of development product candidates, including our proposed merger with Cend, which could include an acquisition, merger, business combination, in-license or other strategic transaction, and whether any of such efforts will result in us entering into or completing any transaction or that any such transaction, if completed, will add to shareholder value;
- 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 and the need of patients to meet the inclusion criteria of the trial or otherwise;
- the extent to which the COVID-19 pandemic may impact 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").

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.

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

CALADRIUS BIOSCIENCES, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
(In thousands, except share data)

	June 30, 2022	December 31, 2021
ASSETS	**(Unaudited)**	
Cash and cash equivalents	$ 33,348	$ 24,647
Marketable securities	39,643	70,323
Prepaid and other current assets	1,956	1,212
Total current assets	74,947	96,182
Property and equipment, net	282	62
Investment in Cend Therapeutics	10,000	—
Other assets	648	764
Total assets	$ 85,877	$ 97,008
LIABILITIES AND STOCKHOLDERS' EQUITY		
Liabilities		
Accounts payable	$ 1,097	$ 1,934
Accrued liabilities	2,260	2,589
Total current liabilities	3,357	4,523
Other long-term liabilities	383	485
Total liabilities	3,740	5,008
Commitments and Contingencies		
Stockholders' Equity		
Preferred stock, authorized, 20,000,000 shares Series B convertible redeemable preferred stock liquidation value, 0.001 share of common stock, $0.01 par value; 825,000 shares designated; issued and outstanding, 10,000 shares at June 30, 2022 and December 31, 2021, respectively	—	—
Common stock, $0.001 par value, authorized 500,000,000 shares; issued 60,594,329 and 59,800,792 shares at June 30, 2022 and December 31, 2021, respectively; and outstanding, 60,583,249 and 59,789,712 shares at June 30, 2022 and December 31, 2021, respectively	61	60
Additional paid-in capital	546,976	545,988
Treasury stock, at cost; 11,080 shares at June 30, 2022 and December 31, 2021	(708)	(708)
Accumulated deficit	(463,868)	(453,016)
Accumulated other comprehensive loss	(70)	(70)
Total Caladrius Biosciences, Inc. stockholders' equity	82,391	92,254
Non-controlling interests	(254)	(254)
Total stockholders' equity	82,137	92,000
Total liabilities, non-controlling interests and stockholders' equity	$ 85,877	$ 97,008

See accompanying notes to consolidated financial statements.

CALADRIUS BIOSCIENCES, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)
(In thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	**2021**	**2022**	**2021**
Operating Expenses:				
Research and development	$ 3,239	$ 4,329	$ 6,517	$ 9,405
General and administrative	3,481	2,818	6,823	5,828
Total operating expenses	6,720	7,147	13,340	15,233
Operating loss	(6,720)	(7,147)	(13,340)	(15,233)
Other income (expense):				
Investment income, net	94	47	158	70
Other expense, net	—	(90)	(149)	(90)
Total other income (expense)	94	(43)	9	(20)
Net loss before benefit from income taxes and noncontrolling interests	(6,626)	(7,190)	(13,331)	(15,253)
Benefit from income taxes	—	(1,508)	(2,479)	(1,508)
Net loss attributable to Caladrius Biosciences, Inc. common stockholders	$ (6,626)	$ (5,682)	$ (10,852)	$ (13,745)
Basic and diluted loss per share				
Caladrius Biosciences, Inc. common stockholders	$ (0.11)	$ (0.10)	$ (0.18)	$ (0.27)
Weighted average common shares outstanding				
Basic and diluted shares	60,533	59,510	60,546	50,862

See accompanying notes to consolidated financial statements.

CALADRIUS BIOSCIENCES, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(Unaudited)
(In thousands)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Net loss	$ (6,626)	$ (5,682)	$ (10,852)	$ (13,745)
Other comprehensive loss:				
Available for sale securities - net unrealized gain (loss)	126	(4)	—	(4)
Total other comprehensive gain (loss)	126	(4)	—	(4)
Comprehensive loss attributable to Caladrius Biosciences, Inc. common stockholders	$ (6,500)	$ (5,686)	$ (10,852)	$ (13,749)

See accompanying notes to consolidated financial statements.

CALADRIUS BIOSCIENCES, 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 Caladrius Biosciences, Inc. Stockholders' Equity	Non-Controlling Interest in Subsidiary	Total Equity
	Shares	Amount	Shares	Amount							
Balance at Mar 31, 2022	10	$ —	60,544	$ 61	$ 546,580	$ (196)	$ (457,242)	$ (708)	$ 88,495	$ (254)	$ 88,241
Net loss	—	—	—	—	—	—	(6,626)	—	(6,626)	—	(6,626)
Unrealized gain on marketable securities	—	—	—	—	—	126	—	—	126	—	126
Share-based compensation	—	—	(15)	—	367	—	—	—	367	—	367
Net proceeds from issuance of common stock	—		65	—	29	—	—	—	29	—	29
Balance at June 30, 2022	10	$ —	60,594	$ 61	$ 546,976	$ (70)	$ (463,868)	$ (708)	$ 82,391	$ (254)	$ 82,137

	Series B Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Treasury Stock	Total Caladrius Biosciences, Inc. Stockholders' Equity	Non-Controlling Interest in Subsidiary	Total Equity
	Shares	Amount	Shares	Amount							
Balance at December 31, 2021	10	$ —	59,801	$ 60	$ 545,988	$ (70)	$ (453,016)	$ (708)	$ 92,254	$ (254)	$ 92,000
Net loss	—	—	—	—	—	—	(10,852)	—	(10,852)	—	(10,852)
Share-based compensation	—	—	728	1	959	—	—	—	960	—	960
Net proceeds from issuances of common stock	—	—	65	—	29	—	—	—	29	—	29
Balance at June 30, 2022	10	$ —	60,594	$ 61	$ 546,976	$ (70)	$ (463,868)	$ (708)	$ 82,391	$ (254)	$ 82,137

	Series B Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Treasury Stock	Total Caladrius Biosciences, Inc. Stockholders' Equity	Non-Controlling Interest in Subsidiary	Total Equity
	Shares	Amount	Shares	Amount							
Balance at Mar 31, 2021	10	$ —	59,510	$ 60	$ 544,601	$ (72)	$ (433,613)	$ (708)	$ 110,268	$ (254)	$ 110,014
Net loss	—	—	—	—	—	—	(5,682)	—	(5,682)	—	(5,682)
Unrealized gain on marketable securities	—	—	—	—	—	55	—	—	55	—	55
Share-based compensation	—	—	—	—	270	—	—	—	270	—	270
Net proceeds from issuances of common stock	—	—	19	—	22	—	—	—	22	—	22
Balance at June 30, 2021	10	$ —	59,529	$ 60	$ 544,893	$ (17)	$ (439,295)	$ (708)	$ 104,933	$ (254)	$ 104,679

	Series B Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Treasury Stock	Total Caladrius Biosciences, Inc. Stockholders' Equity	Non-Controlling Interest in Subsidiary	Total Equity
	Shares	Amount	Shares	Amount							
Balance at December 31, 2020	10	$ —	19,389	$ 19	$ 458,748	$ (13)	$ (425,550)	$ (708)	$ 32,496	$ (254)	$ 32,242
Net loss	—	—	—	—	—	—	(13,745)	—	(13,745)	—	(13,745)
Unrealized loss on marketable securities	—	—	—	—	—	(4)	—	—	(4)	—	(4)
Share-based compensation	—	—	273	—	683	—	—	—	683	—	683
Net proceeds from issuances of common stock and warrants	—	—	39,860	41	85,438	—	—	—	85,479	—	85,479
Proceeds from option exercises	—	—	7	—	24	—	—	—	24	—	24
Balance at June 30, 2021	10	$ —	59,529	$ 60	$ 544,893	$ (17)	$ (439,295)	$ (708)	$ 104,933	$ (254)	$ 104,679

See accompanying notes to consolidated financial statements.

CALADRIUS BIOSCIENCES, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)
(In thousands)

	Six Months Ended June 30,	
	2022	**2021**
Cash flows from operating activities:		
Net loss	$ (10,852)	$ (13,745)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	1,128	867
Depreciation and amortization	14	33
Accretion on marketable securities	900	1,133
Changes in operating assets and liabilities:		
Prepaid and other current assets	(744)	(1,232)
Other assets	118	166
Accounts payable, accrued liabilities and other liabilities	(1,268)	176
Net cash used in operating activities	(10,704)	(12,602)
Cash flows from investing activities:		
Purchase of marketable securities	(30,291)	(105,792)
Sale of marketable securities	60,070	29,558
Purchase of property and equipment	(235)	(60)
Investment in Cend Therapeutics	(10,000)	—
Net cash provided by (used in) investing activities	19,544	(76,294)
Cash flows from financing activities:		
Proceeds from exercise of options	—	24
Tax withholding payments on net share settlement equity awards	(168)	(184)
Net proceeds from issuance of common stock	29	85,479
Net cash (used in) provided by financing activities	(139)	85,319
Net increase (decrease) in cash and cash equivalents	8,701	(3,577)
Cash and cash equivalents at beginning of period	24,647	16,512
Cash and cash equivalents at end of period	$ 33,348	$ 12,935

See accompanying notes to consolidated financial statements.

CALADRIUS BIOSCIENCES, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

Note 1 – The Business

Overview

Caladrius Biosciences, Inc. ("we," "us," "our," "Caladrius" or the "Company") is a clinical-stage biopharmaceutical company dedicated to the development of treatments and reversal of severe diseases. The Company is developing what are intended to be first-in-class therapeutics based on the characteristics of naturally occurring CD34+ cells and their ability to stimulate the growth of new microvasculature. Its technology is intended to leverage these cells to enable the body's natural repair mechanisms using formulations unique to each medical indication.

The Company's leadership team has decades of collective biopharmaceutical product development experience in a variety of therapeutic categories. 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:

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

- HONEDRA® (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

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

- On April 26, 2022, the Company and Cend Therapeutics, Inc., a Delaware corporation ("Cend"), entered into an Agreement and Plan of Merger and Reorganization (the "Merger Agreement"), pursuant to which, among other matters, and subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, a wholly-owned subsidiary of Caladrius will merge with and into Cend, with Cend surviving as a wholly-owned subsidiary of the Company (the "Merger"), subject to the terms of the Merger Agreement and stockholder approval of the transaction. Under the exchange ratio formula, as of immediately after the Merger, the former Cend stockholders are expected to own approximately 50% of the outstanding shares of Caladrius Common Stock and the Company's stockholders as of immediately prior to the Merger are expected to own approximately 50% of the outstanding shares of Caladrius Common Stock. The actual allocation will be subject to adjustment based on our net cash balance at the time of closing and the amount of any transaction expenses of Cend in excess of $250 thousand at the time of closing.

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.

The Company's 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, Caladrius seeks to promote the development and formation of new microvasculature and thereby increase blood flow to the impacted area. The Company believes that a number of conditions caused by underlying ischemic injury can be improved through its 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), the Company initiated its 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, the Company commenced enrollment in its 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 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 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. Protocol amendments to the initial FREEDOM Trial protocol, as agreed to by the FDA, were implemented with the goal of enhancing breadth and speed of subject enrollment. In May 2022, the Company announced that enrollment in the FREEDOM Trial had been suspended and that it intends 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 and corroborate the ESCaPE-CMD study results. The interim analysis is expected to be completed in the third quarter of 2022, and the next steps in development of XOWNA® will subsequently be determined after appropriate regulatory and business review, expected to be announced prior to year-end 2022.

HONEDRA® for Treatment of Critical Limb Ischemia

The Company's 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, Caladrius suspended further enrollment in the fourth quarter of 2021. Following study suspension, the Company completed all protocol-defined patient observations and is 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 is expected to be reviewed by PMDA during the third quarter of 2022 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. The Company is focusing its 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 the possibility 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 FDA in March 2021 in the U.S. for CLBS12 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 the Company decided not to pursue U.S. development in Buerger's disease at this time.

CLBS201 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, the Company elected to move forward with a Phase 1b, open-label, proof-of-concept trial evaluating CLBS201 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 the 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 at the six-month follow-up visit for all patients. A key criterion for continued development of CLBS201 will be its 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 CLBS201 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 by the first quarter of 2023.

Additional Out-licensing Opportunities

The Company's broad intellectual property portfolio of cell therapy assets includes notable programs available for out-licensing in order to continue their clinical development. The Company's current long-term strategy focuses on advancing its 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. The Company believes that it is well-positioned to realize potentially meaningful value increases within its own proprietary pipeline if it is successful in advancing its product candidates to their next significant development milestones.

Cend Merger Agreement

On April 26, 2022, the Company and Cend entered into the Merger Agreement. Consummation of the Merger is subject to certain closing conditions, including, among other things, approval by the stockholders of the Company and Cend and the Company's satisfaction of a minimum net cash threshold at closing, expected to be approximately $64.9 million assuming a closing at the end of the third quarter of 2022, and as described further in the Merger Agreement. The Merger Agreement contains certain termination rights for both the Company and Cend, and further provides that, upon termination of the Merger Agreement under specified circumstances, the Company may be required to pay Cend a termination fee of $1.0 million, Cend may be required to pay the Company a termination fee of $4.0 million, or in some circumstances reimburse the other party's expenses up to a maximum of $1.0 million.

At the effective time of the Merger, the Company's Board of Directors is expected to consist of nine members, four of whom will be designated by the Company, four of whom will be designated by Cend and one member who will be mutually agreed between the Company and Cend.

Stock Purchase Agreement

In order to provide Cend with capital for its development programs prior to the closing of the Merger, the Company and Cend entered into a Series D Preferred Stock Purchase Agreement (the "Purchase Agreement"), pursuant to which the Company purchased from Cend 1,135,628 shares of Series D Preferred Stock, $0.00001 par value per share (the "Series D Preferred Stock"), of Cend at a purchase price per share equal to $8.8057 per share (the "Series D Original Issue Price"), or approximately $10 million in the aggregate. The Series D Preferred Stock ranks senior to Cend's common stock and the other series of preferred stock with respect to rights on the distribution of assets on any voluntary or involuntary liquidation, dissolution or winding up of Cend. The Series D Preferred Stock has a liquidation preference equal to the Series D Original Issue Price plus an amount equal to any accrued and unpaid dividends to the date of payment and will participate with Cend's common stockholders and other preferred stockholders thereafter on an as-converted basis. The Series D Preferred Stock shall vote with the common stock on an as-converted basis on any matters presented to the stockholders of Cend. Each share of Series D Preferred Stock is convertible, at the option of the holder thereof, into such number of shares of Cend common stock as is determined by dividing the Original Issue Price by the conversion price in effect at the time of conversion, which conversion price shall be the Original Issue Price as appropriately adjusted for stock splits, stock dividends, combinations, and subdivisions of Cend common stock, and as adjusted pursuant to a weighted-average antidilution adjustment. The Series D Preferred Stock will automatically convert into shares of Cend common stock upon the closing of a firm-commitment underwritten initial public offering implying a pre-equity offering value of at least $250 million, resulting in at least $50 million of gross proceeds to Cend.

Collaboration Agreement

In connection with such Purchase Agreement, Cend entered into a Collaboration Agreement (the "Collaboration Agreement"), pursuant to which the Company agreed to collaborate with Cend on certain developmental and clinical activities prior to the closing of the Merger. Pursuant to the Collaboration Agreement, the Company and Cend have formed a joint steering committee (the "Committee") comprised of individuals from both entities. The Committee meets regularly and is responsible for monitoring ongoing studies and making recommendations for development activity and trial planning. Cend has agreed to pay each member of the Committee from the Company an hourly consulting fee for such service. As of June 30, 2022 the cumulative services provided under the agreement totaled $0.2 million.

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 and corroborate the ESCaPE-CMD study results.

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 June 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 six months ended June 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. Accordingly, actual results could differ from those estimates and assumptions.

Principles of Consolidation

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

Note 2 – Summary of Significant Accounting Policies

In addition to the policies below, the Company's significant accounting policies are described in Note 2 of the Notes to Consolidated Financial Statements included in its 2021 Form 10-K. There were no changes to these policies during the three and six months ended June 30, 2022.

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. 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.

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. 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.

Investment in Cend Therapeutics

Investments in which the Company has no significant influence (generally less than a 20% ownership interest) or does not have the ability to exercise significant influence are accounted for under the measurement alternative method pursuant to ASC 321, Investments — Equity Securities ("ASC 321") as these investments do not have readily determinable fair values. Under the measurement alternative method, the Company records the investment at cost less impairment losses, if any, unless it identifies observable price changes in orderly transactions for the identical or a similar investment of the same issuer, in which case the Company will measure its investments at fair value as of the date that the observable transaction occurred. Such investments are presented as investments on the consolidated balance sheets and any impairment recognized related to these investments are presented in other income (expense), on the consolidated statements of operations (see Note 5, "Fair Value Measurements").

Note 3 – 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):

	June 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	$ 26,966	$ —	$ (66)	$ 26,900	$ 53,135	$ —	$ (65)	$ 53,070
Commercial paper	2,978	—	—	2,978	—	—	—	—
Money market funds	22,727	—	—	22,727	18,124	—	—	18,124
Municipal debt securities	17,086	—	(3)	17,083	20,263	—	(5)	20,258
Total	$ 69,757	$ —	$ (69)	$ 69,688	$ 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):

	June 30, 2022	December 31, 2021
Cash equivalents	$ 30,045	$ 21,129
Marketable securities	39,643	70,323
Total	$ 69,688	$ 91,452

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

	June 30, 2022	
	Amortized Cost	Estimated Fair Value
Less than one year	$ 69,757	$ 69,688
Greater than one year	—	—
Total	$ 69,757	$ 69,688

Note 4 – Income (Loss) Per Share

For the six months ended June 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 June 30, 2022 and 2021, the Company excluded the following potentially dilutive securities (in thousands):

	June 30,	
	2022	2021
Stock Options	2,612	1,005
Warrants	21,357	21,357
Restricted Stock Units	1,454	798

Note 5 – 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 June 30, 2022 and December 31, 2021 (in thousands).

	June 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	$ —	$ 39,643	$ —	$ 39,643	$ —	$ 70,323	$ —	$ 70,323
Investment in Cend Therapeutics	$ —	$ —	$ 10,000	$ 10,000	$ —	$ —	$ —	$ —
	$ —	$ 39,643	$ 10,000	$ 49,643	$ —	$ 70,323	$ —	$ 70,323

Note 6 – Accrued Liabilities

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

	June 30, 2022	December 31, 2021
Salaries, employee benefits and related taxes	$ 1,397	$ 2,034
Operating lease liabilities — current	178	229
Other	685	326
Total	$ 2,260	$ 2,589

Note 7 – 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):

	June 30, 2022	December 31, 2021
Right-of Use Assets:		
Other assets	$ 608	$ 724
Total Right-of-Use Asset	$ 608	$ 724
Operating Lease Liabilities:		
Accrued liabilities	$ 178	$ 229
Other long-term liabilities	383	485
Total Operating Lease Liabilities	$ 561	$ 714

As of June 30, 2022, the weighted average remaining lease term for our operating leases was 2.0 years, and the weighted average discount rate for our operating leases was 9.625%. Future minimum lease payments under the lease agreements as of June 30, 2022 were as follows (in thousands):

Years ended	Operating Leases
2022	103
2023	217
2024	190
2025	143
Total lease payments	653
Less: Amounts representing interest	(92)
Present value of lease liabilities	$ 561

Note 8 – Stockholders' Equity

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 June 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 HCW, 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 six months ended June 30, 2022 and since inception the Company had not issued any shares under the ATM Agreement. Having received a listing deficiency notice from Nasdaq on February 18, 2022 after the Company's shares traded below $1.00 for 30 consecutive trading days, the Company will not be permitted to sell additional shares under the ATM Agreement until it re-establishes timely compliance. Compliance may be reestablished by various mechanisms, including stock price appreciation at or above $1.00 for a requisite period of time and reverse stock split.

Stock Options and Warrants

The following table summarizes the activity for stock options and warrants for the six months ended June 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	2,131,849	$ 5.64	7.97	$ —	21,356,600	$ 2.84	4.37	$ —
Changes during the period:								
Granted	547,600	0.91			—	—		
Exercised	—	—			—	—		
Forfeited	(17,500)	1.62			—	—		
Expired	(49,664)	27.37			—	—		
Outstanding at June 30, 2022	2,612,285	$ 4.26	7.63	$ —	21,356,600	$ 2.84	3.88	$ —
Vested at June 30, 2022 or expected to vest in the future	2,574,724	$ 4.31	7.61	$ —	21,356,600	$ 2.84	3.88	$ —
Vested at June 30, 2022	1,388,935	$ 6.92	6.24	$ —	21,356,600	$ 2.84	3.88	$ —

Restricted Stock

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

	Six Months Ended June 30,	
	2022	2021
Number of restricted stock issued	1,061,175	300,450
Value of restricted stock issued	$ 973	$ 478

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

Restricted Stock Units

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

	Six Months Ended June 30,	
	2022	2021
Number of restricted stock units issued	1,379,860	458,245
Value of restricted stock units issued	$ 1,265	$ 729

The weighted average estimated fair value of restricted stock issued for services in the six months ended June 30, 2022 and 2021 was $0.92 and $1.59 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 9 – 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 six months ended June 30, 2022 and 2021 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Research and development	$ 141	$ 24	$ 359	$ 12
General and administrative	226	246	769	74
Total share-based compensation expense	$ 367	$ 270	$ 1,128	$ 86

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 June 30, 2022 were as follows (in thousands):

	Stock Options	Restricted Stock Units	Restricted Stock
Unrecognized compensation cost	$ 685	$ 319	$ 869
Expected weighted-average period in years of compensation cost to be recognized	1.56	0.74	2.04

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

	Stock Options	
	Six Months Ended June 30,	
	2022	2021
Total fair value of shares vested	$ 385	$ 407
Weighted average estimated fair value of shares granted	$ 0.61	$ 1.08

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 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 10 – 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 they 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 $173k 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 June 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.

Note 11 – 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.

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 biopharmaceutical company dedicated to the development and commercialization of cellular therapies designed to reverse disease and/or promote the regeneration of damaged tissue. We are developing first-in-class therapeutics based on the characteristics of naturally occurring CD34+ cells and their ability to stimulate the growth of new microvasculature. Our technology leverages these cells to enable the body's natural repair mechanisms using formulations unique to each medical indication.

Our leadership team has decades of collective biopharmaceutical product development experience in a variety of therapeutic categories, including cardiovascular and oncology. 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:

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

- HONEDRA® (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

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

Cend Merger

On April 26, 2022, we, CS Cedar Merger Sub, Inc., a Delaware corporation and our wholly owned subsidiary ("Merger Sub"), and Cend Therapeutics, Inc., a Delaware corporation ("Cend"), entered into an Agreement and Plan of Merger and Reorganization (the "Merger Agreement"), pursuant to which, among other matters, and subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub will merge with and into Cend, with Cend continuing as our wholly owned subsidiary and the surviving corporation of the merger (the "Merger"). The Merger is intended to qualify for federal income tax purposes as a tax-free reorganization under the provisions of Section 368(a) of the Internal Revenue Code of 1986, as amended.

Subject to the terms and conditions of the Merger Agreement, at the closing of the Merger, (a) each outstanding share of Cend common stock and Cend preferred stock will be converted into the right to receive a number of shares of our common stock ("Caladrius Common Stock") equal to an exchange ratio calculated pursuant to the terms of the Merger Agreement; and (b) each outstanding Cend stock option that has not previously been exercised prior to the closing of the Merger will be assumed by us.

Under the exchange ratio formula, as of immediately after the Merger, the former Cend stockholders are expected to own approximately 50% of the outstanding shares of Caladrius Common Stock and our stockholders as of immediately prior to the Merger are expected to own approximately 50% of the outstanding shares of Caladrius Common Stock. The actual allocation will be subject to adjustment based on our net cash balance at the time of closing and the amount of any transaction expenses of Cend in excess of $250 thousand at the time of closing.

Consummation of the Merger is subject to certain closing conditions, including, among other things, approval by the stockholders of Caladrius and Cend, and Caladrius' satisfaction of a minimum net cash threshold at closing, expected to be approximately $64.9 million assuming a closing at the end of the third quarter of 2022, and as described further in the Merger Agreement. In accordance with the terms of the Merger Agreement, (i) certain executive officers, directors and stockholders of Cend (solely in their respective capacities as Cend stockholders) holding approximately 77.5% of the outstanding Cend capital stock have entered into support agreements with Caladrius to vote all of their shares of Cend capital stock in favor of adoption of the Merger Agreement (the "Cend Support Agreements") and (ii) certain executive officers and directors of Caladrius (solely

in their respective capacities as Caladrius stockholders) holding approximately 1.8% of the outstanding Caladrius common stock have entered into support agreements with Cend to vote all of their shares of Caladrius common stock in favor of approval of the Merger Agreement (the "Caladrius Support Agreements," together with the Cend Support Agreements, the "Support Agreements"). The Support Agreements include covenants with respect to the voting of such shares in favor of approving the transactions contemplated by the Merger Agreement and against any competing acquisition proposals and place certain restrictions on the transfer of the shares of Caladrius and Cend held by the respective signatories thereto.

Concurrently with the execution of the Merger Agreement, certain officers and directors of Caladrius holding approximately 1.8% of the outstanding Caladrius common stock and certain officers, directors and stockholders of Cend holding approximately 77.5% of the Cend capital stock have entered into lock-up agreements (the "Lock-Up Agreements") pursuant to which they accepted certain restrictions on transfers of shares of Caladrius Common Stock for the 120-day period following the closing of the Merger.

The Merger Agreement contains certain termination rights for both us and Cend, and further provides that, upon termination of the Merger Agreement under specified circumstances, we may be required to pay Cend a termination fee of $1.0 million, Cend may be required to pay us a termination fee of $4.0 million, or in some circumstances reimburse the other party's expenses up to a maximum of $1.0 million.

At the effective time of the Merger, our Board of Directors is expected to consist of nine members, four of whom will be designated by us, four of whom will be designated by Cend and one member who will be mutually agreed between us and Cend.

Cend Investment and Collaboration Agreement

In order to provide Cend with capital for its development programs prior to the closing of the Merger, we and Cend entered into a Series D Preferred Stock Purchase Agreement (the "Purchase Agreement"), pursuant to which we purchased from Cend 1,135,628 shares of Series D Preferred Stock, $0.00001 par value per share (the "Series D Preferred Stock"), of Cend at a purchase price per share equal to $8.8057 per share (the "Series D Original Issue Price"), or approximately $10 million in the aggregate. The Purchase Agreement contains customary representations, warranties and agreements by us and Cend and customary conditions to closing. The Series D Preferred Stock ranks senior to Cend's common stock and the other series of preferred stock with respect to rights on the distribution of assets on any voluntary or involuntary liquidation, dissolution or winding up of Cend. The Series D Preferred Stock has a liquidation preference equal to the Series D Original Issue Price plus an amount equal to any accrued and unpaid dividends to the date of payment and will participate with Cend's common stockholders and other preferred stockholders thereafter on an as-converted basis. The Series D Preferred Stock shall vote with the common stock on an as-converted basis on any matters presented to the stockholders of Cend. Each share of Series D Preferred Stock is convertible, at the option of the holder thereof, into such number of shares of Cend common stock as is determined by dividing the Original Issue Price by the conversion price in effect at the time of conversion, which conversion price shall be the Original Issue Price as appropriately adjusted for stock splits, stock dividends, combinations, and subdivisions of Cend common stock, and as adjusted pursuant to a weighted-average antidilution adjustment. The Series D Preferred Stock will automatically convert into shares of Cend common stock upon the closing of a firm-commitment underwritten initial public offering implying a pre-equity offering value of at least $250 million, resulting in at least $50 million of gross proceeds to Cend.

In connection with the Purchase Agreement, we and Cend entered into a Collaboration Agreement (the "Collaboration Agreement"), pursuant to which we agreed to collaborate with Cend on certain developmental and clinical activities prior to the closing of the Merger. Pursuant to the Collaboration Agreement, we and Cend have formed a joint steering committee (the "Committee") comprised of individuals from both entities. The Committee meets regularly and is responsible for monitoring ongoing studies and making recommendations for development activity and trial planning. Cend has agreed to pay each member of the Committee from Caladrius an hourly consulting fee for such service.

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 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 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. Protocol amendments to the initial FREEDOM Trial protocol, as agreed to by the FDA, were implemented with the goal of enhancing breadth and speed of subject enrollment. 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 and corroborate the ESCaPE-CMD study results. The interim analysis is expected to be completed in the third quarter of 2022 and the next steps in development of XOWNA® will subsequently be determined after appropriate regulatory and business review, expected to be announced prior to year-end 2022.

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 is expected to be reviewed by PMDA during the third quarter of 2022 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. 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 FDA in March 2021 in the United States for CLBS12 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.

CLBS201 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 CLBS201 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 CLBS201 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 CLBS201 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 by the first quarter of 2023.

Additional Out-licensing Opportunities

Our broad intellectual property portfolio of cell therapy assets includes notable programs available for out-licensing in order to 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.

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 and corroborate the ESCaPE-CMD study results.

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 June 30, 2022 Compared to Three Months Ended June 30, 2021

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

	Three Months Ended June 30,		
	2022	2021	Change
Operating Expenses:			
Research and development	$ 3,239	$ 4,329	$ (1,090)
General and administrative	3,481	2,818	663
Total operating expenses	6,720	7,147	(427)
Loss from operations	(6,720)	(7,147)	427
Total other income (expense)	94	(43)	137
Benefit from income taxes	—	(1,508)	(1,508)
Net loss	$ (6,626)	$ (5,682)	$ (944)

Overall, net losses were $6.6 million for the three months ended June 30, 2022, compared to $5.7 million for the three months ended June 30, 2021.

Operating Expenses

For the three months ended June 30, 2022, operating expenses totaled $6.7 million compared to $7.1 million for the three months ended June 30, 2021, representing a decrease of 6%. Operating expenses comprised the following:

- Research and development expenses were approximately $3.2 million for the three months ended June 30, 2022, compared to $4.3 million for the three months ended June 30, 2021, representing a decrease of $1.1 million or 25%. This decrease was primarily due to a decrease in expenses associated with HONEDRA® in Japan, revenue received from the Collaboration Agreement and one off recruiting expenses in the prior year. Research and development in both periods focused on the advancement of our ischemic repair platform and related to:
  - expenses associated with our XOWNA® Phase 2b study (the FREEDOM Trial) which commenced in the fourth quarter of 2020 with the first patient in the study treated in January 2021;
  - ongoing registration-eligible study expenses for HONEDRA® in critical limb ischemia in Japan which focused on patient enrollment completion. The study's enrollment has been significantly curtailed by the COVID-19 pandemic's impact in Japan, including the States of Emergency that have persisted there for most 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 complete unpredictability of the timing of site enrollment re-initiation, we will focus our efforts on consummating a partnership with a Japanese company in order to complete the study enrollment as well as to explore the possibility of submitting the existing data to PMDA under the SAKIGAKE designation;
  - expenses associated with the preparation of our filing of an IND and study start-up expenses for the clinical study of CLBS201 for treatment of diabetic kidney disease. A Phase 1b, open-label, proof-of-concept trial which includes six subjects in total. The trial commenced in the first quarter of 2022 with the first patient in the study treated in April 2022 and completed treatment for all six subjects during the third quarter of 2022. Top-line data is anticipated from all subjects by the first quarter of 2023.
- General and administrative expenses were approximately $3.5 million for the three months ended June 30, 2022, compared to $2.8 million for the three months ended June 30, 2021, representing an increase of 24%. This increase was primarily due to an increase in fees associated with the proposed merger with Cend Therapeutics, Inc. 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.

Six Months Ended June 30, 2022 Compared to Six Months Ended June 30, 2021

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

	Six Months Ended June 30,		
	2022	2021	Change
Operating Expenses:			
Research and development	$ 6,517	$ 9,405	$ (2,888)
General and administrative	6,823	5,828	995
Total operating expenses	13,340	15,233	(1,893)
Loss from operations	(13,340)	(15,233)	1,893
Total other income (expense)	9	(20)	29
Benefit from income taxes	(2,479)	(1,508)	971
Net loss	$ (10,852)	$ (13,745)	$ 2,893

Overall, net losses were $10.9 million for the six months ended June 30, 2022, compared to $13.7 million for the six months ended June 30, 2021.

For the six months ended June 30, 2022, operating expenses totaled $13.3 million compared to $15.2 million for the six months ended June 30, 2021, representing a decrease of 12%. Operating expenses comprised the following:

- Research and development expenses were approximately $6.5 million for the six months ended June 30, 2022, compared to $9.4 million for the six months ended June 30, 2021, representing a decrease of $2.9 million or 31%. This decrease was primarily due to a decrease in expenses associated with manufacturing start-up costs and process development expenses for our XOWNA® Phase 2b study (the FREEDOM Trial), a decrease in expenses associated with HONEDRA® in Japan, revenue received from the Collaboration Agreement and one off recruiting expenses in the prior year. Research and development in both periods focused on the advancement of our ischemic repair platform and related to:
    - expenses associated with our XOWNA® Phase 2b study (the FREEDOM Trial) which commenced in the fourth quarter of 2020 with the first patient in the study treated in January 2021;
    - ongoing registration-eligible study expenses for HONEDRA® in critical limb ischemia in Japan which focused on patient enrollment completion. The study's enrollment has been significantly curtailed by the COVID-19 pandemic's impact in Japan, including the States of Emergency that have persisted there for most 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 complete unpredictability of the timing of site enrollment re-initiation, we will focus our efforts on consummating a partnership with a Japanese company in order to complete the study enrollment as well as to explore the possibility of submitting the existing data to PMDA under the SAKIGAKE designation; and
    - expenses associated with the preparation of our filing of an IND and study start-up expenses for the clinical study of CLBS201 for treatment of diabetic kidney disease. A Phase 1b, open-label, proof-of-concept trial which includes six subjects in total. The trial commenced in the first quarter of 2022 with the first patient in the study treated in April 2022 and completed treatment for all six subjects during the third quarter of 2022. Top-line data is anticipated from all subjects by the first quarter of 2023.
- General and administrative expenses were approximately $6.8 million for the six months ended June 30, 2022, compared to $5.8 million for the six months ended June 30, 2021, representing an increase of 17%. This increase was primarily due to an increase in fees associated with the review of potential strategic transactions and an increase in fees

associated with the proposed merger with Cend Therapeutics, Inc. 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 June 30, 2022, we had cash, cash equivalents and marketable securities of approximately $73.0 million, working capital of approximately $71.6 million, and stockholders' equity of approximately $82.4 million.

During the six months ended June 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):

	Six Months Ended June 30,	
	2022	2021
Net cash used in operating activities	$ (10,704)	$ (12,602)
Net cash provided by (used in) investing activities	19,544	(76,294)
Net cash (used in) provided by financing activities	(139)	85,319

Operating Activities

Our cash used in operating activities during the six months ended June 30, 2022 was $10.7 million, which is comprised of (i) our net loss of $10.9 million, adjusted for non-cash expenses totaling $2.0 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 $1.9 million.

Our cash used in operating activities during the six months ended June 30, 2021 was $12.6 million, which is comprised of (i) our net loss of $13.7 million, adjusted for non-cash expenses totaling $2.0 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 $0.9 million.

Investing Activities

Our cash provided by investing activities during the six months ended June 30, 2022 totaled $19.5 million and was primarily due to net sales of marketable securities (net of purchases of marketable securities).

Our cash used in investing activities during the six months ended June 30, 2021 totaled $76.3 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 six months ended June 30, 2022 totaled $0.1 million, consisted primarily of tax withholding-related payments on net share settlement equity awards to employees.

Our cash provided by financing activities during the six months ended June 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 biopharmaceutical 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, absent any impact from the Merger, if consummated. Our future capital requirements are difficult to forecast and will depend on many factors, including our ability to consummate the Merger; if the Merger is not completed, 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.

In order to provide Cend with capital for its development programs prior to the closing of the Merger, pursuant to the Purchase Agreement, we purchased 1,135,628 shares of Series D Preferred Stock of Cend for an aggregate purchase price of approximately $10.0 million.

On June 4, 2021, we entered into an At The Market Offering Agreement (the "ATM Agreement") with H.C. Wainwright & Co., LLC ("HCW"), 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. On February 18, 2022, we received a deficiency notice from Nasdaq informing us that we are not in compliance with the Minimum Bid Price Requirement. As such, we will not be able to sell shares under the ATM Agreement until we regain compliance, if ever. As of June 30, 2022, we had not issued any shares under the ATM Agreement. HCW is only obligated to make sales when we are in compliance with all Nasdaq listing standards.

In December 2021, we received preliminary approval from the NJEDA to participate in the NJ Technology Business Tax Certificate Transfer Program (the "Program"). The Program permits qualified companies to sell a percentage of their NJ NOLs to unrelated profitable corporations. On February 22, 2022, we received final approval from NJEDA to sell $2.5 million of our NJ NOL Tax Benefits, which were subsequently sold to a qualifying and approved buyer pursuant to the Program for net proceeds of $2.3 million.

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 six months ended June 30, 2022, compared to those reported in our 2021 Form 10-K.

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 June 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

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

There are no material changes to the disclosures previously reported in our 2021 Form 10-K.

ITEM 1A. RISK FACTORS

Other than as set forth below, there have been no material changes to the risk factors previously reported in our 2021 Form 10-K. See the risk factors set forth in our 2021 Annual Report on Form 10-K under the caption “Item 1 A - Risk Factors.”

We currently do not meet the continued listing standards of the Nasdaq Capital Market, which require a minimum closing bid price of $1.00 per share. Our failure to meet Nasdaq’s continued listing standards could result in the delisting of our common stock, negatively impact the price of our common stock and negatively impact our ability to raise additional capital.

Our common stock is listed on the Nasdaq Capital Market. Nasdaq provides various continued listing requirements that a company must meet in order for its stock to continue trading on the Nasdaq Capital Market. Among these requirements is the requirement that the Company’s stock trades at a minimum closing bid price of $1.00 per share. Our stock has recently and consistently traded below $1.00 per share, including closing bid prices below $1.00 per share. On February 18, 2022, we received a deficiency letter from The Nasdaq Stock Market which provided us a grace period of 180 calendar days, or until August 17, 2022, to regain compliance with the minimum bid price requirement. We may achieve compliance during this 180-day period if the closing bid price of our common stock is at least $1.00 per share for a minimum of 10 consecutive business days before August 17, 2022. If we fail to regain compliance on or prior to August 17, 2022, we may be eligible for an additional 180 day compliance period. Additionally, if we fail to comply with any other continued listing standards of Nasdaq, our common stock will also be subject to delisting. If that were to occur, our common stock would be subject to rules that impose additional sales practice requirements on broker-dealers who sell our securities. The additional burdens imposed upon broker-dealers by these requirements could discourage broker-dealers from effecting transactions in our common stock. This would significantly and negatively affect the ability of investors to trade our securities and would significantly and negatively affect the value and liquidity of our common stock. These factors could contribute to lower prices and larger spreads in the bid and ask prices for our common stock. If we seek to implement a reverse stock split in order to remain listed on The Nasdaq Capital Market, the announcement and/or implementation of a reverse stock split could significantly negatively affect the price of our common stock.

Our merger with Cend may not be consummated or may not deliver the anticipated benefits we expect.

There can be no assurance that the Merger will be completed in a timely manner or at all. In addition, even if the Merger is completed, there can be no assurance that the Merger will enhance stockholder value. The Merger Agreement is subject to many closing conditions and termination rights, as set forth in the Merger Agreement. If we do not close the Merger, our board of directors may elect to attempt to complete another strategic transaction similar to the Merger. Attempting to complete another strategic transaction similar to the Merger would be costly and time consuming, and we cannot make any assurances that a future strategic transaction will occur on commercially reasonable terms or at all. We are devoting a significant amount of our time and resources to consummating this transaction, however, there can be no assurance that such activities will result in the consummation of this transaction or that such transaction will deliver the anticipated benefits or enhance stockholder value.

Our net cash may be less than the required amount at the closing of the Merger, which would result in our stockholders owning a smaller percentage of the combined organization and could even result in the termination of the Merger Agreement.

The Merger Agreement includes a net cash requirement as a condition precedent for closing of the Merger. For purposes of the Merger Agreement, net cash is subject to certain reductions, including, without limitation, accounts payable, accrued liabilities (except those related to the Merger), current liabilities payable in cash, unpaid expenses related to the Merger and certain other unpaid obligations, including declared but unpaid cash dividends. In the event the amount of our net cash is smaller or such reductions are greater than anticipated, our stockholders could hold a significantly smaller portion of the combined organization.

Failure to complete the Merger may result in us paying a termination fee or expenses to Cend and could harm the price of our common stock and our future business and operations.

If the Merger is not completed, we are subject to the following risks:

- if the Merger Agreement is terminated under certain circumstances, we will be required to pay certain transaction expenses of Cend, up to a maximum of $1.0 million;
- if the Merger Agreement is terminated under certain circumstances, we will be required to pay Cend a termination fee of $4.0 million, or in some circumstances reimburse the other party's expenses up to a maximum of $1.0 million;
- the price of our common stock may decline and remain volatile; and
- certain of the costs related to the Merger, such as legal and accounting fees, must be paid even if the Merger is not completed.

In addition, if the Merger Agreement is terminated and our Board of Directors or the Cend Board of Directors determines to seek another business combination, there can be no assurance that we will be able to diversify and enhance our product candidate portfolio on terms equivalent or more attractive than the Merger.

The Merger may be completed even though material adverse changes may result from the announcement of the Merger, industry-wide changes and other causes.

In general, either we or Cend can refuse to complete the Merger if there is a material adverse change affecting the other party between the date of the Merger Agreement, and the Closing. However, certain types of changes do not permit either party to refuse to complete the Merger, even if such change could be said to have a material adverse effect on us or Cend, including:

- any rejection or non-acceptance by a governmental body of a registration or filing relating to certain of our intellectual property rights;
- the taking of any action, or the failure to take any action, by either us or Cend required to comply with the terms of the Merger Agreement;
- any effect resulting from the announcement or pendency of the Merger or any related transactions;
- any natural disaster or any act or threat of terrorism or war anywhere in the world, any armed hostilities or terrorist activities anywhere in the world, any threat or escalation or armed hostilities or terrorist activities anywhere in the world or any governmental or other response or reaction to any of the foregoing;
- any change in accounting requirements or principles of any change in applicable laws, rules or regulations or the interpretation thereof;
- any general economic or political conditions or conditions generally affecting the industries in which we and Cend operate;
- any changes in research in development, clinical trials or other drug development activities conducted on our behalf;
- continued losses from our operations or decreases in our cash balance;
- any epidemics, pandemics, disease outbreaks, or other public health emergencies or the escalation or worsening thereof, including COVID-19;
- with respect to us, any change in the stock price or trading volume of our common stock excluding any underlying effect that may have caused such change; and
- with respect to Cend, any change in the cash position of Cend that results from operations in the ordinary course of business.

If adverse changes occur and we and Cend still complete the Merger, the price of our common stock may suffer. This in turn may reduce the value of the Merger to our stockholders.

The market price of our common stock following the Merger may decline as a result of the Merger.

The market price of our common stock may decline as a result of the Merger for a number of reasons if:

- investors react negatively to the prospects of the combined organization's business and prospects from the Merger;
- the effect of the Merger on the combined organization's business and prospects is not consistent with the expectations of financial or industry analysts; or
- the combined organization does not achieve the perceived benefits of the Merger as rapidly or to the extent anticipated by financial or industry analysts.

Our stockholders may not realize a benefit from the Merger commensurate with the ownership dilution they will experience in connection with the Merger.

If the combined organization is unable to realize the full strategic and financial benefits currently anticipated from the Merger, our stockholders will have experienced substantial dilution of their ownership interests without receiving any commensurate benefit, or only receiving part of the commensurate benefit to the extent the combined organization is able to realize only part of the strategic and financial benefits currently anticipated from the Merger.

Our stockholders will have a reduced ownership and voting interest in, and will exercise less influence over the management of, the combined organization following the completion of the Merger as compared to their current ownership and voting interests.

After the completion of the Merger, our current stockholders will own a smaller percentage of the combined organization than their ownership prior to the Merger. Immediately after the Merger, our stockholders, whose shares of common stock will remain outstanding after the Merger, will own approximately 50% of the fully-diluted common stock of the combined organization, excluding out-of-the-money securities. These estimates are based on the anticipated exchange ratio and are subject to adjustment.

During the pendency of the Merger, we may not be able to enter into a business combination with another party at a favorable price because of restrictions in the Merger Agreement, which could adversely affect our respective businesses.

Covenants in the Merger Agreement impede our ability to make acquisitions, subject to certain exceptions relating to fiduciary duties, or to complete other transactions that are not in the ordinary course of business pending completion of the Merger. As a result, if the Merger is not completed, we may be at a disadvantage to our competitors during such period. In addition, while the Merger Agreement is in effect, we are generally prohibited from soliciting, initiating, encouraging or entering into certain extraordinary transactions, such as merger, sale of assets or other business combination outside the ordinary course of business with any third party, subject to certain exceptions relating to fiduciary duties. Any such transactions could be favorable to our stockholders.

Certain provisions of the Merger Agreement may discourage third parties from submitting alternative takeover proposals, including proposals that may be superior to the arrangements contemplated by the Merger Agreement.

The terms of the Merger Agreement prohibit us from soliciting alternative takeover proposals or cooperating with persons making unsolicited takeover proposals, except in limited circumstances when our board of directors determines in good faith that an unsolicited alternative takeover proposal is or is reasonably likely to be inconsistent with the board's fiduciary duties. Moreover, even if we receive what our board of directors determines is a superior proposal, the Merger Agreement does not permit us to terminate the Merger Agreement to enter into a superior proposal.

If the conditions of the Merger are not met, the Merger will not occur.

Even if the Merger is approved by our stockholders and Cend Stockholders, specified conditions must be satisfied or waived to complete the Merger. These conditions are set forth in the Merger Agreement, which is attached to this Quarterly Report as Exhibit 2.1. We cannot assure you that all of the conditions will be satisfied or waived. If the conditions are not satisfied or waived, the Merger will not occur or will be delayed, and we may lose some or all of the intended benefits of the Merger.

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.

August 4, 2022

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

CALADRIUS BIOSCIENCES, 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).
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).
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.

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 Caladrius Biosciences, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: August 4, 2022

/s/ David J. Mazzo, PhD
Name: David J. Mazzo, PhD
Title: President and 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 Caladrius Biosciences, Inc. (the "Company") for the quarter ended June 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: August 4, 2022

/s/ David J. Mazzo, PhD
David J. Mazzo, PhD
President and 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.