



Caladrius Biosciences Announces 2017 First Quarter Financial Results

May 15, 2017



Conference call scheduled for May 18, 2017 at 5:00 p.m. Eastern time

BASKING RIDGE, N.J., (May 15, 2017) – Caladrius Biosciences, Inc. (NASDAQ: CLBS) (“Caladrius” or the “Company”), a cell therapy company with a therapeutic development pipeline focused on immune modulation and select cardiovascular conditions as well as a subsidiary, PCT, a development and manufacturing partner for the cell therapy industry, announces financial results for the three months ended March 31, 2017.

Highlights of the 2017 first quarter and recent weeks

PCT:

- Entered into a definitive agreement with Hitachi America (Hitachi) whereby Hitachi will purchase Caladrius' remaining 80.1% ownership interest in PCT for \$75 million in cash, subject to potential adjustments based on PCT's cash and outstanding indebtedness as of the closing of the sale, and a potential future milestone payment.
- The shareholder vote on the transaction will take place on May 16, 2017.
- The Company's Board of Directors and management team encourage all shareholders to vote in favor of the transaction.

CLBS03:

- Received initial funding of \$5.7 million from the California Institute for Regenerative Medicine (CIRM) as funding support for the Company's Phase 2 clinical trial of CLBS03, an investigational cell therapy being evaluated as a treatment for recent onset type 1 diabetes (the Sanford Project: T-Rex Study). The CIRM grant is an aggregate award of up to \$12.2 million, payable upon the achievement of certain milestones.
- A \$620,000 research grant from the Juvenile Diabetes Research Foundation was awarded to Benaroya Research Institute at Virginia Mason to support the extensive immune-profiling of CLBS03 as part of the ongoing Phase 2 T-Rex Study. Although the grant was awarded to Benaroya Research Institute, the funds will offset Company costs otherwise payable to Benaroya on a dollar-for-dollar basis.
- Opened eight additional clinical sites in the Phase 2 T-Rex Study including Yale University School of Medicine, Joslin Diabetes Center, an affiliate of Harvard Medical School, UCSF Benioff Children's Hospital San Francisco, Children's Mercy Hospital, the University of Miami Diabetes Research Institute, Vanderbilt University Hospital, University of Florida Diabetes Institute and the Harold Schnitzer Diabetes Health Center at Oregon Health & Sciences University.

Management Commentary

"We look forward to the successful acquisition by Hitachi of our remaining interest in PCT. Their ability to deploy the capital and engineering capabilities needed to achieve PCT's commercial scale manufacturing growth goals and establish a global commercial manufacturing enterprise will benefit all of PCT's clients, especially Caladrius, as PCT will continue to provide development and manufacturing services for our T-regulatory cell programs," stated David J. Mazzo, PhD, President and Chief Executive Officer of Caladrius.

"Following this transaction, Caladrius will emerge as a pure-play, well capitalized development company with the funding needed to complete our Phase 2 clinical program and to selectively and opportunistically invest in other pipeline programs through a disciplined, data-driven process. We also

remain committed to continuing to explore other means of collaborative support, such as grants, partnerships or licensing, to contribute to any development programs we undertake.

"We continue to be excited about the opportunities for our lead program, CLBS03 and the Phase 2 T-Rex underway for the treatment of type 1 diabetes. We look forward to reaching the half-way treatment mark in mid-year. Also, in conjunction with our September 2016 private placement, enrollment of the 70th subject will trigger an additional infusion of capital, which we also expect to occur in the coming months," concluded Dr. Mazzo.

First Quarter Financial Highlights

Total revenues for the first quarter of 2017 increased 6% to \$7.9 million compared with \$7.5 million in the first quarter of 2016. However, first quarter of 2017 gross margin was negative 2% due to significant unused capacity at PCT resulting from lower patient enrollment in client clinical trials, together with the conclusion of a contract with a single large client. This compares to gross margin of \$1.3 million, or 17%, for the first quarter of 2016.

Research and development (R&D) expenses for the first quarter of 2017 decreased 41% to \$3.5 million compared with \$5.9 million for the first quarter of 2016, primarily related to the discontinuation of non-core R&D programs announced at the beginning of 2016 and related reductions in R&D staffing and departmental costs, partially offset by increased costs related to the ongoing Phase 2 T-Rex Study.

Selling, general and administrative (SG&A) expenses were approximately \$5.9 million for the first quarter of 2017 compared with \$6.5 million for the same period in 2016, primarily due to lower operational and compensation-related costs during the 2017 first quarter, offset by \$1.3 million in transaction related expenses in connection with the Hitachi Chemical acquisition of the Company's PCT subsidiary.

The net loss attributable to Caladrius common stockholders for the three months ended March 31, 2017 was \$9.4 million or \$1.12 per share, compared with \$12.0 million or \$2.09 per share for same period in 2016.

Balance Sheet and Cash Flow Highlights

As of March 31, 2017, Caladrius had cash and cash equivalents of \$12.0 million compared with \$14.7 million as of December 31, 2016. During the first quarter the Company received \$5.0 million in connection with the signing of the Hitachi transaction and \$2.0 million paid from Sanford Research with the delivery to them of the second tranche of securities pursuant to their equity investment in Caladrius in September, 2016. We also began making principal payments on our long-term debt with Oxford Finance.

Net cash used in operating activities during the first quarter of 2017 of \$10.1 million was unusually high primarily due to lower gross margins in the PCT business compared to prior quarters, and Hitachi transaction-related costs. The Company expects to provide more specifics on cash usage for the balance of 2017 after the closing of the Hitachi transaction.

Conference Call

Caladrius' management will host a conference call for the investment community on May 18, 2017, beginning at 5:00 p.m. Eastern Time to review the financial results, provide a Company update and answer questions.

Shareholders and other interested parties may participate in the conference call by dialing 877-562-4460 (U.S.) or 513-438-4106 (international) and providing conference ID 20837689. The call will also be broadcast live on the Internet via the Company's website at www.caladrius.com/events.

The webcast will be archived on the Company's website for 90 days.

About Caladrius Biosciences

Caladrius Biosciences, Inc. is a cell therapy development company with cell therapy products in development based on multiple technology platforms and targeting autoimmune and cardiology indications. The Company is investigating its lead product candidate, CLBS03, for the treatment of recent-onset type 1 diabetes in a currently enrolling Phase 2 trial. The Company's subsidiary, PCT, is a well-known development and manufacturing partner exclusively focused on the cell therapy industry and has served over 100 clients since 1999. For more information on Caladrius please visit www.caladrius.com.

Safe Harbor for Forward Looking Statements

This Press Release contains forward-looking statements within the meaning of Private Securities Litigation Reform Act of 1995, including forward-looking statements regarding the Sale, the possibility of obtaining stockholder or other approvals or consents for the Sale and Caladrius' future prospects. These statements are neither promises nor guarantees, but involve risks and uncertainties that could cause actual events or results to differ materially from those set forth in the forward-looking statements, including, without limitation: risks and uncertainties relating to potential adverse reactions or changes to business relationships resulting from the announcement or completion of the Sale; risks related to the failure to complete the Sale; unexpected costs, charges or expenses relating to or resulting from the Sale; restrictions contained in, and termination fees that may be payable pursuant to, the purchase agreement relating to the Sale; litigation or adverse judgments relating to the Sale; risks relating to the completion of the proposed Sale, including the risk that the required stockholder vote might not be obtained in a timely manner or at all, or other conditions to the completion of the Sale not being satisfied; any difficulties associated with requests or directions from governmental authorities resulting from their review of the Sale; any changes in general economic and/or industry-specific conditions; and other risks detailed in Caladrius' filings with the SEC, including those disclosed under "Item 1A. Risk Factors" in Caladrius' Annual Report on Form 10-K filed with the SEC on March 17, 2017 and in subsequent reports on Forms 10-Q and 8-K and other filings made with the SEC. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date of this Press Release. Caladrius does not intend, and disclaims any obligation, to update or revise any forward-looking information contained in this Press Release or with respect to the matters described herein.

-Tables to Follow-

Caladrius Biosciences, Inc.

Selected Financial Data (unaudited)		
(in thousands, except per share data)		
(in thousands, except per share data)	Three Months Ended March 31,	
	2017	2016
Statement of Operations Data:		
Revenues	\$ 7,923	\$ 7,489
Costs and expenses:		
Cost of revenues	8,042	6,228
Research and development	3,463	5,876
Impairment of intangible assets	–	–
Selling, general, and administrative	5,949	6,458
Total operating costs and expenses	17,454	18,563
Operating loss	(9,531)	(11,074)
Other income (expense), net	(44)	6
Interest expense	(168)	(927)
Loss before income taxes and noncontrolling interests	(9,744)	(11,994)
Provision for income taxes	50	53
Net loss	(9,793)	(12,048)
Less – loss attributable to noncontrolling interests	(433)	(67)
Net loss attributable to Caladrius Biosciences, Inc. common stockholders	\$ (9,360)	\$ (11,981)
Basic and diluted loss per share attributable to Caladrius Biosciences, Inc. common stockholders	\$ (1.12)	\$ (2.09)
Weighted average common shares outstanding	8,387	5,738

	March 31, 2017	December 31, 2016
Balance Sheet Data:		
Cash and cash equivalents	\$ 11,998	\$ 14,705
Total assets	48,528	51,833
Total liabilities	31,104	28,366
Total redeemable securities	19,400	19,400
Total equity	(1,976)	4,066



Source: Caladrius Biosciences, Inc.