Caladrius Biosciences Announces 2016 Fourth Quarter and Full Year Financial Results

March 17, 2017

Annual revenue growth of 57% exceeds 2016 financial guidance

Conference call begins today at 8:30 am Eastern time

BASKING RIDGE, N.J., (March 17, 2017) – Caladrius Biosciences, Inc. (NASDAQ: CLBS) ("Caladrius" or the "Company"), a cell therapy company with a select therapeutic development pipeline focused on immune modulation and a subsidiary, PCT, a development and manufacturing partner for the cell therapy industry, announced financial results for the three and twelve months ended December 31, 2016.

2016 and 2017 Year to Date Highlights

PCT:

- Executed a global collaboration and license agreement between PCT and Hitachi Chemical Co., Ltd. in connection with the sale of 19.9% of PCT to Hitachi Chemical Co. America, Ltd. ("Hitachi America") for $19.4 million; and
- Entered into a definitive agreement with Hitachi America whereby Hitachi America agreed to purchase Caladrius' remaining 80.1% membership interest in PCT for $75 million, subject to potential adjustments, including based on PCT's cash and outstanding indebtedness as of the closing of the sale, and a potential future milestone payment.

CLBS03:

- Awarded a grant from the California Institute for Regenerative Medicine (CIRM) for the development of CLBS03 for an aggregate amount of up to $12.2 million, payable upon the achievement of certain milestones, for the Company's investigational cell therapy currently being evaluated as a treatment for recent onset type 1 diabetes (T1D);
- Initiated a Phase 2 trial, the Sanford Project: T-Rex Study (T-Rex Study), for CLBS03;
- Completed enrollment of the initial cohort of 18 subjects of the T-Rex Study and, following a favorable safety recommendation from the Data Safety Monitoring Board, resumed enrollment of the second and final cohort of the study;
- Received Orphan Drug and Fast Track designations from the U.S. Food and Drug Administration for CLBS03; and
- Expanded the strategic collaboration with Sanford Research beyond operational support for the CLBS03 clinical program.

CLBS12:

- Reached agreement with Japanese regulators on a development plan for CD34 cell therapy for critical limb ischemia (CLBS12) which would qualify the product for early conditional commercial approval upon successful execution.

Fourth Quarter Financial Highlights

Total revenues for the fourth quarter of 2016 increased 35% to $10.2 million compared with $7.6 million in the fourth quarter of 2015, primarily due to higher reported Clinical Services revenues at PCT.

Research and development (R&D) expenses for the fourth quarter of 2016 decreased 19% to $2.6 million compared with $3.2 million for the fourth quarter of 2015, 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 costs related to the ongoing Phase 2 T-Rex Study.

Selling, general and administrative (SG&A) expenses were approximately $4.3 million for the fourth quarter of 2016 compared with $5.0 million for the same period in 2015, primarily due to lower operational and compensation-related costs during the 2016 fourth quarter.

The net loss attributable to Caladrius common stockholders for the three months ended December 31, 2016 was $6.0 million or $0.73 per share, compared to $33.2 million or $5.92 per share for same period in 2015.

Net loss for the fourth quarter of 2015 included the impairment of in-process R&D (IPR&D) valued at $34.3 million related to the Company's decision to discontinue its Phase 3 study of CLBS20 in metastatic melanoma. This impairment was partially offset by the reversal of a related deferred tax liability and the reversal of a related contingent consideration milestone obligation. The net impact for these changes was a $24.7 million increase in net loss.

Full Year Financial Highlights

Total revenues for 2016 of $35.3 million represented an increase of 57% compared with $22.5 million for 2015. R&D expenses in 2016 were $15.1 million compared with $23.9 million in 2015. SG&A expenses for 2016 were $20.4 million compared with $30.0 million for 2015.

The net loss attributable to Caladrius common stockholders for 2016 was $32.7 million or $4.99 per share based on 6.5 million shares outstanding, compared to $80.9 million or $16.67 per share based on 4.9 million shares outstanding for 2015.

Net loss for 2015 included the impairments of IPR&D associated with our CLBS20 and CLBS10 clinical programs, valued at $43.7 million. These impairments were partially offset by reversals of related deferred tax liabilities, and the reversals of related contingent considerations obligations. The net impact for these changes was a $24.7 million increase in 2015 net loss.

Balance Sheet and Cash Flow Highlights

As of December 31, 2016, Caladrius had cash and cash equivalents of $14.7 million. The net cash used in operating activities for 2016 was $23.7 million. During 2016, the Company invested $2.8 million in capital expenditures primarily related to equipment and improvements for PCT's Allendale, N.J. and Mountain View, CA manufacturing facilities.

Conference Call

Caladrius' management will host a conference call for the investment community today, March 17, 2017, beginning at 8:30 a.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 95709222. 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 leading development and manufacturing partner exclusively focused on the cell therapy industry and has served over 100 clients since 1999. Caladrius has entered into a definitive agreement pursuant to which Hitachi America intends to purchase Caladrius' remaining 80.1% membership interest in PCT and thereby transform Caladrius into a therapeutics-only development company. The sale of the Company's remaining interest in PCT is subject to the approval of the Company's stockholders and customary closing conditions. There can be no assurance that such sale will be completed in the anticipated timeframe or at all. For more information on Caladrius please visit www.caladrius.com.

Additional Information About the Transaction and Where to Find it

Caladrius intends to file with the Securities and Exchange Commission ("SEC") and mail to its stockholders a proxy statement in connection with, among other things, the sale to Hitachi America of the 80.1% membership interest in PCT that Hitachi America does not already own (the "Sale"). **Investors and stockholders of Caladrius are urged to read the proxy statement and the other relevant materials when they become available because they will contain important information about Caladrius and the Sale.** The proxy statement and other relevant materials (when they become available), and any other documents filed by Caladrius with the SEC, may be obtained free of charge at the SEC's website at www.sec.gov. In addition, investors and stockholders may obtain free copies of the documents filed with the SEC by Caladrius by directing such requests to Caladrius Biosciences, Inc., 420 Lexington Avenue, Suite 350, New York, NY 10170, Attn: Jacquelyn Briggs or jbriggs@caladrius.com, Telephone: (646) 606-2221.

Participants in the Solicitation

Caladrius and its directors and executive officers may, under SEC rules, be deemed to be participants in the solicitation of proxies from Caladrius' stockholders in connection with the Sale. **Information regarding Caladrius' directors and executive officers is contained in Caladrius' proxy statement on Schedule 14A filed with the SEC on May 10, 2016. Additional information regarding the participants in the solicitation of proxies in respect of the Sale and a description of their direct and indirect interests, by security holdings or otherwise, will be contained in the proxy statement when it becomes available**.

Safe Harbor for Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including forward-looking statements regarding the proposed Sale, the possibility of obtaining a milestone payment and the transformation of Caladrius into a therapeutics-only development company. 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 proposed Sale; unexpected costs, charges or expenses relating to or resulting from the proposed Sale; litigation or adverse judgments relating to the proposed 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 proposed Sale not being satisfied; any difficulties associated with requests or directions from governmental authorities resulting from their review of the proposed 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.

Caladrius Biosciences, Inc. Selected Financial Data
(in thousands, except per share data)

	Three Months Ended December 31,	12 Months Ended December 31,

(in thousands, except per share data)	2016	2015	2016	2015
Statement of Operations Data:				
Revenues	$10,176	$7,560	$35,284	$22,488
Costs and expenses:				
Cost of revenues	9,245	6,183	31,136	20,159
Research and development	2,574	3,179	15,109	23,899
Impairment of intangible assets	–	52,873	–	62,273
Selling, general, and administrative	4,274	5,034	20,375	30,006
Total operating costs and expenses	16,093	67,269	66,620	136,337
Operating loss	(5,917)	(59,709)	(31,336)	(113,849)
Other income (expense), net	4	13,325	22	17,724
Interest expense	(186)	(477)	(1,858)	(2,128)
Loss before income taxes and noncontrolling interests	(6,099)	(46,862)	(33,171)	(98,254)
Provision for income taxes	(9)	(13,633)	138	(17,244)
Net loss	(6,089)	(33,228)	(33,310)	(81,011)
Less – loss attributable to noncontrolling interests	(131)	(31)	(653)	(125)
Net loss attributable to Caladrius Biosciences, Inc. common stockholders	$(5,958)	$(33,197)	$32,656)	$(80,886)
Basic and diluted loss per share attributable to Caladrius Biosciences, Inc. common stockholders	(0.73)	(5.92)	(4.99)	(16.67)
Weighted average common shares outstanding	8,176	5,609	6,548	4,851

	December 31, 2016	December 31, 2015
Balance Sheet Data:		
Cash, cash equivalents, and marketable securities	$14,705	$20,318
Total assets	51,833	57,205
Total liabilities	28,366	33,921
Total redeemable securities	19,400	–
Total equity	4,066	23,284

Source: Caladrius Biosciences, Inc.