UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

SCHEDULE 14A

Proxy Statement Pursuant to Section 14(a) of the Securities Exchange Act of 1934

Filed by the Registrant \boxtimes Filed by a party other than the Registrant \square

Check the appropriate box:

- □ Preliminary Proxy Statement
- □ Confidential, for Use of the Commission Only (as permitted by Rule 14a-6(e)(2))
- □ Definitive Proxy Statement
- □ Definitive Additional Materials
- Soliciting Material Under § 240.14a-12

CALADRIUS BIOSCIENCES, INC.

(Name of Registrant as Specified In Its Charter)

(Name of Person(s) Filing Proxy Statement, if other than the Registrant)

Payment of Filing Fee (Check the appropriate box):

⊠ No fee required.

П

- □ Fee computed on table below per Exchange Act Rules 14a-6(i)(1) and 0-11.
 - (1) Title of each class of securities to which transaction applies:
 - (2) Aggregate number of securities to which transaction applies:
 - (3) Per unit price or other underlying value of transaction computed pursuant to Exchange Act Rule 0-11 (set forth the amount on which the filing fee is calculated and state how it was determined):
 - (4) Proposed maximum aggregate value of transaction:
 - (5) Total fee paid:

 $\hfill\square$ Fee paid previously with preliminary materials.

Check box if any part of the fee is offset as provided by Exchange Act Rule 0-11(a)(2) and identify the filing for which the offsetting fee was paid previously. Identify the previous filing by registration statement number, or the Form or Schedule and the date of its filing.

- (6) Amount previously paid:
- (7) Form, Schedule or Registration Statement No.:
- (8) Filing party:

(9) Date Filed:

The following is a transcript of the Caladrius Biosciences, Inc. ("Caladrius") year-end financial results conference call held on March 17, 2017 at which management discussed, among other things, the proposed acquisition of Caladrius' PCT business by Hitachi Chemical Co. America, Ltd. The transcript has been edited to correct erroneous transcriptions and garbled statements.

Operator: Welcome to the Caladrius Biosciences 2016 4th quarter and year end financial results conference call. At this time all participants are in a listen-only mode. Following management's prepared remarks, we will hold a Q&A session. To ask a question at that time, please press the * key followed by 1 of your, on touch tone phone. If anyone has difficulty hearing the conference, please press *0 for operator assistance. As a reminder, this conference is being recorded today, March 17, 2017. I would now like to turn the conference over to Anne Marie Fields. Please go ahead, ma'am.

Anne Fields: Thank you. Good morning. This is Anne Marie Fields with LHA, investor relations firm for Caladrius Biosciences. Thank you all for participating in today's call. Joining me from Caladrius Biosciences are Dr. David Mazzo, Chief Executive Officer, and Joseph Talamo, Chief Financial Officer. Yesterday evening Caladrius issued a news release announcing Hitachi Chemical's acquisition of the company's remaining interest in its PCT subsidiary, and earlier this morning Caladrius issued a news release announcing the company's 2016 4th quarter and year end financial results. If you have not received these news releases, or if you would like to be added to the company's distribution list, please call LHA in New York at 212-838-3777 and speak with Carolyn Curran or email updates@caladrius.com.

Because Caladrius' sale of its remaining interest in PCT is subject to stockholder approval, Caladrius intends to file with the Securities and Exchange Commission and mail its stockholders a proxy statement in connection with, among other things, the sale to Hitachi Chemical Company America, Ltd, or the purchaser, of the 80.1% membership interest in PCT that purchaser does not already own, or "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, New York, 10170, Attention: Jacquelyn Briggs, or jbriggs@caladrius.com. And her telephone number is 646-606-2221.

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.

This conference call contains forward-looking statements within the meaning of Private Securities Litigation Reform Act of 1995, including forward-looking statements regarding the proposed sale, the possibility of obtaining the earnout payments, the possibility of obtaining a stockholder or other approvals or consents for the proposed 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 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 required stockholder votes 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 at the SEC, including those disclosed under Item 1A, Risk Factors, in Caladrius' annual report on Form 10-K filed with the SEC on March 16, 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 conference call. Caladrius does not intend and disclaims any obligations to update or revise any forward-looking information contained in this conference call or with respect to the matters described herein. 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 shall, sale will be completed in the anticipated time frame or at all. So, with that said, let me now turn the call over to Dr. Mazzo. Dave?

David Mazzo: Thanks, Anne Marie, and good morning to everyone. And to those who are celebrating, happy St. Patrick's Day. Thank you all for joining on today's call. Yesterday evening we announced an event that is transformational to Caladrius, both in terms of our financial position and in terms of our business strategy. I'm delighted to report the entry into an agreement for the acquisition of our remaining 80.1% interest in PCT by Hitachi Chemical. This transaction has the potential to unlock the tremendous value of our PCT asset in a way that was unimaginable just a few years ago and create the well-capitalized, debt-free, pure-play, self-therapeutic development company with compelling opportunities for near and longer term value creation.

Before getting into the financial results from 2016, let me begin by reviewing the terms of the agreement with Hitachi. Yesterday we signed a definitive agreement with Hitachi Chemical, under which Hitachi agreed to acquire the remaining 80.1% of PCT that Caladrius owned. As you may recall, Hitachi Chemical purchased 19.9% of PCT in March of 2016. Under the agreement we announced yesterday, we will receive a \$5 million payment immediately, and \$70 million is due upon the closing of the transaction, 5 million of which will be placed in escrow to cover indemnification claims, if any.

We expect the closing to occur in May following our annual stockholders' meeting, at which we will solicit approval of the transaction from Caladrius stockholders. Details regarding the sale will be included in a proxy statement, which will be distributed to Caladrius stockholders in the near future. In addition, we will receive an additional 5 million payment should PCT achieve a pre-defined revenue milestone by the end of 2018. And finally, as part of this agreement, Caladrius will maintain a strong relationship with PCT as a customer and will receive seven years of discounted T-regulatory cell platform development and manufacturing services.

There is a strong rationale underlying this agreement. While we are very pleased and proud of the progress we have made stabilizing and growing the PCT business, especially in the last two years, we are increasingly challenged by the tens of millions of dollars of additional capital investment needed over the next several years for PCT to fully realize its cell therapy commercial manufacturing growth goals. Hitachi, on the other hand, is in a position today to deploy the capital and engineering capabilities needed to ultimately achieve those growth goals and establish a global commercial manufacturing enterprise. All of PCT's clients,

including and perhaps especially Caladrius, stand to benefit from PCT's integration into Hitachi's global footprint along with the resulting access to advanced and/or proprietary engineering applications to improve operations and provide solutions for process optimization and automation for cell therapy development and manufacturing.

This transaction unlocks and creates value. This agreement will redefine Caladrius as a pure-play cell therapeutics development company with multiple proprietary technology platforms and significant capital resources to support future programs. Once closed, we intend to use some of the proceeds from this transaction to fund compelling initiatives, both existing and yet to be identified, including the following. (clears throat) Excuse me. We will now have the capital necessary to complete our US Phase 2 clinical trial for our lead T-regulatory cell product candidate, CLBS03. This trial, the Sanford Project T-Rex Study, is currently enrolling patients in the second of two patient cohorts and is evaluating CLBS03 as a treatment for recent-onset type 1 diabetes.

We will initiate a Phase 2 trial in Japan to evaluate our CD34 cell platform-based product candidate, CLBS12, as a treatment for patients with no-option critical limb ischemia. Recall that we have negotiated a 35-patient open-label protocol with the Japanese authorities that, if successful, should qualify the product for early conditional commercial approval in Japan.

We will access additional clinical development candidates based on our T-regulatory cell and CD34 cell platforms. Our foray into the evaluation of new indications in autoimmune disease and/or cardiovascular disease based on these platforms will be influenced heavily by our ability to secure grant support for the proposed work. We will judiciously and opportunistically evaluate new opportunities to acquire additional products at various stages of development as appropriate and we will fully eliminate our remaining 5.5 million dollars of outstanding debt with Oxford Finance.

During our strategic review in early 2016, we identified our immune modulatory platform as a program with significant competitive potential across multiple indications, with development costs that would allow us to reach the next clinical milestone more in keeping with our financial resources. Throughout 2016 we made significant progress with our CLBS03 program and we can look forward to a number of value-creating milestones in 2017 that will further establish Caladrius as a leading cell therapy development company.

As a recap, in 2016 we initiated our US Phase 2 trial, the T-Rex study of CLBS03, to treat recent-onset type 1 diabetes in collaboration with Sanford Research. We completed enrollment of the initial cohort of 19 subjects of that trial, and, following the favorable safety recommendation from the Independent Data Safety Monitoring Board, which came ahead of our originally planned schedule, we resumed enrollment of the second and final cohort of the study. We received Orphan Drug and Fast Track designations from the US Food and Drug Administration and advanced therapeutic medicinal product classification from the European Medicines Agency for CLBS03 to treat type 1 diabetes.

We expanded the strategic collaboration with Sanford Research beyond operational support for the T-Rex study to include a \$5 million direct investment in Caladrius. And in February 2017 we were awarded a grant of up to an aggregate \$12.2 million from the California Institute for Regenerative Medicine, payable upon the achievement of certain milestones to support the development of CLBS03 as a treatment for type 1 diabetes, specifically directed toward the T-Rex study. We look forward to driving this landmark study through a series of milestones throughout 2017, culminating in the scheduled interim analysis of early therapeutic effect expected at the end of 2017 or early in 2018.

Before we move into a more detailed discussion of our clinical progress and plans, allow me to turn the call over to Joe Talamo, our chief financial officer, for a review of the 2016 4th quarter and year e-, and year end results. Joe?

Joseph Talamo: Thank you, Dave, and good morning, everyone. Before I review the, our 2016 financial results, I'd briefly like to touch upon the financial impact, both immediate and upon closing, of the agreement with Hitachi for the sale of our remaining 80.1% interest in PCT. Under the terms of the agreement, upon closing we will have received a total of 70 million in cash, 5 million of which should be received in the next few days, plus an additional 5 million to be received at the expiration of the escrow period, assuming no in- indemnification claims are made. It goes without saying that an infusion of non-dilutive capital of this magnitude enables us to fully fund our ongoing CLBS03 clinical development program, to selectively and opportunistically invest in other pipeline programs, and to pay off the balance of our 5.5 million debt with Oxford.

In addition, the agreement provides for the potential of an additional 5 million milestone payable if PCT achieves a pre-defined revenue milestone by the end of 2018. Lastly, this agreement will secure long-term manufacturing services with PCT in support of our T-regulatory platform development and manufacturing at very, at a very attractive price point. Overall, this is a transaction that will substantially stabilize our financial position and will enable us to fully pursue our near-term initiatives with financial competence.

Let's now turn to our 2016 financial results. We have completed a very strong 2016, with full-year results meeting or exceeding our guidance established at the beginning of 2016. 4th quarter 2016 revenues of \$10.1 million increased 35%, compared with \$7.6 million last year. Revenues for the full year of 2016 increased 57%, to \$35.3 million, due to higher clinical service revenues at PCT. Overall revenue significantly beat our full-year guidance of greater than \$30 million and better than 30% growth.

Regarding operating expenses, we continue to drive down cost by focusing on prudent expense management. In the 4th quarter of 2016 R&D expenses decreased 19%, to \$2.6 million, from the previous year, and for the full year R&D expenses decreased 37%, to \$15.1 million. R&D declines in both the 4th quarter and the full year were 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 our ongoing Phase 2 T-Rex study.

Moving to SG&A, 4th quarter 2016 expenses decreased 15%, to \$4.3 million, compared with the prior year. And for the full year, SG&A expenses were down 32%, to \$20.4 million, showing the results for our continued focus on improving cost management. The net loss attributable to Caladrius common share stockholders for 2016 4th quarter was \$6 million, or 73 cents per share, compared with a net loss of \$33.2 million, or \$5.92 per share for the same period in 2015.

For the full 2016 year, the net loss attributable to Caladrius common stockholders was \$32.7 million, or \$4.99 per share, compared with the net loss of \$80.9 million, or \$16.67 per share, in 2015. As a reminder, the 2015 net losses did include non-cash, in-process R&D and goodwill impairment charges and the reversal of deferred tax and contingent consideration liabilities related to the discontinuation of our non-core programs announced at the beginning of 2016.

Looking now to our balance sheet and cash flow, we ended 2016 with cash and cash equivalents of \$14.7 million and long-term debt of \$5.5 million due to Oxford Finance. Of particular note, we began 2016 with \$15 million of long-term debt, and over the course of 2016 we aggressively paid down nearly two-thirds of this amount by year end. Our net cash used in operating

activities during 2016 was \$23.7 million, which was below the lower end of our \$25-28 million 2016 guidance range. In 2016 we invested \$2.8 million in capital expenditures for equipment and improvement, primarily in our PCT facilities.

One additional note: our financial statements included in our Form 10-K filed last night include an unqualified audit opinion from our auditors and also include a going concern opinion, which is measured as of the date of filing the Form 10-K. However, with last night's announcement of the agreement with Hitachi, we believe upon closing, the closing of this transaction we will have mitigated any going concern.

As a note about financial guidance, given the announcement today and our agreement with Hitachi Chemical, we will defer providing financial guidance for Caladrius for 2017 until after the transaction closes. With that, let me turn the call back to Dave.

David Mazzo: Thanks, Joe. As the Hitachi Chemical agreement has the potential to redefine Caladrius as a pure-play cell therapy development company, let's turn now to a discussion of our business strategy. Our clinical strategy is to develop select assets and to advance them to the next development milestone, representing a significant increase in value, most often to proof-of-concept demand. Our long-term goal will be to partner those assets for further clinical development and ultimately commercial sale. We believe this strategy will create value for our shareholders, first by virtue of simply achieving development maturation and de-risking and then through the ultimate economics associated with partnering them.

As I noted earlier, last year we identified our immune modulation program based on T-regulatory cell technology as one with significant competitive potential across multiple indications, and we made CLBS03 our primary clinical focus. CLBS03 is a personalized, autologous cell therapy consisting of each patient's own regulatory T cells, or Tregs, which have been expanded in number and functionally enhanced by a proprietary method developed through the collaboration with renowned researchers at the University of California, San Francisco, or UCSF. The program is supported by promising published early clinical work conducted by respective leaders in the area of T-regulatory cell science.

In a Phase 1 open-label, dose-escalating study using a product analogous to CLBS03 and conducted at UCSF and Yale University, evidence for safety and tolerability of autologous expanded polyclonal T-regulatory cell therapy in 14 adults with established type 1 diabetes was shown. Supportive two-year follow-up data from this study were published in November 2015 in the peer review journal Science Translational Medicine. Additionally, early evidence of the utility of Tregs for type 1 diabetes was provided by a study of pediatric patients age 5-18 with new-onset type 1 diabetes as published in Clinical Immunology.

In that open-label, non-randomized study, the authors reported that treatment with expanded autologous Tregs preserved function of pancreatic beta cells and reduced the need for exogenous insulin in a majority of patients treated. Prominent clinicians and scientists on our scientific advisory board and the T-Rex study executive steering committee, such as Drs. Jeff Bluestone and Steve Gitelman of UCSF and Kevan Herold of Yale University, are associated with the trial and provide us confidence in the clinical and scientific rationale underlying CLBS03.

As to the specifics of the Phase 2 T-Rex study, the Sanford Project T-Rex Study is a prospective, randomized, placebo-controlled, double-blind Phase 2 clinical trial to evaluate the safety and efficacy of CLBS03 in adolescents with recent-onset type 1 diabetes. The allowable range for the study has been expanded from ages 12-17 to ages 8-17. The study will include 111 subjects across approximately 12-15 US sites. We have already completed the 19-patient first cohort and an interim safety review, and following a favorable safety recommendation from the

Independent Data Safety Monitoring Board, we resumed enrollment of the second and final cohort of the study in October of 2015.

Patients are being randomized to placebo for one of two active arms, receiving either 2.5 million or 20 million of their own Treg cells per kilogram of body weight, respectively. The study uses standard endpoints for a diabetes study, including C-peptide measurement, which is an accepted measure of the preservation of beta cell function, insulin use, severe hypoglycemic episodes, and hemoglobin A1C levels. (clears throat) Pardon me.

The study has a pre-specified interim analysis of early therapeutic effect that is scheduled when half of the subjects reach the sixth month post-treatment follow-up visit. Given the high level of interest in this study, we expect to reach the corresponding enrollment milestone by mid-2017, with the top-line data from the interim analysis to be announced in late 2017 or in early 2018. Data from the 12-month follow-up of all subjects are expected in late 2018 to early 2019. In conjunction with our private placement from September 2016, enrollment of the 70th subject will trigger an additional infusion of capital, which was previously defined to occur in mid-2017.

As the name study ... Excuse me. As the study name implies, we are in partnership with Sanford Research for the conduct of this Phase 2 trial. Sanford Research is a non-profit research organization that is part of Sanford Health and supports an emerging translational research center focused on finding a cure for type 1 diabetes. Through our partnership, Sanford is providing the operational resources to execute subject recruitment, enrollment, treatment, and monitoring, along with corresponding support services at their two clinical sites. In addition, Sanford agreed to make a \$5 million equity investment in Caladrius in support of this very promising program in the September 2016 private placement, 60% of which has been received. The remaining 40%, originally agreed to be received when the 70th patient has been enrolled, is being accelerated based on their enthusiasm for the study and should be received shortly.

The potential of Tregs as a therapeutic platform has applicability in many other immune modulated diseases. Our redefined focus on cell therapy and the funds expected to be available through the agreement with Hitachi Chemical for the sale of our remaining interest in PCT will allow us to identify and pursue the most promising of these opportunities. Additionally, Dr. Jeff Bluestone, one of the originators of the technology at UCSF and an advisor to Caladrius, is currently running clinical trials, supported by the National Institutes of Health, evaluating autologous Tregs as a treatment for cutaneous lupus and to induce tolerance in post-kidney transplant patients, two indications for which Caladrius holds intellectual property rights. We look forward to the completion of those studies and the results of Dr. Bluestone's work, as that information will contribute to our decision to further pursue development in these indications.

Let me now move to an update regarding our CD34 technology. CD34+ cells have been shown to induce the development of new blood vessels, preventing tissue death by improving blood flow. CD34 cells have been investigated in clinical studies encompassing over 700 patients, with over 400 receiving CD34 cell therapy exposure. Notably, one potential application of this technology is in critical limb ischemia, or CLI. Our program for CLI, CLBS12, is based on previous studies of autologous CD34 cell therapy for no-option CLI patients in both Japan and the United States. From those previous studies, researchers found that CD34 cell injection was safe, led to improvement in CLI-free status, and improved amputation-free survival and other clinical parameters.

We have constructed a development program for CLBS12 in Japan based on that country's new regenerative medicines law. Under their newly-defined process, we worked with and reached an agreement with the Japanese regulators on a Phase 2 clinical development plan

that, if successful, should qualify CLBS12 for early conditional commercial approval in Japan for the treatment of CLI. The agreed trial is a 35-patient Phase 2 prospective, randomized, controlled, open-label, multi-sensor study in patients with no-option CLI to be conducted in Japan.

Those patients randomized to treatment will be dosed with autologous, G-CSF mobilized, peripheral bloodderived CD34+ cells, which is CLBS12, through intramuscular injection in addition to standard-of-care. Patients randomized to the control arm will receive standard-of-care pharmacotherapy alone. The study is expected to cost between \$7 and \$8 million over approximately three years, including an initial investment of approximately \$2.5 million in the first year. Our goal is to initiate the study in 2017 and to follow results closely ... Recall that it is openlabel ... not only to decide on timing and appropriateness of continued investment, but also to manage discussions with potential development in commercial partners.

CLI is just one entry point to explore the broader applicability of the CD34 cell therapy platform, a platform which could potentially be effective in the treatment of major conditions such as chronic heart failure or dia-, dilated cardiomyopathy. We have two grant applications pending and a third expected to be submitted later this year to support clinical work for our CD34 cell technology in coronary microvascular dysfunction and other cardiovascular indications. We expect to learn the results of these applications during 2017. Our plan is to initiate clinical studies of our CD34 cell therapy technology platform based on the results of these grant applications. We also continue to explore other means of collaborative support, such as partnerships or licensing, to contribute to any development programs on which we embark for this technology.

In closing, we are excited by the opportunities unfolded by the proposed acquisition of our remaining interest in PCT by Hitachi Chemical, and we are thrilled with the significant opportunities for Caladrius as a cell therapydevelopment-only company if the acquisition is completed. In the expected new form, Caladrius would be in a strong position to contribute to and capitalize on the clinical utility of cell therapy as a viable approach to disease treatment. We appreciate the continued support of our shareholders and look forward to sharing with you our successes in cell therapy product development.

And now, operator, we're ready to take questions.

Operator: At this time I'd like to remind everyone: in order to ask a question, press * then the number 1 on your telephone keypad. Your first question comes from the line of Keay Nakae from Chardan. Your line is open.

Keay Nakae: Yes. I know you're not giving guidance for the obvious reasons; but, at least for the things you are committed to doing, such as the continuation of the T-Rex study, what do you think the R&D spend allocated to that will be in 2017?

David Mazzo: Okay. Thanks for, for joining and thanks for the question. I'll let Joe, you know, perhaps, embellish upon what I'm about to say. But, as you noted, we're not prepared to give specific guidance and one of, one of the reasons is that, as those who have paid attention to the terms of the CIRM grant recognize that, there are two conditions within the CIRM grant which determine exactly how much of the \$12.2 million, if not all, that we will receive during the course of the trial.

One of those conditions is that the manufacturing cost, that is, the preparation of clinical supply, will basically be covered for all patients going forward, because we do our

manufacturing in, in California. The other condition is that the clinical, costs for those patients who are enrolled in California will also be covered.

And given that, we don't know exactly, at this point in time how many patients we can project in California, because we are presently opening additional sites in that state. It's difficult to provide exact guidance. But I think it's fair to assume that the majority, perhaps, certainly a good portion of the CLBS03 R&D spend in 2017 will be offset by the the CIRM grant.

Joe, would you like to add anything?

- Joseph Talamo: No. I think that's good.
- David Mazzo: Okay.
- Keay Nakae: Okay. And then, you know, with respect to the Hitachi purchase going through, other than shareholder approval, are there any other conditions that need to be satisfied that, if not, prevent it from, from going through?
- David Mazzo: No. It's just the customary closing conditions. You know, the specific details are in the filings that we made. But, no, it's really just the shareholders' vote that is, I would say, you know, the critical path to closing.
- Keay Nakae: Okay. And then with respect to the CLI study in Japan, what other work needs to be done before you commence that study again, predicated on the Hitachi transaction being completed?
- David Mazzo: Right. The rest, the only work that remains is sort of the typical operation planning and startup work for a study. So, we already have an arrangement with a manufacturing facility in, in Kobe that we helped establish and it's basically standing by, you know, ready, and we'll just have to then you know, initiate sites, identify and initiate sites. But all that planning work can, can take place now. It really costs nothing, other than internal effort. No capital will be outlaid until the closing of the Hitachi deal, and then we'll be poised, hopefully, to initiate patient enrollment fairly quickly after that.
- Keay Nakae: Okay. And, and while, you know, 35 patients doesn't sound like a, a large study, given the criteria, no-option patients with what degree of disease ... And I guess at the end of the day, what I'm looking for is how difficult it ... How difficult will it be to actually find these patients to participate in the study?
- David Mazzo: The, you know, our chief medical officer, is actually on a flight at the moment, unfortunately. Otherwise, I would defer to him to give you the specifics of the, the scoring criteria necessary for the patients to enroll. But, based upon previous work done in this population in Japan by the person who will be the principal investigator for our study, we, we believe that the study will enroll very readily, especially given that, in conjunction with the agreement with the Japanese PDMA, this is an open-label trial.

Typically, the difficulty, especially in Japan, of enrolling patients has been due to the, you know, the previous, requirements of the regulators to have a double-blinded trial. And people with no-option CLI, who are facing amputation and perhaps, you know, death as a result of their disease, are generally not enthusiastic about joining a trial where they might be randomized to placebo; so, this open-label trial, our ability to enroll this program relatively facilely.

Keay Nakae: Okay. That's all I have. Thanks.

David Mazzo: Thanks, Keay.

Operator: Your next question comes from the line of Steve Brozak with WBB. Your line is open.

- Steve Brozak: Hey, congratulations, Dave. Getting an 81% premium to your entire market cap on PCT is obviously an accomplishment. Let me ask you, 'cause (clears throat) obviously Caladrius has you know, been known for, as a research entity, a clinical entity, and, you know, a manufacturing entity, how would you, describe yourself going forward in terms of ... You still have an expertise and an understanding of the manufacturing requirements for cell-based therapies. How would you describe yourself going forward as far as that goes? And, I've got a follow-up question on the different programs, please.
- David Mazzo: Sure. Thanks, Steve. Appreciate your comments and thanks for joining. No. I think, you know, as I, as my introductory comments, indicated, we'll be describing ourselves as a, you know, pure-play cell therapy development company, one which we hope will have you know, a very attractive and promising pipeline of a variety of clinical programs a- and one I, I think that will be noted that will be, you know, still very conservative in the way that we deploy capital, even though we will now, you know, be in a in a much more favorable capital situation than the company has been maybe ever, but certainly over the course of the last several years.

You know, the arrangement with Hitachi, both in terms of our, you know, I would say commitment to continue to work on CLBS03 and the T-regulatory platform with them, the favorable rates, you know, ironically post-closing I think we'll actually be have less expenses associated with manufacturing those products than, than we did pre-closing. I think all of those things will allow us to maintain a certain level of manufacturing and CMC expertise on the Caladrius side of the business, using PCT as many of our common clients do, as that arm of the business, but, without the burden of having to try to support and grow that business, due to the, you know, very, very large capital needs necessary to remain competitive.

So I think that, you know, we'll be a pure-play cell therapy company, one that is well-capitalized and, and one that I hope people will see will have a, you know, diversification of risk as we spread our, you know, our capital across, several programs, across several cell therapy platforms, and where we will be exploiting maximally our ability to acquire non-dilutive support through, partnerships and grants.

- Steve Brozak: Actually, you just hit on the topic that I wanted to ask about. On the non-dilutive supports and grants, you probably have more collaborations than any other company, certainly any other, cell, cell therapy company. What do you think this is going to add as far as your ability to go out there and just focus on additional collaborations and the ability to go out there and raise additional funds on a non-dilutive basis?
- David Mazzo: Well, in some cases, our, our ability to attract some non-dilutive grants was hampered by our capital shortage, because in some cases -- not always, but in some cases -- the, the grantor requires a contribution to the program, a capital contribution from the company to which the grant was made. And, you know, in the past we've had such a shortage of capital that we weren't able to actually take care of that. Going forward now we'll be able to, you know, very carefully and judiciously decide how much of our capital that we may want to contribute to certain programs, but that will now open the door to a wide variety of, of grants, substantial grants, that we really couldn't consider in the past.

I think that, you know, the fact that we also in the past at times had our financial viability questioned by granting agencies. You can imagine that, that, whether it's a government agency or an NGO that's providing millions of dollars of support for a clinical program to a company they want to be sure that that company is going to, you know, stay in business throughout the

life of the trial that they're supporting. And with this transaction, a lot of those concerns, you know, dissipate. In fact, I think they're eliminated. And, and as a result, that will, I think, also open the door to our ability to collect grants from, you know, more conservative agencies. So, I think, overall, you know, the simple answer to your question is I think this is gonna help us.

Steve Brozak: Well, again, congratulations on the transformation, and I look forward to all the results in 2017. Thank you.

David Mazzo: Thank you, Steve.

Operator: And your next question comes from the line of Robert LeBoyer with Aegis Capital. Your line is open.

- Robert LeBoyer: Good morning and congratulations on this transaction. My, my question has to do with the pipeline and some of the products that may be moving into clinical or advancing through more pre-clinical stages. There was a mention of Dr. Bluestone's work, and I was wondering if you could just briefly elaborate on that or any other products that you would call our attention to in order to get an idea what the pipeline looks like.
- David Mazzo: Sure. Thanks, Robert, and thanks for joining this morning. Appreciate you being on the line. So, the, the pipeline obviously will develop and, and mature, and we'll be able to provide, you know, a lot more specific information over the coming weeks. And I'll just add that a lot of what I'm about to say, you know, is contingent upon the closing of the transaction.

But, you know, our vision of a post-closing Caladrius obviously encompasses a fully-funded CLBS03 program in type 1 diabetes and, and I would say, the strong possibility that we will engage at least one other clinical indication for that technology. We have in the, in the corporate presentation that will be made available in the coming days, you know, sort of a palette of those autoimmune diseases where we believe T-regulatory cells could play a therapeutic role.

And, you know, and we'll be looking at which of those indications make the most amount of sense from a clinical perspective based upon a set of criteria that will include, you know, the commercial viability, the size and extent of the unmet medical need, the competitive environment in which we would work, and the time necessary to get to a meaningful clinical result, the availability of accepted regulatory and medical endpoints in those, in those states and the ability to enroll those studies relatively quickly, and ultimately, how much those studies would cost and our ability to garner, you know, perhaps partnerships in there.

So, among the things that we'll be looking at will be a variety of autoimmune diseases, but I think that there's a, you know, an interest at the moment in the orphan disease, neuromyelitis optica. That could be one that meets all of our criteria and one for which there may be some grants, collaboration available. So we'll be exploring that over the next couple of weeks and months and hopefully be in a position to initiate at trial, testing T-regulatory cell therapy in, in NMO.

And then, as you mentioned, Dr. Bluestone and UCSF under NIH funding is performing a series of Phase 1 studies evaluating autologous T-regulatory cell therapy as a treatment for a number of diseases. He's chosen initially to look at dermal lupus and also at the ability to induce tolerance in kidney transplantation patients. And we expect that he'll be publishing the results of those studies in the coming months.

And of course, positive results in those areas will give us, I think, a set of information to consider as to whether or not, in the context of all the other criteria that I outlined previously, whether we might want to, you know, engage in some work in those areas as well. We're going

to be very careful, though, as I said several times now, about how we deploy the capital, making sure that the capital that comes from this transaction will be deployed judiciously and conservatively so that it will last for, for quite some time.
On the CD34 front, in addition to the CLI program in Japan, which we do plan to initiate, we have grant applications in to several agencies, to study coronary microvascular dysfunction, which is CMD, or sometimes called
Sundrome V which is a disease that manifests itself as insunlisable anging often in females. And so we support ever

Syndrome X, which is a disease that manifests itself as inexplicable angina, often in females. And so we expect over the course of the next several months to get results on those grant applications, and we're, you know, I think, cautiously optimistic that, that one or both of them will be funded, in which case we would be in a position to initiate Phase 1 or Phase 2 work with our CD34 cell technology in that area.

And we're presently investigating other potential indications, and collaborations for the CD34 program. And, as always, as every company of our size is, we're, we're, you know, we're looking broadly at complementary technologies or partnerships, that either make sense from a therapeutic complementarity or a technology complementarity. And we'll evaluate those carefully and judiciously as they arise.

Robert LeBoyer: Okay. Great. Thanks. And just one other question about the transaction ... in terms of the assets that are being transferred, could you just specify which laboratories and the asset values that have been assigned to them?

David Mazzo: I can give you the, you know, the general rule. I'm not sure that the values assigned to them is public, and I'll let Joe comment in a moment. But, but generally, the agreement defines or describes the acquisition of our 80.1% share of PCT by Hitachi Chemical. PCT comprises, two manufacturing facilities, one in Mountain View, California, which is a leased facility, and of course, all the personnel, equipment, and know-how that goes with that facility, and our flagship facility in Allendale, New Jersey, which is an owned facility, and all of the personnel, equipment, and know-how that goes with that. And so that's basically what, , what's being transferred at the closing of this.

Joe, I don't know if, what we can say about value, other than, you know, it's valued at 75 million plus 5 million if the milestone is met.

- Joseph Talamo: Yeah. And, Robert, we'll, there'll be more clarity coming through. We, when we do put out our proxy statement, that will include the carve-out information, and provide a little more granularity around the operations of PCT that's being sold and the assets. For, for the most part our fixed assets, PP&E on the books, are largely, on the PCT side and, and that is going to be purchased by Hitachi with the remainder of this. So, you'll see that. The Allendale site, as you know, is owned, so that's going to go with the transaction as well. So, there'll be granularity that you'll, you'll be able to see once we put the proxy up.
- Robert LeBoyer: Okay, great. Thank you. You just anticipated my next question. So, I'll just thank you very much. And, congratulations, again.

David Mazzo: Thanks, Robert.

- Operator: And your next question comes from the line of Yi Chen with H.C. Wainright. Your line is open.
- Yi Chen: Thank you for taking my questions. First question: just to clarify, you have already received 5 million from Hitachi and you expect to receive the rest, 70 million, in May. Is that correct?

David Mazzo:	Hey, good morning and thanks for joining us. To be technically correct, the first 5 million is expected to be transferred today. You know, and so I haven't had a chance to speak with our treasury, function, so I don't know if the, if the wire has come through, but that's the agreement. Five million should, should arrive today and then the remainder arrives on the day or within a couple days of closing.
Joseph Talamo:	Yeah. And, and just one, one point: 5 million of the remainder, would be placed in escrow-
David Mazzo:	Right.
Joseph Talamo:	for 12 months. So, 60 So, of the total 75 million, 70 million of that amount will be available to us on closing.
Yi Chen:	Okay. So, for the 2nd quarter of 2017 on your income statement you will still recognize part of the PCT revenue. Is that correct?
Joseph Talamo:	Yeah. So, so we have both a 1st quarter and a 2nd quarter, and this is scheduled to close in the 2nd quarter, and we would report the PCT operation through the closing date. We would expect beginning with the 1st quarter, that the PCT operations would be reported as discontinued operations, but we'll Clearly, the 10-K was filed last night and, and it is still as you've seen in the past. But effective with the 1st quarter, the presentation of all the PCT operations will be, it's likely to be collapsed into discontinued operations.
Yi Chen:	Okay. Thank you. Regarding the ongoing trial of CLBS03, before the interim data analysis, which can potentially reported in late 2017, do you still plan to report some initial biomarker analysis from the first cohort in near term?
David Mazzo:	We haven't yet decided on that, and one of the reasons why is that we are actually working on, on a partnership for the generation of that data that, you know, may affect the timing of when that information from the first cohort would actually be available for public consumption. So, I think that, you know, as we identify material or noteworthy information, that, you know, we can communicate, we certainly will do so.
Yi Chen:	Okay. Got it. So for the Phase 2 trial of CLBS12 in Japan, do you plan to fully fund that trial yourself, or do you, are you in the process of looking for some partnership in Japan?
David Mazzo:	We've actually had partnership discussions ongoing for a while with two categories of potential partners. One would be, I guess, under the general category of pharma companies, and the other in the general category of you know, venture capital, or something, or just financial capital.
Yi Chen:	Yeah.
David Mazzo:	And so, our plan is to initiate the trial using the, you know, using the capital proceeds, or a very small portion of the capital proceeds from the closing, and at least to plan to fund the trial through its first year and, and probably the first roughly third of the patient enrollment, although there's still a possibility that a partnership could be consummated that would allow us to minimize, or even, avoid any capital outlay ourselves.
	But the, the goal would be, if, if nothing could be consummated under terms that we find acceptable prior to the closing, then after closing we'll initiate the trial ourselves. And we believe, since it's open-label, as we'd generate data that would be positive, enthusiasm for the product from potential partners. And our ability to negotiate a partnership that is attractive to

us and our shareholders will increase with time. So, our initial commitment is, you know, \$2.5 million or less, and, and we'll play it by ear after that. Yi Chen: Got it. And this trial is likely to be started in the second half of 2017, right? David Mazzo: Yes, correct. Yi Chen: Okay. Got it. Thank you. David Mazzo: All right. Thanks. Operator: This concludes the question and answer portion of the presentation, and I will now turn the call back over to Dr. Mazzo for closing remarks. David Mazzo: Again, thank you all for participating on today's call. We look forward to making continued progress executing our new business strategy and to providing you with timely reports on our achievements. We appreciate your continued interest in and support of Caladrius Biosciences and look forward to updating you again on our next quarterly

conference call. Have a great day, everyone. Bye bye.