Cytori Therapeutics Fourth Quarter and Fiscal 2015

Earnings Conference Call

March 3, 2015 – 5:30 pm ET

Opening:

Good afternoon, ladies and gentlemen. Welcome to the Cytori Therapeutics Fourth Quarter and 2015 Earnings Results call.

At this time, all participants have been placed in a listen-only mode and the floor will be open for your questions following the presentation. If you would like to ask a question at that time, please press *1 on your touch tone phone. If at any point your question has been answered you may remove yourself from the "Q" by pressing the pound (#) key. We ask that you please pick up your handset to allow optimal sound quality. If you should require operator assistance, please press *0.

Before we begin, we want to advise you that over the course of the call and question-and-answer session, forward-looking statements will be made regarding events, trends, business prospects, and financial performance which may affect Cytori's future operating results and financial position. All such statements are subject to risks and uncertainties, including the risks and uncertainties described under the Risk Factors section included in Cytori's Annual Reports on Form 10-K and Quarterly Reports on Form 10-Q filed with the Securities and Exchange Commission from time to time. Cytori advises you to review these Risk Factors in considering such statements. Cytori assumes no responsibility to update or revise any forward-looking statements to reflect events, trends, or circumstances after the date they are made.

It is now my pleasure to turn the floor over to Dr. Marc Hedrick, Cytori's President and Chief Executive Officer. Sir, you may begin...

Marc Hedrick -

Thank you, Kris, and good afternoon, everyone. Welcome to our fourth quarter 2015 earnings call. As Kristen said, my name is Marc Hedrick. I am the President and CEO of Cytori. And joining me on our call today is our Chief Financial Officer, Tiago Girão; our Chief Medical Officer, Dr. Steven Kesten and joining us from Japan is our Global General Manager of Cell Therapy, John Harris.

We have recently issued our Q4 earnings release and proxy which should be posted on our website and a copy of this transcript will be available there soon as well.

So here's the agenda for today's call. I want to start off with a brief update on our clinical programs, then turn it over to Tiago who will update you on the financials and then I am going to ask John Harris to

provide us with a more full update on our progress in our Managed Access program in Europe and Japan. And then I am going to drill in on some of our plans for 2016 including the clinical, commercial and operating fronts and this will include more about how we intend to get the company on an optimal financial footing, a path to breakeven and on a real growth trajectory. After that we will discuss forthcoming milestones and then Q&A.

So, as I begin, I'd like to just touch on 2015. 2015 was a very productive year for this company all across the board. On the clinical side we have multiple late-stage trials in enrolling. Operationally we hit or exceeded just about every external and internal measure we've set. Financially it's the same story. The capital deployment in my view and our utilization of capital was targeted and effective and we established internal policies and procedures that should continue to drive financial performance well into the future.

In parallel, and I haven't talked too much about this publicly, but we substantially strengthened our leadership team and it's a group of fully committed leaders that are committed to making this company very successful in the future. So in summary I just can't say enough good things about 2015. It was an outstanding year for this company on every front.

Now on the clinical side. First scleroderma...

We recently reported 24 month follow-up data from our EU pilot trial and that data showed ongoing evidence of safety of our ECCS-50 therapeutic in these patients and the longevity of clinical response. The clinical response that we saw was consistent and concordant among a number of clinically relevant patient reported outcomes and other meaningful functional endpoints. And although that data is important, I think in the interest of time today I would just refer you back to the transcript of our call approximately two weeks ago, but in summary from that data, I think there are two key takeaways that I'd like to reiterate.

First of all, the data showed a significant sustained benefit of a single administration of the therapeutic and that's important because it really strengthens our own internal convictions on the ultimate utility of that therapy for the hand manifestations of scleroderma and also I think gives us comfort on confirmation on our powering calculations of the STAR trial.

The second thing is that sustained benefit that we saw out to two years underpins arguments that we are having in an ongoing fashion with potential payers around the pricing strategy for this therapy, two

years response is pretty remarkable. In Europe, these points should help support our utilization under the recently launched Managed Access Program and I think John is going to have some more comments on that later in the call.

In terms of our enrolling clinical trials in scleroderma, our STAR trial which is the 80 patient pivotal Phase 3 trial is on track to enroll as planned by middle of the year. The SCLERADEC-II which is a 40 patient investigator initiated Phase 3 trial, very similar in design to STAR is also enrolling and continues to enroll in Europe.

From the regulatory perspective, in terms of our approval plan for scleroderma, in the US, we're on track to file PMA approval in the second half of 2017 pending positive data from the STAR trial. And in the interim we are increasingly preparing to be able to launch that product in the US towards the second half of 2018, pending the positive response from FDA, reimbursement etc.

In Europe, while we are actively making a therapy available on a compassionate use basis today via our Managed Access Program, we intend to file for full market approval based either on the EU data from SCLERADEC-II or the US STAR datasets or ideally both.

In terms of additional developments on the scleroderma front, we feel that there is an opportunity to continue to build out a substantial scleroderma oriented franchise leveraging all that we have learned about the adipose derived regenerative cell therapy technology and its safety and efficacy profile in scleroderma. I think this would really leverage the scientific info we learned over the last few years particularly regarding the mechanism of action in scleroderma in the hand and apply that same learning to other unmet indications in scleroderma. We think this is a great opportunity to build out our pipeline in the future.

Speaking of pipeline, first osteoarthritis. Earlier in Q1 we discussed top line interim data from the ACT-OA trial, this data from a pre-specified 24 week time frame. Data although early in the overall follow up period, was encouraging at 24 weeks both on the issue of being safe and feasible, but also from the perspective of showing evidence of a therapeutic benefit over placebo.

We intent to have the 48 week data in Q3 and at that time we should be able to determine next steps in that development plan. The insight from that trial will also give us better insight into longer-term improvement in the symptoms, whether it lasts into 48 weeks, and MRI assessment at 48 weeks, in

other words is there a cartilage effect. So in the meantime the limited unblind with 24 week interim data allows us to use that data for partnering discussions and support other corporate uses.

Our Incontinence trial called the ADRESU trial is primarily funded by the Japanese government MHLW enrolling multiple sites in Japan to 45 patient open-label trial. That's continuing to enroll and the timeline suggest that we should look for data sometime in the 2018 timeframe.

Regarding our program with BARDA on thermal burn and radiation injury, we are in the process of transitioning that program from the preclinical work over the last two years to the more clinically oriented development phase of that work. Partially that work is geared towards developing the next generation of the solution manufacturing technology which is the cornerstone of the medical countermeasure development we've been asked to complete by BARDA.

An important advance as part of that BARDA related R&D is that based on what we've learned in developing the next generation of this technology we've been able to back engineer that into our current existing commercial and clinical trial platform. That's not to say that the need for the next generation is not still there, it absolutely is. That's a much more fully upgradable platform, but we're able to reap some of the benefits in terms of higher cell number and it equates to potency and shorter manufacturing time as part of our current platform today.

So as part of this transition and the successful completion on usually negotiated milestones, Cytori intends to file for IDE approval and begin a US feasibility trial under that BARDA contract later in this year and that should open up additional pre-negotiated funding support for the US government. We are on track to file that IDE in the second half of 2016.

Also I'd like to just mention the ATHENA trials. Remember that the ATHENA trials were trials to study the use of autologous adipose-derived regenerative cells for refractory chronic myocardial ischemia with left ventricular dysfunction. That data which is 12 month follow-up on 31 patients has been selected for presentation at the SCAI Meeting, or the Society for Cardiovascular Angiography and Interventions to be presented in May 4 through 7 in 2016. And just recall that the top line data was summarized last year noting trends in endpoints related to symptomatic benefit in these patients, but the trials were truncated at 31 patients.

We're also developing a manuscript which should be submitted this year to a peer review journal and then once again as a reminder, despite the promising signals that we've seen in these trials and other

cardiovascular trials, it's currently not in strategy at present to invest in further development for cardiovascular disease. However, we may at some point revisit that in the future, pending funding.

I think with that I will turn the call over to our CFO, Tiago Girão.

Tiago Girão -

Thank you, Marc, and good afternoon everyone.

During the fourth quarter we continued to fully invest in our key R&D programs while working to reduce our cash operating burn. We reduced cash operating burn to $4.5 million as compared to $4.9 million in Q4 of last year. Our net loss is also trending in the right direction. When adjusted for non-cash charges related to the changes in fair value of warrant liabilities, net loss was $5.4 million in Q4 or $0.03 per share as compared to $6 million or $0.07 per share in Q4 of 2014.

On a similar basis, for fiscal 2015, our operating cash burn was $20.5 million compared to $30.3 million in fiscal 2014. That is a 30% reduction or approximately $10 million decrease on a year-over-year basis and over $1 million better than what we provided as revised operating cash burn guidance in just December of 2015. The reduction in cash burn was largely related to the reductions in headcount, discretionary spend and the improvements in working capital management.

Our 2015 net loss when adjusted for non-cash related to changes in fair value of warrant liabilities was $26.4 million in 2015 or $0.19 per share as compared to $37.7 million or $0.47 per share in 2014, again a 30% decrease or just over $11 million better than last year. Through 2016 we believe we can realize further additional improvements in operating efficiencies and expect to continue to narrow our losses and operating cash burn in 2016 and beyond.

As mentioned earlier, despite the decrease in operating cash burn, our primary focus is to bring an approved therapy to market in the US.

In 2015, our research and development expenses, excluding share-based compensation, were $18.4 million, an increase of 27% over the $14.5 million expense in R&D in 2014. The increasing spend from 2014 to 2015 is primarily related to investments in trials as well as our BARDA related activities.

As a percentage of overall spend, our R&D spend increased to 63% of total operating expenses, when excluding share-based compensation and charges for warrant liabilities, as compared to 42% in 2014. This is intentional and indicative of our focus in late stage clinical programs.

We continue to optimize sales and marketing activities and related expenses, which excluding share-based compensation, were down to approximately $2.6 million in 2015 compared to $5.9 million in 2014. The decreases are mainly attributed to reductions in salaries and benefits as we focus resources onto most profitable sales activities. Our sales and marketing organization delivered approximately $200,000 in contribution to our bottom line in Q4 and we expect those contributions to increase going forward.

G&A, excluding share-based compensation, was $8.5 million or a decrease of 39% from $14 million a year ago. The reduced G&A expense was related to reductions in salaries and benefits as well as reduction in professional services as a result of the renegotiated service contract and a reduction in discretionary spend.

With respect to our revenues...

In 2015, we recognized total revenues of $11.7 million which is an increase of 53% when compared to revenues of $7.6 million in 2014 and in line with our overall revenue guidance range for 2015. Product revenues were $4.8 million during this year compared to $5 million in 2014. Contract revenues were $6.8 million during the year as compared to $2.6 million in 2014.

There was only a partial fulfillment of the purchase obligations from our licensee Lorem Vascular in 2015. As a result, we are in the process of renegotiating our agreement and based on the current status of the contractual commitments, we elected to not incorporate any of its potential revenues in our 2016 revenue and operating cash burn guidance, which we will discuss in a minute.

Turning to the balance sheet...

At the December 31, we had $14.3 million of cash and $17.7 million of debt. Last week, we received an acknowledgement from our lender that they extended our interest only period under the facility. We will now begin to amortize it in 2017. That extension is based on their determination that preliminary six-month data from our US OA trial announced earlier in February was positive.

With respect to 2016 financial guidance...

We expect operating cash burn of $18 million to $20 million, and expect revenues to range from $12 million to $14 million with growth coming primarily from product revenues in Japan and our Managed Access Program in Europe.

Looking beyond 2016 based on the current projections including recent Japan achievements the MAP, cash burn trends would significantly improve on a year-over-year basis narrowing our losses into breakeven territory by the end of 2018.

With that, I'll turn over the call to John Harris, our VP of Cell Therapy.

John Harris -

Thanks Tiago and good afternoon everybody.

Previously, Marc provided background on our initiative to provide hand scleroderma patients with access to ECCS-50 in EMEA beginning in 2016 via a managed access program. Cytori's MAP partner in Europe, Idis, is in the process of setting up the required program documentation, product supply chain, packaging, and labeling, and conducting a country by country regulatory assessment with competent authorities in every country to ensure compliance and prioritize target list. Effectively acting as a commercial licensee.

Cytori is also performing an independent pricing strategy assessment for ECCS-50 in EMEA that will support both the MAP and downstream commercialization- critical to get it right. We have included in our 2016 guidance a conservative utilization scenario specifically regarding adoption and pricing, however, based on Idis' typical operating experience and positive patient and physician interest and feedback about the MAP, we see potential scenarios for upside utilization in the 2016 – 2018 horizon may be achievable.

In the coming months, Cytori plans to exhibit and answer questions about the MAP at the Rheumatology 2016 conference in Glasgow and the Annual European Congress of Rheumatology in London.

Now with respect to Japan…

I have been with the company since October of last year and here are some of my insights since joining Cytori. I joined Cytori from directly from Becton Dickinson and in that role was intimately familiar with the market dynamics in Japan regarding cell therapy and RM. My decision to join the Cytori team was driven based on my view of the opportunity for both the Cytori technology and the opportunity on Japan generally.

First, what's our focus and strategy here in Japan? ONE- maximize the near term revenue opportunity made available to us with the current class I approval and the permissive new regulations and, TWO- build the leading RM company in Japan based primary on a combination of: compelling clinical data and an effective business model

NEAR TERM – let me quickly tee-up some near-term accomplishments in Japan:

We have a comprehensive and complete understanding of the new regulations. These new regulations permit broad use of our technology via the combination of the class I approval- sort of Like a 510k in the US) and a relatively simple registration process for each provider. Two supporting data points:

Thus far we have supported the facility certification and procedure approval in over 50% of our installed base in 2015. We anticipate double digit increases in our installed base in 2016

To strengthen growth, we have selectively offered incentives for both instruments and consumables, resulting in placement of a number of new instruments in Q4 and early Q1. More importantly, we've seen a 130% year on year increase of consumable utilization.

It's best to think about this near term or 'early access program' opportunity for Cytori like a systems supplier, wherein customers (hospitals / clinics) source instruments and the necessary consumables for use in their facilities for a variety of conditions they determine for patients willing to "self-pay" for the procedure. Cytori provides the systems and support and the clinics / hospitals determine the treatment modalities. We see a growth runway in Japan for this self-pay, systems supply model, particularly with the growing buzz surrounding regenerative medicine. It is the normal situation for a patient to self pay to the tune of 30% of their normal everyday healthcare costs in Japan anyway and that provides a reasonable starting point for bringing SP aggressively to market today.

As Marc mentioned in his recent SH letter, our installed base targets are focused in 3 specific areas, aesthetic, self-pay medical and academic/clinical research. Near-term growth will be largely driven by the aesthetic and self-pay medical areas.

We've made a few strategic moves in late 2015 in the aesthetic and self-pay medical areas that will support an anticipated uplift in 2016 and beyond.

Expanded partnership with the largest privately owned chain of aesthetic clinics in Japan to deploy Celution in a number of its clinics throughout the country. Very happy with what we see, their success should spillover to other clinic chains.

Developed relationships with top tier physician groups who are treating certain orthopedic indications such as OA on a self pay basis. Growing global safety and clinical efficacy data on medical indications should drive this trend going forward and there are a number of ways to increasingly leverage this. Obtaining reimbursement and approved indications for use is a long-term mission critical initiative.

As mentioned Nagoya University UI trial is tracking towards 2018 data.

While these are all very encouraging mileposts and we see continued growth in Japan, challenges remain. We need to better refine our strategy for other key indications such as scleroderma in Japan and optimize our ultimate post approval, go-to-market strategy. A solid foundation has been built and our long-term strategy is rapidly taking shape. More to come on this.

Beyond Japan and Europe- Other sources of product revenue represent upside opportunity for us. One such upside opportunity is China and SE Asia. I am very familiar with this market from my previous positions in AP. We are in the process of conducting and in-depth analysis of the opportunities in this region, assessing the appropriate next steps and will make recommendations to our leadership team

Looking forward, globally….

I have a strong personal belief that we need to deliver on the opportunities of today in parallel to building for the future. I think the time has come for this technology in many markets.

For 2016 , I believe we have achievable revenue targets that when met, will result in an increase over 2015 and a growing positive contribution margin to the business. Beyond the 2016 plan, I am very excited as we formulate our plan for the 2-3 year horizon. I see enormous opportunity. To best address that opportunity, we have developed relationships with a number of leading experts and business advisors who are fully engaged alongside us both in the Japanese market and for the global opportunity- New markets and technologies as this require deep, creative thinking – I assure you that is ongoing as we focus on the corporate priorities Marc has clearly laid out: US Scleroderma approval, Achieving BE by 2018, Building out a pipeline with executable niche indications.

Now let me throw it back over to Marc.

Marc Hedrick -

Thank you John, I appreciate those remarks and thanks for joining us this afternoon. So to sum up then, in terms of our 2016 financial plan here is what we see. A continued emphasis on burn reduction in 2016 and despite the substantial efforts our team has made since I took over as CEO, which includes reducing the headcount by about 40% and reducing the operating cash burn by nearly 40%.

The future gains will not come as easily as they did over the last couple of years. As next we focus on further cost containment activities and some other initiatives that we think are going to drive operating efficiencies. Things like structural reductions such as overhead reduction and ongoing initiative to lower our current products cost of goods and increase the margins related to sales of those products and continued pressure on discretionary expenses.

We also see revenue opportunity as John mentioned. First of all, revenue growth in Japan and that's primarily due to clarity that we see on the regenerative medicine law front as well as implementation of some new strategies that John mentioned that we think have legs. The second thing is an important new source of revenue, the Managed Access Program which provides us immediate on ramp and to a sizeable market in scleroderma that we think is going to materialize this year and then grow until we get the full approval in the US which is where growth should rally. And then finally, we are anticipating continued government contract revenue and related offsets.

Now as Tiago mentioned we can forecast a further reduction in burn in 2016, however most planned expense reductions will largely be implemented in the 2016 timeframe and therefore we see continued burn reductions in '17 and '18 primarily related to anticipated revenue growth with the MAP in Europe and in Japan. Operationally, with the ground work laid in 2015 and due to our increasingly positive outlook in 2016 and beyond, we are increasingly becoming confident that we are on a path to overall cash flow breakeven territory by 2018. So as we started to understand that we really had an opportunity to leverage this operational progress, we asked how do we more beneficially engineer our financial and capital structure. And I think we did this in several ways.

First, it sounds like a broken record, but continuing to preserve existing cash and put pressure on burn is key for us and related to that, over the past 18 months, we've retired or restructured essentially all the key outstanding liabilities the Company had, including our Olympus liability. In December, we scrubbed our capital structure such that we now only have about 3.5 million of very straightforward warrants outstanding. We also accomplished a deferral of loan principal repayment by virtue of a good lender

relationship in our interim OA data which triggered a pre-negotiated interest only extension and reduction and about $3 million in amortization payments. And we preserved an active $33 million ATM facility to be used if and when appropriate.

So one way to look at this albeit sort of artificial, but you can look at the world and say, if Cytori adds up the cash it has on-hand at year-end and adds to that all the elements I mentioned such as declining burn trajectory, the anticipated revenue growth, throw in the flexibility provided by the ATM and then add in a reasonable upside scenario from our active licensing program, on a pro forma basis today, we have enough current cash, access to capital and visibility to non-dilutive opportunities to get us to overall corporate breakeven in 2018. And to be clear, that's prior to formal US scleroderma launch and that's without any additional new financing transactions.

So in a big picture, we view this situation as a major improvement in the fundamental outlook of the company and a great point of differentiation for us in a potential challenging market environment.

Obviously though, there is a practical risk to relying on this approach alone and a stronger balance sheet is critical. So what we think about financing at this point?

Our plan right now is to focus on the above activities. Management has thus far declined every available opportunity to further increase capital via some of the structured financings of 2014 and 2015 and strongly prefers to continue that avoidance posture. However, with those off the table, we are open to more shareholder-friendly, non-dilutive transactions should the opportunity arise.

So beyond this bridge, the profitability plan, which is really a key theme of this call and as we bring this exciting technology to market, and I can tell you that, the more I see from our data feedback from customers and investigators, the more I am excited about what we're seeing out there in the market in our clinical trials. The Company has got to optimize its financial and capital market strategies. So over time, we can attract broader set of long-oriented funds with investors.

As part of this strategy, we want to ramp up or enhance our investor relations activities, which we are now doing to expand internal resources and external resources.

Another part of this strategy is to remove the overhang related to our current NASDAQ compliance issue. Our NASDAQ listing and the cache and liquidity that it provides is important to Cytori's Board and the management. And the universe of institutions that are able to invest or conduct open-market buying on companies not in full compliance is limited.

So to show full compliance we will need to regain the dollar bid price for 10 days prior to May 31. Now realistically, there are only two ways to do that.

Plan A is organic appreciation, that's obviously preferable, and we did that last spring. We think it's possible to do that again, but we need a Plan B. And Plan B is reducing the outstanding shares via reverse split.

So we need to be prepared for Plan B if Plan A fails and therefore on our proxy filed earlier this afternoon, we have asked our shareholders to allow our Board to effect a reverse split if needed. We have asked for a range, but philosophically if we need to do this, I want to make it clear what the goals would be. Number 1, minimize the conversion ratio. Number 2, decrease substantially the number of outstanding shares, which is really the overhang from an outstanding share perspective, and then maximize liquidity and access for a broader set of long-oriented funds and investors. And it should go without saying, but to be very clear, avoid the need for any such future actions.

If you take all these things together, the ultimate goal of these capital markets efforts is to support the core operational activities of the Company, such as our clinical development programs, which are increasingly strong, the commercial traction, which we see as growing over the next few years, and then all of that could be bolstered by a partnering licensing transaction with upfront dollars and that should drive valuation in a way of sound foundation for future share price appreciation.

Ultimately the breakout growth is the kind of thing that we are looking for and kind of thing investors we want to see with a new innovative therapy such as this. That's the real driver. And for US scleroderma lead indication represents legitimate, significant dollar-based opportunity. It's an unmet medical need and it's a prototype of what I think we can do clinically in our development program going forward.

In the background, we are going to continue to operate efficiently, deploy resources wisely, expand our pipeline of indications that can be brought to market quickly and efficiently.

So let me just finish up by pointing out where we are in terms of our near-term milestones.

In 2016, we've completed the following milestones, launching the EU MAP program reporting the 24-week ACT-OA data, and reported out the two-year follow-up data from our scleroderma pilot trial. Approximately mid-year, we anticipate having full enrollment in both our STAR Phase III trial and our SCLERADEC-II trial.

In the second half of the year, we can look towards 48-week ACT-OA Phase II data and the reporting of that data. By second half of the year, we should have significantly more insight into how our Japanese revenue and MAP progress are rolling out. We potentially could have the SCLERADEC-II 40 patients' data available towards the end of the year. And then also, we should have our BARDA IDE trial filed and announced and then we should begin to be able to discuss what our plan is in terms of expanding our scleroderma portfolio.

So with that, I would like to ask Kristen to open up the call for Q&A.

Operator -

Our first question comes from the line of Jason Kolbert with Maxim.

Jason McCarthy -

Hi, Guys. It's Jason McCarthy for Jason Kolbert. Marc, can you describe for us the scleroderma market in Japan where - I know you have units being placed in Japan for stress urinary incontinence and I was wondering what the feedback has been from KOLs and physicians there about adoption for an indication like scleroderma. And just a follow up to that, it was mentioned that you're thinking about going into China and Southeast Asia, what's the scleroderma opportunity is in those markets as well?

Marc Hedrick -

Hey, Jason. Thanks for the question. It's a good one and it's one that's pretty central to our planning right now. So in terms of scleroderma in Japan, the number is around somewhere between 5,000 and 15,000 cases in terms of prevalence. We are in active discussions with the key KOLs in that market and there is a relatively small number of centers that are centers of excellence for scleroderma, sort of mirrors what we are seeing in the US. And that's great thing about this opportunity just from a - for company like ours to be able to address the key treatment centers are going to a small number of centers. It looks like in Japan, it's between five, maybe up to 10 centers and you could pretty much capture the entire market there. So I think there is a market opportunity that's there that's consistent with what we see in Europe and the US. There is a similar sort of strategy that one could envision in terms of limited leading centers of excellence.

And then finally on the regulatory and business model side, although in the past we have been focused on selling devices and consumables, the new Regenerative Medicine Law and potentially orphan

designation, it looks like that could really come into play and help speed our ability to enter that indication there and begin to treat patients.

In terms of China and Southeast Asia, right now we are - the rights to China are with our partner Lorem Vascular. As Tiago said, we are negotiating with them to amend their contract. I think until we get that contract re-negotiated, it will be tough to make much progress there, but if you add the territories encompassed by the current license agreement and there is opportunity on the scleroderma side, but we will have to work through those on an individual basis country by country.

Jason McCarthy -

Right. And if you have the SCLERADEC-II study that's ongoing now, the pivotal study, in Japan - sometimes they really want a study to be conducted in Japanese patients there. Do you have plans to move into Japan to do a clinical study, so you can have adoption for scleroderma, or would you expand one of the ongoing studies in the US over to Japan just to include maybe one center, so you can get some traction with Japanese regulators for scleroderma?

Marc Hedrick -

Yes, we are crafting out that strategy right now. Our plan right now is to leverage published data from Europe, take that to Japan and then do a Japan-specific study. There is really no advantage time wise or other wise to do a broader the study in our view. It should be - it's considered a niche orphan indication in Japan and we think based on discussion so far with PMDA, similar to discussions in Europe and so forth, given the indication like that, we wouldn't need a very big trial, and going and doing a direct Japan trial would be a way to go.

Jason McCarthy -

Okay, great. Thanks Marc.

Marc Hedrick

Thanks. Appreciate the question.

Operator

Our next question comes from Brian Matthews with Payden & Rygel.

Brian Matthews

Thank you. Hi, guys. Really good call. Very encouraging. So I have two comments and a financing question. So regarding the reverse split or your Plan B, as you call it, it's obviously not something that I would call as rational, but it is the right thing to be prepared to do. I think that's a no-brainer. And if you need to do it, I think giving the Board some flexibility on the split ratio is exactly the right thing to do. Regarding operational performance, really impressed with the improvement, keep it up.

So my question is about financing needs. Have you considered a rights offering? I mean, if your capital needs are limited, what it now seems to be and you're getting real close to putting the ball in the end zone, why wouldn't you let existing shareholders participate at these levels as opposed to doing anything else for capital? Thanks. I will get back in queue now, and again nice job guys.

Marc Hedrick

Hi, Brian. I appreciate the comments and the question. Is the rights offering a possibility? The answer to that question directly, it is a possibility. It's one of the portfolio of things we've looked out over the last year or two as an opportunity. We have had some interest similar to that you have articulated. There are some good things and bad things about it. The good things are that it's non-dilutive to participants, it's basically the most democratic way of doing an offering. Of course, we spent so much work cleaning up our capital structure at the end of the year, it is one thing that maintains that clean capital structure and then allows existing shareholders to benefit from where we are today. So I guess I would agree that maybe a company like ours where I think we have an increasingly defined gap between where we are today and getting to profitability as we execute on the strategy. It could be a good alternative for us. So no decisions. I think we will take a deeper look at that. I think we are open-minded, but I think right now, we are just going to focus on the execution, business development, sales and maintain the cost controls.

Operator -

Our next question comes from Steve Brozak with WBB.

Steve Brozak -

Hi, good evening gents. I would like to go back to one of the items that you started to talk about, specifically the approach that you take, everyone has always really looked at Cytori on a device side, but

in terms of what you're looking at on sclero and everything else, you're actually migrating to a therapeutic side. And can you talk about that specifically vis-à-vis how you would work that with Japan? And also specifically, because you are obviously interested in non-dilutive financing. If you were to partner with someone, in theory how does that lend itself well to bifurcating different indications with potentially different partners? And I have one follow-up after that please.

Marc Hedrick -

Hey, Steve, I appreciate the question. Obviously, you're doing your homework, you know the Company well, and it's a great question. So let me start off by saying, you're absolutely right. So I'd say over the last two years for a lot of reasons, and I am happy to discuss those in greater detail. We migrated the Company away from more of a razor blade device-oriented model to a more therapeutics-oriented model. Some of the high-level reasons are the regulators are pushing us in that direction. We don't fit nicely into the device pattern because you look at the FDA, they regulate the cell therapy and the device under the PMA umbrella, but they largely get the device in the safety and the operations. What they really care about is the safety and efficacy of the cell therapy. You see that in Europe, we have an orphan drug designation in Europe and then now as we really kind of begin to dog-ear the pages on the new regenerative medicine law, it's pretty clear that we have an opportunity there on the regenerative products side, which is really geared more towards cell therapeutics, not devices.

So the global regulatory winds are growing in that direction. As you look at some of the indications that we've developed over the last couple of years, scleroderma for example, they lend themselves nicely to that model. In other words, you can have a small number of centers that can create, manufacture cell therapies at the bed side or nearby the bed side. And then also I think it helps us on the pricing side and I think there is a cache and a benefit that comes with a highly differentiated cell base therapy.

We can - our model really lends itself nicely to that on an autologous basis, and so, we're really moving aggressively into that space and you mentioned Japan, absolutely, it's because we increasingly talk to PMDA and John gets closer and closer to them, as they understand kind of the, where our technology fits in the picture, we see that that approach is the proper approach and the most rapid approach to really get to the significant market opportunities in Japan. And I think you had a follow-up right, Steve?

Steve Brozak -

Yeah. I do. Okay. So you're going out there and in terms of potential partnering, the potential partners that you would be interested in working with are probably the people that are familiar with the indications you are looking at. What kind of therapies or - even if they're palliative therapies, what are they looking at and what kind of compensation, what kind of rates are they getting for that and how would you go out there and very, very briefly explain the value proposition obviously or what you're offering and why they would be interested in terms of partnering with you and I'll hop back in the queue? Thank you.

Marc Hedrick

Okay. So little bit related question, what are they seeing us, I think on the big pharma side, Astellas, as a shareholder, we talk to increasing amount of big and medium-size pharma about the technology. I think what you are seeing from them is they're looking for highly differentiated new technology platforms and opportunities, and I think we very much fit into that. I think those types of companies with the profile I just mentioned like this more therapeutic drug oriented approach there, is there is some un-comfortableness with the device space approach.

In our partnering discussions, we've got a standard approach to how Cytori handles the device-related component and the pharmaceutical partner would handle the typical things like sales and marketing, reimbursement, KOL management, and so forth. So I think we've got a really nice approach on the partnering side. I think there are three things that emphasize in terms of this partnering discussion: uniqueness of our technology, market size and stage of development. And I think with scleroderma, we got all three and then in our partnering discussions with Japan, I think we also have all three. So I think we've got a lot to add to the discussion, and I think our ongoing growing discussions with partners has really allowed us to sort of refine that message and better adapt our partnering approach to those types of companies.

Steve Brozak -

Great. Obviously looking forward to the progress that you make and obviously the next call should give us a whole lot more. Thank you.

Operator -

Our next question comes from Ed Woo with Ascendiant Capital.

Ed Woo -

Yeah. Thanks for taking my question. A quick housekeeping question, what's the share count we should be using going forward?

Tiago Girão -

Hey Ed, this is Tiago here. We have right now about 195 million shares outstanding. That is not fully diluted, that's the number of shares that we have outstanding as of the end of the year and those I believe were disclosed in the press release that we just issued. The other thing that is important for you to know is that the fully diluted share account is about close to 207 million shares and that was a decrease from the last call we had and the last 10-Q we had as a result of the restructuring of the warrants that we did at the end of December. The gap between the fully diluted today and the outstanding that we have is primarily related to plain-vanilla warrants, 3.5 million outstanding, as well as some options and RSAs that were outstanding at the end of the year. So I think we're good from that front, but if you have any follow-up, I'm happy to take it.

Ed Woo -

Great. And then you guys mentioned earlier about guiding conservatively for your MAP program in Europe and what are some of the big challenges to probably to reach the potential upside and what are the market opportunities you think you guys can get?

Marc Hedrick -

Okay. It's Marc. On the MAP program, I think, I have to caveat everything we say about that because we are just getting it up and running right now and so our operating experience on that particular thing is limited, however, to make that determination about what we can forecast for 2016 and then some of our projections going forward, we take in what we hear from Idis, our MAP partner who is the best in the world at these programs in Europe. We look at the feedback, we get reverse inquiries from patients and doctors, we keep the running tally of who is interested in the MAP program, we feed that to Idis. That gives us a sense of demand.

And then, we talk to doctors and we know kind of what the challenges they're having in treating these patients, and how our technology potentially fills that gap. So what we know from Idis is that their party line is you can generally get and address about 10% of the addressable market in your compassionate

use managed access program. So if it’s 100,000 patients, maybe 10,000 patients in scleroderma is a reasonable guess.

Now, having said that, we think that's probably aggressive for our case, but it is a benchmark. Our growing list of potential patients and doctors is - pretty much grows on a daily and weekly basis. So we’re continuing to feed that over to them. On the kind of key operational elements of that relationship, right now, we are at a phase where Idis, much like a licensee would put all the things in place to commercialize the technology. They are doing that right now. Also, as part of that, they are reaching out to every single competent authority in Europe and figuring out what the key details are for this particular technology.

They pretty much already know about it, but to get on record feedback from those competent authorities that would allow us to tweak our response, see what countries to emphasize which ones should be emphasized, that's all happening in the background and at the same time, we’re giving lists of patients and doctors to them and then they will take over that key marketing responsibilities from our side, we will be at all the key meetings, primarily in Europe, but around the world talking to doctors, talking about the technology and not only providing information related to the MAP program in Europe, but also planning for what we ultimately have planned in the US and in Japan.

Operator -

Our next question comes from David Musket with ProMed.

David Musket -

Thanks and appreciate all the details here. Now you have different perception of the way The Street felt about your OA data than you did, and to the extent that that's one of your prime candidates for a non-dilutive partnering deal, do you have any sense as to when we might see a little bit more of the metrics from that trial that would help us get on the same page that you are?

Marc Hedrick -

Hi, Dave. Thanks for the question. Yes. So I think we'll be able to talk publicly about the trial after we've reviewed the 48-week data and just so to bring everyone up to speed, so in the ACT-OA trial, we've built in a 24-week pre-specified end point at that time and we looked at the data. These sorts of pre-specified end points are, it's not unusual to build those in, and but in particular cases, where the trial is heavily

based on patient-reported outcomes, it becomes critical to maintain the blind and integrity of that data, because the key investment after that trial is going to be 48 weeks, which is probably around the Q3 timeframe and we will see that data and make that public.

So we've got to maintain the integrity of the data. Yeah. We could put all the data out there, we contemplated that and discussed that internally and just felt like that it was the best thing for the trial and ultimately for the Company to maintain a limited blind, report the top level data, which frankly was - even though it was early, it was encouraging to us, with cell effect above and beyond what we saw in placebo.

So just to summarize, yeah, it, looks like it's going to be, but as we look at the 48-week data, we will evaluate the data, reveal that publicly and then we will have our decisions ready about how to move forward with the Phase 3 or further development work.

David Musket -

Thank you. Do you expect that there will be any possibility of partnering that project before the 48-week data is available?

Marc Hedrick -

Well, hard to know. Here is my guess. A key benefit to us of having a 24-week data is that we can now have at least a limited un-blinded set to go, talk to partners which is exactly what we are doing. So the partners we have been talking to prior to that knew the basis of putting that in the trial and that data is being shared under NDA with those partners and we think we can use that to help prepare partners for discussion in the 48-week data. So I think it does accelerate it.

However, I think in terms of how I would prioritize our partnering discussions, first and foremost is to identify European partner for scleroderma. We think that's where we have the greatest chance of getting a significant therapeutic partnership. Number two is Japan, given all the other things that are going on over there in our history there and the data, and so forth. And then I think probably third in that is OA, I think it's possible to have a partner before that 48-week data is available, but I think that is probably less likely than not, I think the partner is likely to wait until the 48-week data.

Operator -

That concludes today's Q&A session. I will now turn it back over to Dr. Hedrick for any closing remarks.

Marc Hedrick -

Well, thanks, everyone. It's been a long call. I appreciate the Q&A and appreciate your interest in Cytori. It's obvious to the management and to the board and hopefully we've done a good job in communicating to you that the Company is very well positioned, better positioned than ever and I'm more confident than I've ever been that we are absolutely on the right track with the technology, with the team that we have in place, with a growing track record of execution and getting things done, and most importantly, we have the will and the persistence to get this awesome technology to market. So we thank you for your attention again and have a good evening. Thank you.

Operator

Thank you. This does conclude today's conference call. Please disconnect your lines at this time and have a wonderful day.