PolarityTE, Inc.

Earnings Call and Update Transcript

September 12, 2018

PolarityTE

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Operator: Good day, and welcome to the PolarityTE Inc. Third Quarter 2018 Earnings Conference Call. Today's conference is being recorded. At this time, I would like to turn the conference over to Mr. Rich Haerle. Please go ahead, sir.

Rich Haerle: Thank you very much. Good morning, and welcome to the PolarityTE financial results and corporate update conference call for the fiscal third quarter of 2018. We've issued a press release summarizing our financial results, which you can find on our website at polarityte.com. I'm Rich Haerle, Vice President, Investor Relations, and with me today I have Denver Lough, CEO; Paul Mann, CFO; Ned Swanson, COO; Nick Sopko, Chief Scientific Officer; Jen Burdman, Chief Intellectual Property Officer; and Cameron Hoyler, General Counsel and EVP of Corporate Development and Strategy.

I'd like to remind investors that this call will include forward-looking statements within the meaning of the Safe Harbor provisions of the Private Securities Litigation Reform Act of 1995, including but not limited to the types of statements identified as forward-looking in our annual report on form 10-K for the year ended October 31, 2017; quarterly reports on form 10-Q for the quarters ended January 31 and April 30, 2018; and our quarterly report on form 10-Q for the quarter ended July 31, 2018 that will be filed soon, as well as our subsequent periodic reports filed with the SEC, which will be available on our website in the Investor Relations section. These forward-looking statements represent our views only as of the date made and involve substantial risk and uncertainties, including many that are beyond our control. Please note that the actual results could differ materially from those stated in any forward-looking statements. For a further description of the risks and uncertainties that could cause actual results to differ materially from those expressed in the forward-looking statements, as well as risks relating to our business, see our periodic reports filed with the SEC.

I'd like to highlight to participants that this call is being recorded, and we are making this call available to investors and the media via webcast. This call is the property of PolarityTE, and any redistribution, retransmission or rebroadcast of this call in any form without PolarityTE's expressed written consent is strictly prohibited.

I'd now like to turn the call over to Dr. Denver Lough, our Chairman and CEO.

Denver Lough: Thank you, Rich, and thank you to all the shareholders and listeners for joining us today on this call. We at Polarity are incredibly excited to present to you today on all of the

accomplishments that have occurred over the last year, as well as future endeavors which will occur for years to come. Please go to slide five.

As many of you know, the company has sought primarily to develop incredible technologies to treat patients which are tangible, pragmatic, and simply do what they are supposed to do, but also to make sure that the use of these technologies and products are easy and that they are simple so that providers, whether surgeon, medical doctor, physician assistant or nurse, can more efficiently treat more patients more effectively in a variety of care settings and systems. We want to reduce barriers so that all patients can have the ability to receive complete care.

We also want to deliver a cost-effective answer to real problems by providing a technology and lower price points, as well as preventing the accumulated cost of stocking products and inventory for providers as well as healthcare facilities. And last but not least, we want to deliver a rational reimbursement mechanism so that patients, providers and payers can receive true value and improved health economics. It is with these goals and (ph) our mission of creating a company by providers and for providers and the patients that we serve together that I believe we, Polarity, have seen such tremendous success over this last year. Please go to slide six.

Highlights from this pivotal year include a true transformation and growth of the Polarity team. With now over 100 employees, 50% of which have advanced graduate degrees, PolarityTE has built a management team and Board of Directors which will allow the company to grow, develop and execute both effectively and efficiently. These include industry veterans, the likes of Medtronic, Smith & Nephew, McKesson, Pharmacyclics, and seasoned financial market experts with experience at premier investment funds and investment banks, including Highbridge Capital Management, Cowan, UBS, Soros, Morgan Stanley, and Deutsche Bank. Please go to slide seven.

We are all proud of these additions, and in particular have been working to continue strengthening our finance and commercial teams, with Paul Mann, our CFO, and Alain Adam, our VP of Sales. Please go to slide eight.

They are you can see our new additions to the Board in the last few months, which include Peter Cohen, Willie Bogan, Ramses Erdtmann, and David Seaburg. We are very excited to have them all on our team. Please go to slide nine.

We've also seen an effective translation of our first commercial product, SkinTE, from bench to bedside ahead of schedule. In the second half of 2017, we registered our first commercial product, SkinTE, beginning with a limited market release in the first quarter of 2018. The progress from the bench to animal models to commercial production in just 18 months is a great testament to the abilities of our amazing team of scientists and clinicians that have joined our company from leading research institutions and companies.

We have successfully initiated a strategic and staged commercial launch process for SkinTE ahead of schedule in parallel through a head-to-head clinical trial comparing SkinTE to current clinical standard of care, split-thickness skin grafts. During our limited market release, providers used SkinTE to treat patients suffering from a spectrum of complex wounds, including acute and chronic wounds, burns, traumas, and surgical reconstruction, many of which had failed skin grafts, advanced wound care products, and other conventional therapies. Data received from a limited market release, as well as the interim data and outcomes from the head-to-head clinical trials, gave our management,

research and clinical team the confidence of initiating a regional market release, and thus regional sales in certain targeted key metropolitan areas, which we have continued to grow over just the last few months.

We have seen success with SkinTE reimbursement in a range of inpatient and outpatient settings, as well as filed for specific CMS reimbursement product codes for SkinTE. In fact, in 2018, PolarityTE applied for HCPCS code for a SkinTE tissue product and received a recommendation from CMS for a SkinTE-specific product code to be initiated in January 2019, which can be utilized by providers in the reimbursement of SkinTE in outpatient settings.

We have continued to see successful results from our inpatient head-to-head clinical trials and will be initiating additional trials targeting outpatient utilization of SkinTE technology to show improved outcomes in health economics. Dr. Sopko will speak more about this in the research and development section of this call.

We have also designed and built our first scalable biomedical manufacturing facility. In the first half of 2018, we moved our headquarters to a new 200,000 square-foot facility in Salt Lake City and completed the construction and validation of our first series of high-throughput manufacturing suites, which were designed not just to support the manufacturing of SkinTE, but the other core TE technologies and pipeline products.

We have continued to fiercely develop and evolve PolarityTE's pipeline platforms and technologies. Our research and development teams have continued to develop our core TE pipeline products, again ahead of schedule, and we have now completed our preclinical studies for our first bone regeneration product, OsteoTE, which we hope to register by the end of 2018 with a subsequent limited market release commencing in early 2019.

In addition, our R&D team has continued to advance Related Technology Derivative programs, also known as RTDs, as well as our new Advanced Research Center, or ARC program, which were established around the utilization of our platforms for dynamic small molecule synthesis and gene transfer therapies in complex fields related to antimicrobial peptide therapies, transplant immune tolerance, oncology, as well as composite tissue neo-generation and gene therapy.

In 2018, we performed a strategic growth acquisition of the region's only preclinical GLP contract research organization. This fully operational CRO business, facility and team is expected to continue to deliver high quality work to outside parties while the advanced PolarityTE preclinical product prototypes and technologies will be separately monitored and developed by our Johns Hopkins recruit and Chief Veterinary Officer, Dr. Caroline Garrett.

We have successfully developed PolarityTE's digital space through the development and deployment of the Polarity RTA, also known as the Real-Time Assistant. In an effort to improve quality and direct communication with medical providers, PolarityTE released the RTA, our real-time product support system, which puts providers in touch with a provider-led clinical operations team 24 hours a day, seven days a week.

We have successfully continued the development of our intellectual property estate. The company continues to actively file patent and trademark applications to protect its intellectual property and build out its patent portfolio as it relates to core cell tissue biotechnologies, related technology derivatives, and our new Advanced Research Core

programs from the new ARC. The PolarityTE vision and pragmatic translation of technology into tangible, real products, going forward, is simple. Over the next year, we look forward to the continued execution of our business plan. We expect additional SkinTE clinical data to become available. We'll plan for the evidence of our product's clinical and utility to be presented at conferences and published in journals. And finally, we expect to grow the organization globally. We aim to grow revenues and build a company that will be capable of becoming a profitable enterprise which we hope will continue to deliver strong returns for our shareholders. Please to go slide 10.

Finally, I'm pleased to announce, at the beginning of Monday, September 17th, the new ticker symbol for our stock will change from COOL to PolarityTE. Please go to slide 11.

With that said, I'd like to introduce an individual many of you already know, our recently appointed Chief Financial Officer, Paul Mann, who will speak about our core (ph) corporate finance results.

Paul Mann: Thank you, Denver, and good morning, everyone. We issued a press release early today that included the financial update, which I'll briefly summarize. Please turn to slide 13.

For the fiscal third quarter of 2018, we reported $416,000 in total revenue, which includes revenue from SkinTE and our contract research organization. In the fiscal third quarter 2018, cash used in operations was $7 million compared to $2 million in the fiscal third quarter of 2017. Net loss for the fiscal third quarter of 2018 was $17.2 million, or $0.86 per share compared to a net loss of $5 million, or $0.93 per share in the fiscal third quarter of 2017. At this early point in our product launch, we're not providing any financial guidance. However, I expect that our total revenues will likely exceed the current Bloomberg estimate of $766,000 in the fourth quarter.

As Denver noted, based on clinician feedback, we accelerated the SkinTE regional market release for 2019 activity into a 2018 activity. We are focusing on expanding our sales force and pursuing independent distributor opportunities. We had a 100% track record with Value Analysis Committees. So, far, every Value Analysis Committee that has reviewed and assessed SkinTE has determined that SkinTE should be used in that institution.

To date, the average time for us entering into discussions with a provider or an institution and SkinTE successfully navigating the Value Analysis Committee at that provider or institution have been a little under three months. Additionally, the average time between SkinTE successfully navigating the Value Analysis Committee and PolarityTE entering into a commercial contract with the provider and SkinTE being used as a paid product for the first time at that provider is a little over one month. Therefore, the average time between PolarityTE entering discussions with a provider or an institution and that provider or institutions' first paid use of SkinTE has been approximately four months.

You should assume the majority of the commercial activity has been in the two regions where we have active salespeople. And as we expand our sales team and our clinical operations team over the next several months, we expect to see additional growth in institutions using SkinTE.

When I look at the current Bloomberg revenue estimate for 2019, I view that as conservative. Currently, we only have one sell-side equity research analyst covering our stock, but we have met many other analysts at other institutions, and we look forward to additional coverage in the coming months.

I will now turn the call over to Dr. Ned Swanson, the company's Chief Operating Officer, who will review the addressable markets for SkinTE and provide an update on the commercialization strategy.

Ned Swanson: Thanks, Paul. Please turn to slide 14.

When looking at the total addressable market for SkinTE, it's helpful to segment the market into three large categories: burn wounds, surgical and reconstruction and traumatic wounds, and chronic wounds. Looking at the United States markets alone, burn wounds present a greater than $3 billion opportunity within a highly concentrated market that is served by 127 burn centers, 30 to 40 of which do the majority of the volume. In addition, acute burn wounds that require grafting are most commonly admitted to the hospital and reimbursed under bundled DRG payments, allowing burn centers and hospitals to make product decisions independently, which is similar for the surgical reconstruction and traumatic wounds market.

The surgical reconstruction and traumatic wound market presents an even larger opportunity, similar in size to the chronic wound market, around $23 billion. The majority of the volume in this market takes place within the approximately 600 level I to level III trauma centers and is comprised of over one million wound grafting procedures per year. The chronic wound market presents the largest opportunity, but is spread across more healthcare facilities, more settings of care, and more patients with approximately eight million to 10 million new chronic wounds in the U.S. every year. Worldwide, as seen in the charts at the bottom of the slide, the prevalence of each one of these wounds is rising year-over-year, following similar trends to the rise in many comorbidities and presents an extremely large total addressable market across the globe. Please go to slide 15.

How do we plan to commercialize SkinTE within the United States to penetrate these large market opportunities? As Denver mentioned earlier, the launch of SkinTE began with a limited market release targeting the entire spectrum of wounds. And due to the success achieved throughout the limited release, our regional market release was accelerated, originally planned to begin in 2019 and initiated at the beginning of the fiscal third quarter in two high-volume regions on the East Coast, the New York tri-state and Mid-Atlantic regions. The limited release provided a controlled setting for leaders in the field to utilize the product across every possible wound type, size, and setting, highlighted in the graphs in the bottom left of the slide. This gave us a deep insight into the product and logistics and provided the opportunity to build the initial evidence and develop key opinion leaders that will be instrumental as we move commercialization forward.

As you can see, providers are most commonly requesting turnaround times of two to three days. And following the limited release and early regional release, we feel confident that we have the manufacturing capacity and logistics solutions to continue to deliver on these timelines as demand continues to scale up. We are now building our sales force to cover the entire country and expect the regional releases to continue into 2019 and for our planned national launch to be accelerated and begin within the first half of 2019 once our regional teams have completely covered the entire continental U.S. The national launch will follow numerous medical conferences, the anticipated SkinTE publications, and the expected SkinTE Q code preliminarily recommended by CMS to be established in January 2019.

As we think about how we will scale up our manufacturing operations over time, we anticipate building PolarityTE manufacturing nodes in high-volume metropolitan regions. Regionalized manufacturing nodes will reduce turnaround time, reduce COGS, and improve logistics. Just imagine: a patient with a chronic wound could arrive at clinic in the morning, have a skin harvest performed, leave to get lunch, and come back for the application of SkinTE. all in one day. This is where we envision Polarity going, and this strategy will provide synergistic advantages with our other pipeline products.

At this point, I'd like to turn the presentation over to Dr. Nick Sopko, our Chief Scientific Officer, who has been working hard to further develop not only our core TE technologies but also our other R&D programs and technology arm.

Nick Sopko: Thank you, Ned, and to all of those listening on the call today. Please go to slide 18. It is my pleasure to provide updates on where we have been, where we are now, and where we are going, which, as Denver said, not only our core TE technologies but also our Related Technology Derivatives, which we refer to as RTDs, as well as our newly-announce Advanced Research Center programs, or ARC programs.

First and foremost, I would like to provide updates on SkinTE, our currently-marketed regenerative skin product. As Denver described, the first of the cutaneous platform products, SkinTE was designed, developed, and translated to a commercial product during 2017 and launched under a strategic limited market release in parallel to head-to-head clinical trials in the first quarter of 2018.

Following successful results during a limited market release and review of interim data from the head-to-head clinical trial, we are pleased to move forward with the next stage of commercialization. This next stage, defined as a progressive regional market release, targets essentially 10 of the nation's largest metropolitan areas with established sales reps as Polarity sales directors for sales growth in the region throughout large and small hospital systems, but also ASCs, clinics, and physician offices. It is with this transition and the current successful utilization of SkinTE product in outpatient settings that we have also designed and developed additional clinical trials focusing on wound care in non-inpatient systems.

We have already seen the capability of SkinTE in larger wounds, including many that have previously failed the current clinical standards of care. A small sampling of those represented at the SkinTE KOL event in June 2018, and we look forward to presenting additional results as we aim for SkinTE to become a first-line treatment in the growing population of chronic wounds and data related to health economic benefits we believe it can deliver to patients, providers, and payers.

Moving on from our current SkinTE product and looking at our newly updated pipeline, OsteoTE remains ahead of schedule following successful completion of our preclinical studies in which we treated critical size defects in large animal models related to cranial maxillofacial, long bone and spine defects. We believe these studies clearly indicate the incredible capability of OsteoTE product as it relates to the regeneration of hierarchical organized cortical cancellous bone, which not only functions like native bone, but also develops a nearly-exact molecular fingerprint.

As Denver stated, release of the product will likely look similar to SkinTE, with both a limited market release and parallel clinical trials being implemented at the same time prior to moving into regional market release. This will, of course, occur in a manner that

permits OsteoTE to be appropriately tailored to the more segmented practices and specialties within the bone market.

CartTE, our autologous regenerative cartilage product, is currently initiating preclinical critical size defect studies with target completion of the studies by mid to late next year and potential registration of the product to occur late 2019 or early 2020.

As it relates to the rest of the core TE technologies, we are in active discussions and are pursuing the acceleration of the core TE pipeline so that we will eventually begin to announce the ability to progress multiple regenerative substrates through our rigorous translational R&D processes annually. While other core TE substrates are actively being further developed and translated, we believe that it will not be until after the release of CartTE that the company will be targeting the release of multiple tissue products and/or substrates per year.

While much of the focus from patients, providers, payers and the investment community has centered around the SkinTE product and the speed at which it was introduced to the market, we would like to take the opportunity to remind all the respective parties that Polarity is not solely a skin company, nor are we solely a human cell and tissue product company. Without going into too much detail, these RTD and ARC programs were initially developed as extensions of the core TE platform because we discovered, through the design and development of products like SkinTE, OsteoTE and our solid and hollow organ regeneration, more than we could have initially imagined. Moreover, our research showed us how we could create even more advanced and dynamic regenerative, and perhaps neo-generative technologies that could be readily translated into tangible and pragmatic products and answers for patients.

While I know this has been a lot of information to digest, and it may appear that there's a lot of stuff going on with Polarity R&D groups, I can assure you that; one, there is a lot going on; but two, the company remains laser-focused on progressing real technologies into real products. As we have said time and time again, the company is and will remain focused on our absolute priority, and that is the delivery of tangible, pragmatic and cost-effective products to patients. Moreover, this priority will not be lost simply due to curiosity to investigate what-ifs, but rather our research will always be conducted with a defined goal and understanding in mind.

Thank you so much for the opportunity to be on this call with you today. And I look forward to meeting more of you in the future. As Denver has always said when he speaks about the company, we have not even ignited the engines yet, let alone started lift-off, and I truly believe that. And I've now certainly seen it after having left my career at Johns Hopkins as a Surgeon Scientist, and I'm very proud to be a part of the Polarity team.

With that said, I would like to introduce Jennifer Burdman, our Chief Intellectual Property Officer, who will speak to protecting our IP.

Jennifer Burdman: Thank you. As you just heard from Dr. Sopko, there is quite a bit of activity in research and development at the company. We are also very focused on developing, protecting and leveraging the intellectual property surrounding the incredible innovations being made at the company. We actively seek patent protection where appropriate and protect others certain aspects of our technology, particularly those surrounding commercial manufacture of products as trade secrets.

At present, while we do not have any issued patents yet, we have a number of pending patent applications in the U.S. and around the world, only some of which are currently published and publicly available. Similar to what we have in the R&D pipeline, the process of building a patent portfolio also has a pipeline. Applications get filed, published, and there is an ongoing dialogue with the patent office regarding the scope of the claim.

Office (ph) actions will get issued, and we will respond to each one in time. This is the standard process and takes years for each and every application. In each patent application, we endeavor to describe our innovation in a manner in which the breadth of the innovation can be appreciated, a variety of embodiments identified and claimed. Keep in mind that not all embodiments will necessarily be commercialized by the company. The patenting process is exactly that - a process. It takes years for each application, for each set of claims being pursued, for each embodiment described in those claims. We've got a lot of innovation and are incredibly excited to build out our patent portfolio.

In addition to the protection of our technological innovation, we believe it is important to protect our brand. As such, we have a robust and growing trademark portfolio. The PolarityTE trademark has been registered in 14 countries. In the U.S., we have a number of trademarks allowed and registered, including the PolarityTE logo and the phrase "Where Self Regenerates Self". I'm excited and proud to be part of the PolarityTE team and to lead our efforts to build the PolarityTE IP estate. I've been helping companies to protect their intellectual property for almost 20 years, successfully starting patents and trade secrets in federal and state ports throughout the country and around the world. After working with the company as outside counsel and getting to know the team, I left my position as a partner at King & Spalding to focus full-time on the amazing PolarityTE technology and continue to build a strong IP portfolio from the ground up.

Now, I would like to turn the call over to Paul Mann to address some recent corporate developments.

Paul Mann: Thanks, Jennifer. Please go to slide 23. During the past 12 months, the management team has focused on making changes to the corporate structure into one that promotes the goals of a biotechnology company.

We now have only one class of equity outstanding, common stock, which facilitated two capital raises in 2018 with institutional investors. As a result, we now have approximately 21 million shares of common stock outstanding and no preferred stock or debt financing on the books.

At the end of the fiscal third quarter 2017, the company had only $3 million of cash on its balance sheet. At the end of July 31, 2018, we have $84.8 million of cash. We are well capitalized to meet our foreseeable capital needs for at least the next 12 months.

We've also spent considerable time strengthening our Board of Directors. At the end of calendar year 2017, the Board of Directors consist of six individuals, only three of whom are deemed to be independent.

As Denver mentioned previously, we have managed to hire some exceptional people during the past few months. And we now have eight Board members, six of whom are classified as independent, and only one Board member is also an employee of the company.

Finally, our institutional ownership has grown considerably. Per the most recent data on Bloomberg, approximately 49% of our equity is held by institutional investors. So, we've done a considerable amount to enhance the corporate structure of the company. To make it simpler for the market to measure and evaluate our progress and results, we intend to change our fiscal year-end from October 31 to December 31 after we file our annual report on Form 10-K for the fiscal year ending October 31, 2018. Slide 24 provides a schedule of what we currently expect our Board and (ph) calendar to look like if we effectuate the fiscal year change.

Finally, I would like to say how thankful I am to be given the opportunity to join PolarityTE. It was a difficult decision to leave Wall Street after almost 20 years. However, I'm extremely excited by the opportunities we have in front of us. Never in my career have I seen such an opportunity set like the one we have here, with a commercial product with blockbuster potential and some of the science being conducted in our labs is simply incredible. I think Denver and Nick have just provided you with a small glimpse of the types of things that will come out of our pipeline during the next several years. I really believe that our science is going to change the world, and I feel we're going to generate incredible returns to our shareholders along the away.

I will now turn it over to Cameron Hoyler, company's Chief General Counsel, for some further remarks related to recent events.

Cameron Hoyler: Thank you, Paul. In light of the recent news about the SEC filing a civil complaint against several individuals and entities, which included the company's former CIO, John Stetson, I do want to take a minute to address that issue. As we stated in our press release issued on Friday afternoon, PolarityTE's management team and Board of Directors are committed to upholding the highest standards of integrity. Following the SEC's announcement on September 7, 2018, the company immediately terminated its contractual relationship with Mr. Stetson. None of the other defendants listed in the complaint filed by the SEC has any recent management, employment or consulting relationship with the company. The company's prompt action with respect to the situation should demonstrate that management and the Board do not tolerate the behavior outlined in the SEC's complaint.

It is also important to note that PolarityTE is not one of the three companies referenced in the complaint, and PolarityTE has no involvement with or knowledge of the activities mentioned therein, all of which pertain to other entities.

Please note that, other than the information provided on today's call about Mr. Stetson and the company's press release issued on September 7, we do not have any additional comments and do not intend to address questions regarding Mr. Stetson during the Q&A, which will be focused instead on the company's results and business operations.

With that said, I'd like to turn this back to Denver for his closing remarks.

Denver Lough: Thank you, Cameron, and thank you, Paul. As we wind the presentation side of this call down, I'd like to say how excited we are about the corporate, R&D, and clinical success and advances that we've made this year. And we remain relentlessly focused on bringing our core TE platform out of the lab and into the clinic ahead of schedule.

On behalf of my colleagues, I want to extend my gratitude for your support of PolarityTE and our mission, as well as welcome you all to the shift. I want to remind everyone again that this company is now a little over 1.5 years old and that we are ahead of schedule.

Whether it be the staged commercialization of SkinTE nationally or planned expansion into international markets, or the preparation of OsteoTE for segmental market release in 2019, or the aggressive translation of Polarity R&D technologies from bench to bedside, or even the continued and accelerating development of the company's intellectual property and patent claims sets, we will always be focused on delivering real, effective solutions for real problems that patients and providers face each and every day.

Before I turn the call over to the question-and-answer session, I'd like to take a brief moment and focus on something that is very important, and that is the answer to the questions that I have received, many of you asked other members of the company before and that is, "Why"? Why does Polarity do things so differently than everyone else? Why are we not more like all the other biotechnology companies that are out there? And I'll tell you, the answer is simple. We innovate in a completely different way than they do, and we, therefore, are completely different and unique from what it is that they do. We have produced a different technology. We have assembled a different team. We have taken a different view. And we have executed on a different approach. We've also pursued a different cause.

Now, I know there has been volatility in the stock and volatile commentary by uneducated entities which are simply not true, again, not true. But, one simple way to overcome these elements is to listen to the truth and become educated on what really is going on with Polarity and where we are going with our growing and dynamic technology platforms. It is this simple. Our technology works. We have an incredible team to deliver and evolve this technology, and we have a business strategy that is not simply disruptive. In fact, it's much bigger. It is truly constructive, and it's also a comprehensive system.

We certainly recognize that different and/or unique systems can often be scary and difficult to understand when you first look at it. Believe me, it was not easy for so many of us to leave our stable careers behind to start and build and operate Polarity. But, we have something so different, so unique and so promising that we all did. We look forward to changing the paradigm and welcome you all to the ship.

Saying that, we'd like to open the call to questions if the time permits.

Operator: Thank you. Ladies and gentlemen, if you'd like to ask a question, please signal by pressing star-one on your telephone keypad. If you're using a speakerphone, please do make sure that the mute function is turned off to allow your signal to reach our equipment. You may also place a question via the webcast. Just simply type your question in and click "Send." So, to place an audio question live, simply press star-one to ask your question now. We'll give a short pause to allow everyone an opportunity to signal for a question.

We will now take our first audio question from Elemer Piros from Cantor Fitzgerald. Please go ahead. Your line is open.

Elemer Piros: Yes. Good morning, gentlemen. I have a question related to slide 15, where you talk about the distribution, the size of the wounds and the types of wounds where the product

has been used. First of all, just to clarify, this slide or these board (ph) charts referred to the commercial setting or the commercial setting combined with the initial sampling period?

Denver Lough: Thank you for that question. Let me pass it over to our Chief Operating Officer, Ned Swanson, to answer those details for you. Thanks, Elemer.

Elemer Piros: Thank you.

Ned Swanson: Yes, to just answer the question up front, this is all use of the product to date, whether in the limited release or the commercial regional release that's taken place over the last fiscal quarter.

Elemer Piros: And if you look at and compare in the commercial setting, Ned, could you give us a little more granularity of what types of wounds do you see where the product is actually sold for treatment?

Ned Swanson: In the commercial setting, it mirrors pretty closely what you're seeing here, even though this includes all use to date, even in the limited release or trial evaluation period. And the split of the types of defects, again, you would see here in the middle graph of the three in the bottom of the slide. So, it is a pretty even mix of acute burns, chronic wounds and even surgical reconstruction and traumatic wounds already.

Elemer Piros: Okay. Have you seen any examples, Ned, where the product was actually reimbursed directly outside of a DRG code?

Ned Swanson: Yes, we have had the product reimbursed directly outside of a DRG code in the clinic and outpatient setting, both for the procedures that were performed and for the products specifically that was built.

Elemer Piros: I just have a couple of more, if you could. I think, Denver, you've alluded to that you had an opportunity to take an interim look of the head-to-head comparison of SkinTE with the standard of care. Can you give us a little bit more of an update of the trial itself? How close to are we being completing enrollment? And how would the data be disseminated by these three centers where it's individually combined? What are the options at the moment?

Denver Lough: Yes, absolutely. So, we have seen some of the interim data, as we've made public previously. We have had some of that information made public, both in our Qs, Ks, and on a couple different discussions. It's running in parallel to essentially what you've seen and been presented at both KOL events, as well as the materials that are put online themselves.

With regards to the trial itself, we have our ongoing head-to-head clinical trial comparing SkinTE to the clinical standard of care, as you know, the split-thickness skin graft. And these centers are now enrolling patients. We can't comment on the interim data in the actual enrollment, per se, but we know that the data will likely read out and be available towards the end of 2019. And that's what we're expecting as it correlates to the different centers that are performing these trials.

Additionally, Elemer, we've also prepared, I think as I had pointed out, as well as Dr. Sopko, we've also prepared some randomized control trials for chronic wounds in the outpatient setting, which would further demonstrate essentially the efficacy to

successfully treat both acute and chronic wounds that affect millions of Americans each year. It should also demonstrate the positive outcomes, the clinical utility and competitive health economics of using SkinTE compared to other advanced wound care products, or even skin grafts themselves, essentially to meet these patient needs.

Elemer Piros: And on -- at the commercial part of the organization, how large it is at the moment? And where do you plan to take it by the time of national launch in the first half of '19?

Denver Lough: Are you talking about sort of the commercial arm of the company, the sales team, or the PolarityTE entire entity?

Elemer Piros: Yes, no, the commercial part, the sales team, regional manager, et cetera, all in. Where is the headcount now? And where do you plan to grow that?

Denver Lough: Absolutely. We will be releasing more information on some of the major metropolitan areas that are now being staffed with regional sales directors. But, to go into more granularity, I'm going to pass it over to Ned Swanson, our COO.

Ned Swanson: Yes, thanks, Elemer. To get into a little more detail than I discussed earlier in the call, we are targeting building out every region across the country into 2019, and once every region's established, starting the full national launch. What that looks like to date is between 10 to 15 sales members to be added to cover every major metropolitan region. And we're not projecting what that will look like, going forward, in the next one to three years. But, to say the least, we believe we can do this with the pretty concentrated sales team, and we don't see this becoming a massive arm of the company in terms of hundreds of reps. And the reason for that is because we don't need our sales team in the OR once someone has learned how to use the product. So, they can continue to expand the regions and grow the demand of the product without being tied to everyone who's using this.

Elemer Piros: Yes. And just maybe a last one. You described the bone market as somewhat more segmented. What might be the initial indications where you would make the product available for sampling?

Ned Swanson: Yes. We anticipate initiating the limited release, similar to SkinTE, by the end of this year or beginning of next year. And we haven't disclosed yet what the market segments are that we're going to prioritize and enter first, but we will disclose those details more as we get closer to that launch.

Elemer Piros: Thank you very much. I'll get back into the queue.

Operator: We now move to our next question, which is from Ash Thomas-Watson from Bybrook Capital. Please go ahead. Your line is open.

Ash Thomas-Watson: Hi, guys. Thank you for the time. I completely understand that you asked during the Q&A that questions not be about Mr. Stetson, so I think that's fair enough. I will respect that. But, I did have a question about a statement Dr. Lough made in 2016 where he thanked Barry Honig and Phillip Frost for their confidence in the company. So, Barry Honig and Phillip Frost are described in the SEC's complaint as being part of a group of prolific South Florida-based microcap fraudsters. Michael Brauser, who is the number two disclosed shareholder in your company, was also named in the complaint. Barry Honig is the number three disclosed shareholder in the company, and Philip Frost owns more equity in the company than your new CFO does. So, can you elaborate on any

current involvement you have with the individuals named in the SEC complaint, whether it would be ownership or otherwise, please?

Denver Lough: Absolutely. As you pointed out with regards to ownership, you're correct, but we cannot control who does or does not own certain elements of the equity in this company if they're buying it in the open market. We don't comment on any individual shareholders who are not members of the management team. Mr. Honig is not a member of the PolarityTE management team and is not on the company's Board of Directors. He was an investor in the entity that later merged with PolarityTE, and remains an investor, to the best of our knowledge. To clarify so people know, the merger itself with -- was with Majesco Entertainment, and he was the CEO of that time. So, obviously there was a transition during the merger itself. And once Polarity itself was essentially built and formed, that group stepped away.

Ash Thomas-Watson: And have you guys had any correspondence with the SEC? And is there an ongoing SEC investigation into PolarityTE?

Denver Lough: We have not had any communication with the SEC related any element of this, and there's no current investigation. As we tried to make clear, and I hope it came across -- as it came across in the press release itself, we -- again, we were not involved in that investigation related to those individuals named in that SEC complaint. We're not one of the companies there.

Rich Haerle: Operator, can you check for any further questions via telephone?

Operator: Yes, certainly. I'll just give a further reminder, as we have no further questions in the audio queue at present. So, ladies and gentlemen, as a reminder, just please press star-one on your telephone keypad to place your audio questions now. We'll give a further short pause.

Rich Haerle: Okay. And before we -- and I was going to say before we move on to that, I do have a webcast question. Question, can you please expand on the two new sections of the R&D slide outside of the TE line? Denver?

Denver Lough: Yes, absolutely. Thanks so much for that question. We've always sort of said until we're blue in the face that the technology itself is really based off of a platform. We are not simply a skin company. We don't simply just treat burns and wounds and traumas related to sort of cutaneous substrates. There are a whole host of other types of tissue substrates, the core TE technologies that we've developed.

But, in addition to that, and while essentially developing and evolving those technologies, we further move forward with what we call our Related Technology Derivatives, which are certain components related to the core TE technology that are slightly more advanced that you can use for a variety of different types of targets and programs. As you can see on the slide, the ARC program is even more advanced, and it has -- focuses more on arms of gene therapy, therapeutics, and small molecule synthesis. Materials related to that will become available shortly as we continue to present both publicly at investor meetings as well as national and international research and clinical conferences.

We wanted everyone to be aware, again, that these were arms of research and development at this company that we're moving ahead very quickly and that you would begin to hear certain elements surrounding each one of those programs shortly. So, we

found that this was a good time to begin to introduce some of these arms as it relates to small molecule synthesis, antimicrobial therapies, as well as gene therapies.

Operator: We will now move to a follow-on question from Elemer Piros from Cantor Fitzgerald. Please go ahead. The line is open.

Elemer Piros: Yes, this question may be directed to Paul. Paul, what is your current revenue recognition policy? And is this the way you envisioned to recognize revenue in the future as well? Or is there a transition to a different model?

Paul Mann: Thank you, Elemer, for your question. So, we recognize revenues from SkinTE as they arrive at the provider. So, we get an order from the provider. The harvest arrives as our facility. We process it, and then we deploy -- we send it back to the provider. When it arrives at the provider, that's when we book the revenue.

Elemer Piros: Okay. And one last clinically related question. Have you seen patient examples when the product was used in one particular area, and then subsequently, a second or third area was also treated with a product that was made subsequently?

Ned Swanson: Yes, this is Ned. We have seen the same patient have the product applied on one area of their body, and then the provider, in conjunction with the patient and/or patient's family, ordered SkinTE again to apply on another area of the patient's body. If you're referring to have we had one harvest saved over multiple applications, that has not occurred to date, but it is certainly something we are planning to make available. We have never had a (inaudible) wound have multiple applications within the same wound.

Elemer Piros: Thank you.

Operator: We have another question now queued from Raj Denhoy from Jefferies. Please go ahead. The line is open.

Raj Denhoy: Hi, good morning. Relatively new to this story, so I apologize for some basic questions. But, when you look at the revenue you're generating right now, the $416,000 in the quarter, can you characterize how many sites that's from? I gather you're still in relatively limited rollout, but how many individual hospitals or customers are currently ordering from you?

Denver Lough: Ned, do you want to go in any elements concerning the commercial rollout of the product itself?

Ned Swanson: Sure. We haven't provided any specific guidance on the number of total patients treated. Our limited release targeted about 50 patients, and we've moved on to the regional release. And we expect those numbers of patients treated to scale up accordingly with new regions that we launch. We've also been pretty pleased with the progress we've made with different Value Analysis Committees at a number of hospitals and healthcare facilities. But again, we haven't given metrics or guidance on those.

And for one reason, it's because we don't think those translate necessarily to the info you're looking for where you can get through one committee. And it's a single small community practice versus you get into a much larger system where you get access to 15 hospitals, and it doesn't translate the way we believe people are looking to find. But, as we can say, we have a 100% success rate going into the VAC review process at every place we've entered and a decision has been made. And we hope to provide more

information on this front (ph) on future calls as we begin to scale up regions across the country.

Raj Denhoy: Okay, fair. That sort of segueways into my other question, which is really just trying to characterize what that funnel looks like in a sense of the number of interested hospitals, physicians. Clearly, the technology is getting a little bit of -- generating some interest, right, certainly, but how is that translating into hospitals and surgeons or practitioners that are seeking to learn more about it or to bring it into the hospital? Is there any way you can characterize what that funnel looks like?

Ned Swanson: So, again, we're not providing any guidance on the precise numbers or total centers at this time. As we continue to scale up the commercialization and bring on more regions and have more information following regional releases, we think that will become more granular in the future. But, at this time, we don't see any guidance or projections being made.

Raj Denhoy: Okay. That's fair. Then maybe just one last one. You mentioned the progress towards getting a Q-code for the technology. Is there any early discussions around what that reimbursement level would look like or whether there could be some sort of early new technology uplift in that reimbursement rate?

Ned Swanson: So, we haven't gotten into anything in terms of the reimbursement levels or price points, but that Q-code has been preliminarily recommended to be established for January. So, we expect that will be the case, and providers will be able to start billing for SkinTE with that Q-code in the outpatient setting beginning in January. Currently, they're using other available codes, and that's how the product has been reimbursed directly currently.

Raj Denhoy: Okay, great. Thank you.

Rich Haerle: And I have another question from the webcast. Question is, "Any update on OsteoTE and CartTE as associated with spine would be appreciated."

Denver Lough: Thanks, Rich, really appreciate the question from UBS. Yes, absolutely.

So, first and foremost, as we explained in the presentation, the spine market or the bone market itself is segmented into a variety of different types of segments ranging from craniomaxillofacial, dental, long bone, total joint, spine, foot and ankle, as well as hand. As you guys are probably well aware, there are a variety of different types of specialists and physicians that actually fit into those different types of groups. For example, craniomaxillofacial can be plastic and reconstructive surgeons. It can be ENTs or otolaryngologists or oral and maxillofacial surgeons.

So, knowing that the bone market is so segmented, we wanted to make sure that we were applying a truly methodical approach appropriately. And the first groups that we will be essentially targeting, the first segments that we will be targeting are on craniomaxillofacial and foot and ankle likely in the 2019 into 2020. Following that, we will then target more of the spine, as well as long bone and total joint recon. But, the first segment of bone markets we will be approaching are craniomaxillofacial, oral maxillofacial, as well as the foot and ankle, spine, long bone to follow after that.

Rich Haerle: Thank you for the question.

Operator: And just to confirm that we have no further questions queued on the audio side. So, I'll turn the conference back to you, Mr. Haerle, for any additional or closing remarks. Thanks.

Rich Haerle: We appreciate everyone's time, and we are -- we're focused on executing on the business. We're focused on getting the product in the hands of physicians to get it in on patients. And that is our number one focus. And we look forward to interacting with the investment community overtime. And again, our goal is on execution.

Operator: Thank you. Ladies and gentlemen, that's now concludes today's conference call. Thank you for your participation. You may now disconnect.