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RenovaCare Investor Presentation
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C: Alan Rubino; RenovaCare, Inc.; Chairman & CEO
C: Dr. Robin Robinson; RenovaCare, Inc.; Chief Scientific Officer
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Amit Singh^ Good morning, ladies and gentlemen. Welcome to today's RenovaCare Investor Forum. My name is Amit Singh and I will be the host of today's call.

Today's call involves presentation by management, followed by a question and answer session.

As a reminder, the format for today's presentation is the following:

The Company will make presentations by Mr. Alan Rubino, Chairman and CEO, covering business and strategy. The Company's scientific and regulatory updates will be delivered by Chief Scientific Officer, Dr. Robin Robinson. And finally, the Company's financial updates and outlook will be delivered by Chief Financial Officer, Mr. Robert Cook.

Before the presentation commences, we are required to review the Safe Harbor Statement under the Private Securities Litigation Reform Act of 1995. At this time, we would like to give the audience an opportunity to review this important information. We would also like to urge you to read the company's SEC filings by visiting our website at www.renovacareinc.com/sec-filings.

With that being said, it is my pleasure to introduce you to Mr. Alan Rubino, Chairman of the Board and Chief Executive Officer of RenovaCare.

Alan Rubino^ Thank you, Amit, and good morning to everyone. As you know, from the title, we will be focusing on RenovaCare, the SkinGun and the CellMist and the next generation ultra-gentle cell spray.

I want to welcome you all to our very first investor forum. And we'll all be pleased to be reporting on our progress in 2020, which has been significant. The presentation will include key facts and data on results as well as the activities that are pending.

It is an important year and RenovaCare really evolved this year into a development-stage company, which is quite important, and Dr. Robinson will speak to it a little bit more later. But in general, we will be over viewing the company, reviewing its science, talking about the SkinGun and the CellMist assets, and then also providing you all with insights into the business strategy on how we intend to build shareholder value.

Now, you see the handsome pictures up on the screen. I'm very pleased to present two of my executive team colleagues. Both have joined the company in the last 18 months. And along with the team that was already here have -- had an extensive value and great dimension to RenovaCare with their scope of experience and their strong track records.

If you go to the next slide, I want to be able to give you a snapshot and perspective on the RenovaCare including our current priorities.

Quick history, if we look to the left on the past, present, and the future, on the left, you can see the company's focus was early research and development, sort of discovering preclinical and developing intellectual property. And we worked on 70 human case studies, which you'll hear about later. And then of course, we began the early development of our SkinGun spray device cell isolation process.

As we look to the current, and I put a big accent on the current, that emphasis looking at at least the next 12 to 18 months. But now, we've advanced our research and development efforts. We're moving into clinical trial program. We have strengthened our intellectual property. Our regulatory submissions are beginning and will last over the next five years for the first submission. And corporate development is already in progress. We'll talk to this as we move.

And of course, if you go to the bottom of the evolution of the technology, we now have a more perfected electronic SkinGun we're working on and disposable SkinGun, a new CellMist system -- CellMist system overall. And our work in progress is really vital on our closed cell isolation device, all of which you'll hear more about.

As we look to the future, we're talking about the near future first that certainly burns that continues to be the focus followed by wound and other therapies we'll speak to. And the future is here in many ways. Strategic partnerships and product collaborations are very much a part of our core competencies and will figure well into the company's business model.

And again, I'll emphasize why burn is the focus. We are assessing and will assess areas in advanced regeneration therapies as mentioned, adipose tissue as well as skin and

other clinical indication. But virtually everything will be addressed during this presentation that you see in this spectrum. Next slide, please.

In this slide, basically, there are four focus strategy of how the company will meet its objectives. And it's really important that they all really feed off of one another. The first is developing and we have developed a diverse product portfolio, again, emphasizing burns, chronic wounds initially, and then we've been looking at the spectrum that we have listed there.

Second, we have a very robust and expanding and a very strong intellectual property estate. That's already not only strong but defensible. We are growing this intellectual property and our R&D portfolio simultaneously in the core areas. And we are focused on differentiated products for unmet needs and particular right now in the full/partial thickness second -- full and partial thickness -- I'm sorry -- thickness second degree burn space.

Then, the third item here is disciplined capital allocation. What do we mean by that? Well, we operate with iterative resource allocation to maximize and balance the investments. Those are the dollar investments and people investments that will support the portfolio growth opportunities, future financings, and current corporate development activities and shareholder return as a part of that of course.

And all of the confluence of these three items together leads to the fourth. These areas really lead to execution of our growth strategy. And we have mentioned already that the portfolio growth is in key therapeutic areas. I emphasized strategic partnerships again because in this progressive marketplace that we live in this is a very important part of opportunities and sharing.

Operational efficiency is a continuous core competency here. So, we're always right size and effective. And we do have world-class leadership. And I'd like to speak to what we mean later on about that and the importance of that along with our technology. If I can have the next slide, please.

Again, I mentioned in 2020, we became an important transition from this discovery, preclinical stage company to a development stage. We are focused in this development stage on next generation products in our sector that we choose to compete in.

I think it's most appropriate at this time that I hand the next portion of the presentation to Dr. Robin Robinson, who is our chief scientific officer. Robin will take us through this important section so that you, as our audience, our shareholders, potential shareholders,

and interested parties come away with a better understanding of our technology and its applications. So, Robin, I'd like to turn this over to you at this point.

Robin Robinson^ Thank you, Alan, and good morning and good afternoon to all of you. The regenerative medicine stem cell sector is a relatively newcomer to medicine over the last 20 years; it was really based off of the NIH moratorium in 2001 on the usage of fetal and placental tissue for research and clinical investigation.

That moratorium spring boarded stem cell research in a different and unexpected way; as usual, scientists really looked for other ways to isolate and study stem cells. We have to find another way. And imagine what we did. We found that you could get stem cells from adult somatic tissues. And then that led to what we now have as cell and stem cell therapy. And it's just now blossoming in the United States and most parts of the world; although it blossomed in Japan in 2014 by farsighted government finding and regulatory policies.

And resulted of course in 2012, a Nobel Prize being given to John Gurdon and Shinya Yamanaka for showing that you could take an adult somatic cell and actually engineer it into stem cells. Essentially, they would reengineer its development to be a stem cell that can differentiate into all kinds of different tissues.

From that moment, we've seen a real cross current and cross related developments of many stem cell products; many of these have not worked, but many of them have. So, what we do know is that from a number of stem cell therapies particularly from peripheral blood lymphocytes and the bone marrow can be used for a number of oncology treatments that had been approved by the FDA, some blood disorders, one knee treatment, and one skin treatment from skin tissues.

I wish to pay tribute to two of my favorite people Harmel Rayat and Jay Bhogal, who talked me into coming to RenovaCare in August of 2019 with their perspective of how to actually move forward to address a very big and unmet need with burn wounds. Next slide, please. Next slide. There we go.

We know that up until about two years, the way that you actually would treat burn wounds especially if they were severe and covered more than 10% of the body surface area, they were either partial or thickness as a second- or third-degree burn that you would actually have to have a skin graft and that would require then a equal-sized tissue being excised from another part of the body and then being placed on the burn wound. And this was the normal standard of care for burn wounds.

But with stem cell developments and regenerative medicine coming to into its own, we saw over the last decade real progress. And so, we --

Alan Rubino^ Robin?

Robin Robinson^ Yes.

Alan Rubino^ Robin, excuse me. It's Alan. Just because we realized from -- the sound is a little bit broken up here. If you may be too close to the mike.

Robin Robinson^ Okay. This any better? Is this better?

Alan Rubino^ Yes. That's a lot better. Thank you.

Robin Robinson^ Thank you, sir.

Alan Rubino^ Appreciate it.

Robin Robinson^ So, as we move away from both skin grafts and mesh, we actual are able –to start utilizing stem cells. And when I was the BARDA Director, we actually supported development of these stem cell therapies for thermal, chemical, and radiation burns in mass casualty events. And we've seen one of those actually obtain FDA approval in September 2018.

But what really became -- next slide, please -- what really became exciting to me was when I saw the RenovaCare story in 2019. Of the 1.5 million cases of burns in the U.S., 40,000 actually need definitive burn care. Over the past ten years clinical observational data have been collected by some of the founders of RenovaCare and their inventors in investigator-initiated clinical case studies in Germany and also the United States in the University of Pittsburg using our skin cell therapy.

It showed that in 71 patients you could actually facilitate the healing in these physician-initiated case studies that healing took, not months, but actually days and weeks to heal with complete closure of the wounds and rapid re-epithelialization, and functionality and appearance or cosmesis being restored to what it was before the burn incident.

And this was manifested by two scientific thoughts and based on a scientific principle. instead of actually taking skin and do something to it with growth factors or cytokines or put it into tissue culture to generate sheets of skin or treating it, or adding a gene to it, let Mother Nature do what it does best.

That is this -- take the tissue -- take a small piece of skin tissue, render cells from that tissue, both skin cells and pluripotent stem cells from it and actually apply them onto the burn wound directly without any perturbation. And the way that you can do this effectively is with a what we call our Cell Mist System and SkinGun technologies together.

So, our CellMist System isolates the cells. And then, we apply those skin cells topically onto the burn wound using a gentle mist of air mixed with the cell suspension that is applied as single cells onto the burn wound.

And this is what really excited me to come to the company. And this is now the next generation of stem cell therapies for burn wounds and other types of acute and chronic wounds.

This is exemplified -- the next slide, please -- so, if you could imagine looking at the far left panel what has happened in the past with skin grafts and mesh. You had to actually take a large skin graft that was the same size as the burn wound in the past and use that to hopefully heal and probably require several surgeries to actually have effective healing. And that would take not only months but maybe even year, and similarly with mesh.

But with our stem cells, what we see is a very small, silver-dollar-type size of tissues -- healthy tissues removed and the cells are removed from that tissue both from the dermal and epidermal layers and then applied with our SkinGun very finely onto a large area that is affected by the burn. And that is a major improvement and what we think is transforming in this space.

So, by doing that, we're actually able to then come up with four new products. Next slide, please. So, you see our portfolio, the far left, we have our CellMist system coupled with our SkinGun. And that is actually then on its way through the regulatory pathway through a safety and feasibility study towards a Pre-Market Approval (PMA) we hope in the next four or five years.

And then, the actual devices themselves could be standalone. And we see our electronic SkinGun in the second panel that we'll be going forward with the 510(k) submission early next year. And then with next panel, we have our disposable SkinGun that might be the best solution for a particular problem in the field or out-patient clinical setting.

So, not only can the electronic and disposal SkinGun spray devices be stan alone products for cell suspensions but they also can -- be able to spray and apply a medical solution of importance that might not involve cells at all.

And lastly then, what we have been working on in the last couple of years is a cell isolation device that is a closed, automated system so that you can imagine you take your tissue, you then put it into the cell isolation device, add the necessary ingredients like enzymes to render the cells from the tissue, and in 90-120 minutes or less then you're able to actually isolate those cells and then load them into the SkinGun and spray them onto the burn wound.

And therefore, that would be our cell isolation device be our -- hopefully our final product as we go forward for our PMA and a stand alone 510(k) product for isolation of cells skin and other tissues..

Okay. I hope you can hear me better now.

Alan Rubino^ No. Actually, we're just having a little bit volume drop problem. I'm not sure if it's you. We're working on it in a moment.

Robin Robinson^ We're back. Okay. Can you hear me now?

Alan Rubino^ Thank you again. Yes.

Robin Robinson^ Thank you.

Alan Rubino^ We can.

Robin Robinson^ All right. So, next slide, please. So, what is the pathway with our milestones and timelines for these four products in our pipeline?

Well, what you can see is that we are moving forward with our PMA pathway for our CellMist system and electronic SkinGun system. We start with our clinical study for safety visibility that's built off of these 70 patients and these case studies that we were so -- that are really invaluable to our development of these products.

And then, we will have our cell isolation device once it is validated, to do a second study that will allows us to validate in the clinic our electronic SkinGun with the cell isolation device. Those data from the feasibility studies will then inform our clinical protocol for the pivotal clinical trial that we think that will start in 2024. And then, we'll be able to move forward with PMA submissions thereafter when that study concludes.

In the meantime, as I've said, with the 510(k) submissions for our electronic SkinGun, our disposable SkinGun and our cell isolation device which could not only isolate cells from

skin but also from other tissues and make available stem cells from other tissues for other clinical indications will be over the next two to two-and-a-half years.

And we think this is not only a conventional type of timelines but they're based off of the fact that it's evidence based. As we gain information and are able to have everything in place then we will move forward. And so, we don't think that this is over aggressive, but it's actually very straightforward and very conservative.

Now, how does this stand -- how do our four products stand with what's out there in the field now? Next slide, please.

So, one of the things that we've learned from our surgeons and physicians that have used stem cell therapies with a spray device is that the autologous skin cells really do need to adhere to the skin. And so if you look in the panel, you see stem cells from our CellMist System sprayed using our SkinGun spray device onto an arm of an individual. And you see a nice pattern that's consistent, that's comprehensive and it adheres very rapidly to it.

And what does this allow, as you can see the far right panel, is you have single cells that actually then populate the burn wound and that expand very rapidly by talking and communicating with its neighbors. And then within days, not weeks or months but days, then you can see complete closure of the burn wound and its re-epithelialization. And so that we haven't even met at the full potential or the ceiling for the product for the amount of the cells that are afforded for the burn wound closure.

So right now for every centimeter of donor skin from the patient you can treat up to 100 centimeters of burn wound; we think that's the basement. We think it is actually much higher than that. In addition by actually using dermal and epidermal layers of skin, we get not only a large amount of cells but we get the right kinds of cell to facilitate this healing. And certainly, this is -- was seen in the -- so many patients that we have actually already done case studies already.

And lastly, that once the spray is applied then, it doesn't come off. It doesn't roll off and -- it doesn't drip and everything. So, that's actually another very big advantage of what we have as opposed to other stem cell therapies that are out there.

And with that, I'm going to turn it over to Alan again. Thank you.

Alan Rubino^ Thank you, Robin and thank you for touching upon an important in a series of products and innovations. Dr. Robinson has its own R&D organization here in the U.S. where it focuses on clinical regulatory quality manufacturing. But I want to also

feature here, the additional depth of RenovaCare that includes specialized experience with our German counterparts.

It's a strategic alliance with stem cell systems and now we have -- we even more formalized, this is a longstanding relationship, and we really -- it comes out of RenovaCare R&D Innovation Center. This is fully integrated. We have experiences that points out here in the slide with surgery, bioengineering and manufacturing, et cetera. The CellMist and skin gun really has been invented, prototype, patented and really clinically translated first of all with stem cell systems partner.

And you can see all the capabilities and bioengineering and more recently we enhanced our cell biology capabilities. They have expertise in regenerative medicine, medical device engineering and prototyping and all this continues today. They even become more regulatory-centric as we pursue the opportunities with the FDA pathway that Dr. Robinson spoke to.

And obviously, they're very driven around IP and understanding engineering both on the device as well as on the cell isolation side, the quality support documentation. And there's a formidable team of partners here, there are nine people. As you can see, we have two MDs and PhDs, we also have an MBA-engineer and four engineers including biomedical engineering.

So, the very specialized capabilities in Germany coupled with our R&D organization here in the U.S. make us a really formidable group to continue the success pathway that we're on in a very organized and methodical manner.

I'd like also now change gears and speak to IP, to all of you out there, really stands for intellectual property in the state, the patents that you developed. And we have -- that's the lifeblood of a company to protect your innovations, to also give you a competitive advantage in the marketplace. So, it's really a critical part of our success formula and it's always front and center.

And if you look at the next slide, again this just gives you a snapshot of the innovations overtime that we've expanded this, in particular the last two years they had been really significant but all the items, spray guns, the various spray guns, the closed cell isolation system, all of these are covered by really important patents.

And without giving it too much -- over done, I will say that we have a robust and strong patent portfolio. We have eight-patent families, three U.S. patents, one German patent and one [allowed] European patent. We have applications pending in multiple countries

and an important point, one of our main patents, it's already been successfully defended, right, someone that was challenging.

So, we had no loss of patent claims and another important item is just that these patent issues extend to 2036. Our issued patents include cell isolation from skin, skin wound treatment and uses of cell spray gun.

And one final important point is that we have sole patent ownership. RenovaCare owns all technology developed and underdevelopment and has not in-license any technology. So, ownership and prevent unintended consequences as to licensing, the ability to enforce a patent by patent litigation and prosecuting applications. So all in all, a very important part and we had a very strong intellectual property position.

I'd like to go to the next slide and just talk about our disciplined pathway and what we mean by world class management, define that a little better. But first of all, I'd like to talk about the market price itself in the next slide.

In this slide, we talked about regenerative cell therapies and there is a significant market. I just like to give you a quick build on the market and the focus of that. To your left, you see the current market and that's really the inpatient burn, that's what we're pursuing now, that's what Dr. Robinson spoke to in a regulatory pathway. This is the current market focus, it's $200 to $300 million market currently. It's a meaningful size for a specialty med tech device company.

And of course as you move to the right, a natural progression and one that seems to be well in our grasp in the future is the advanced burn care. This is outpatient burns, pediatric scalds and mostly handled in the clinical setting, maybe the hospital, the burn centers as well and that's the $600 million, $700 million. And again, we like to be sober about these and if you move to the right as we want to expand in very clear areas of wound care where we think we can add value such as diabetic foot ulcer and others.

We will certainly be reviewing those areas, dermatologic as well and that would add an additional $1 billion. So, it's a really nice market opportunities that sit within our realm over the period. So, the commercial potential is well over $2 billion.

If I could have the next slide, I'd mentioned many times by design the importance of partnerships to our company and why that's a core competency and why that's a very good for a progressive company to this day and age. They are critical to our business model, they will be critical in clinical and eventually, potentially in commercial as well.

But, I thought it will be nice just to -- I would like to ask Dr. Robinson just to speak to these. These are our partners in our clinical development program and they're all quite established but I'd like that Dr. Robinson comment. Robin?

Robin Robinson^ Yes. Thank you, Alan. So, we have actually engaged the services of MCRA, a Washington D.C. consulting group that specializes in interactions with the FDA in the area of medical devices and biologics. And they had been working with us and we were successful with their help of obtaining a conditional IDE approval and expect a full approval of our IDE as we can start a clinical trial early next year. And so that's already a successful relationship will blossom further as we go forward.

In manufacturing, we actually needed to have our manufacturing of components for our clinical supplies, whether the enzymes and other products including the skin guns done in a way that would be compliant with the current manufacturing practices outlined by the FDA.

And so Berkshire still manufacturing in Massachusetts, Roche in Germany and also PRO-TECH Design & Manufacturing on California had been instrumental and [I] as our CMO is going forward and of course our innovation R&D partner as stem cell systems has been the producer of our skin gun, both electronic and developing new ones.

And then finally as we go forward in the planning and execution of our upcoming safety and feasibility, clinical study for next year, we have engaged the services of advanced clinical and also [MCRA] with our regulatory filings. So, now we have a very strong and successful cadre of partners that could take us all the way through our PMA and 510(k) filings going forward and help us with the development towards our commercial launch [in] several years. Thank you.

Alan Rubino^ Thank you, Robin. I'd like to switch to the next slide where we just give you a little insight into our milestones for 2020 and the goals that we have in terms of our transition activities for developing stage growth. First, you could see on the left, our planned current trials as Robin mentioned. We have five major burn centers selected and we intend to be working with them, with patients in the first quarter of next year. We have already selected these.

Our regulatory priorities had been mentioned here but I'll mention them again that the FDA submission, the IDE went in. We have received the conditional approval. We'll have the full approval, we believe, by the end of the year. And of course, we look ahead for the 510(k) submission on skin gun in the first half of 2021.

Another critical point here is that corporate development activities, having the great technology we have in developing is critical but it's also having the right people and the right approaches to maximize that. We have been hiring a strategic talent and we've continued to do that right up until today to drive these corporate activities, especially our clinical trials and our FDA submissions.

We also look to expand our portfolio into burn or beyond burn to a multiple collaborative partnerships and strategic alliances. We know how to do these well and we know the value of these. So, this is something we'll continue to pursue.

And of course like every company, especially public companies, we always want to be properly financed. Mr. Cook and I had been working on a comprehensive financing plan. We are focused on proper and timely financings, whether it be traditional and non-dilutive and he'll speak a little bit later to our finances overall. And in the next one, again I'd like to -- next slide, please.

I'd like to talk about very quickly what an experienced leadership team means and why -- I don't like to toss around words like world class unless it's meaningful. I will not belabor the time here but I invite you to go to our website to look at the bios and the CVs of our management team, those listed here. You will see they are extremely well-heeled and I'll leave that to your discretion to look at but they were carefully crafted selections.

It is a customized set of skill sets and competencies really that are very unique to the burn and wound care area. The analogy I'd like to make to the boxes won't do us justice but I'd like to make the analogy here. It's sort of like a fine orchestra and we have an array of ensemble heads, whether it's Robin but we have clinical and regulatory R&D and science, we have manufacturing, alliances and collaborations as well.

And all of these ensembles play as an integrated orchestra and that's why we've been, I believe, so very effective in our approach and our implementation this year. And I look ahead to that but we are -- we do have fully integrated capabilities as mentioned there in that line below. We have high experience in all of these areas, so it's really been very exciting.

And myself joined the company just about a year ago now and really engaging with the new management players, the existing players, it's really come together in a very nice way and results are what we're summarizing here with you today.

I'd like to go to the next slide. How will we build the current success and we are focus on results. First, I'm going to talk a little bit about our -- the investment plan whatever some

key financial summary points and I'd like to turn that over to Mr. Cook to go to the next slide.

Robert Cook^ Thanks very much, Alan. As the newest member of the team here at RenovaCare, let me start by saying that I am delighted to be joining the company at this very exciting time and also very delighted to be working with the great team of professionals that are dedicated to moving the company's technologies forward.

Today's presentation is being directed both to our existing shareholders as well as to potentially new investors and analysts who are less familiar with the company. And so with that in mind, I thought it would be appropriate for us to at least just sketch out some of the headline numbers that are important for the company and that will form the basis for our future discussions.

First of all just as a note, RenovaCare has been in existence since 2014 and as Robin has been saying, we spent the first few years developing and patenting core technologies that had been part of today's presentation. And very importantly, we've now reached the point where we are moving our core product into clinical development and therefore to support that activity, the finances of the company become both relevant and important to its success.

So, just looking at some of these important numbers here on the slide, we have 500 million shares, common shares that are authorized, and approximately 87 million shares of those are outstanding. And importantly, about 12 million of those shares are actually held in Street name at various brokers. The vast majority of our shares, some 75 million are in registered form and of that amount, about two-thirds are owned or controlled by our largest shareholder.

In addition, we have outstanding stock options and warrants that amount to about 18 million shares and most of those are held by insiders. As the company continues to grow, one of the important objective that we have is to broaden the stock ownership of the company at both the institutional and retail levels and we'll be talking about this I think for the next several months.

From a financial statement point of view, the company's fiscal year ends December the 31st. So, we're, at this point, preparing our third quarter financial statements which we're planning to release in mid-November. So as we look at the second quarter which is public, our balance sheet reported cash of $10.2 million and we had shareholders' equity of $14.3 million.

The cash burn as you can see for the six months of the year was $1.9 million. Now in the third quarter once we report, you'll be able to see this. It was a particularly active period for us because we spent that time basically manufacturing the clinical material that we're going to need in our feasibility study. And therefore, the third quarter burn is -- when you see it, it will be higher than either of the first two quarters of this year but within the budget.

And based on our budget, the current cash on hand is sufficient that can take us more than 12 months. And perhaps more importantly, we believe it's sufficient to fund us through the end of the feasibility study. Keep in mind, we are a development stage company, so we had no revenues and therefore our future success is dependent on financing to complete the clinical development and obtain approval and then to commercialize the products.

Possible sources for this financing, obviously include partnerships or other non-dilutive capital but it could include as well as the sale of equity or debt securities. And again, this will be a topic of discussion that we'll cover over the next several quarters.

And finally, the company relocated its corporate office, so we're now here in Roseland, New Jersey since late last year. We currently have 10 employees and staff consultants working at the Roseland office but also at various locations around the U.S. and in fact in Europe.

And then perhaps very cogently today, we should say that the impact of COVID-19 on our operations, happily, has not been significant. But as I'm sure you can understand, it's difficult to know with any degree of certainty what future impact it may have on our operations or on the conduct of the clinical study.

And with that, I'll turn it back over to Alan.

Alan Rubino^ Thank you, Bob, very, very helpful. In the final slide here is, again, how we build shareholder value and how we build the company. And it's in -- a lot of this is just really summarizing if we -- the things we would – the five things we'd like you to remember most today is that the company does have not only a focused portfolio, it's a cutting edge stem cell spray therapy.

We have a cell isolation and spray technologies and developments outlined and will be focused on acute and chronic wounds including burns. Certainly, we have multiple growth drivers. There is a worldwide market demand for self-donated autologous stem cells.

We have diverse therapeutic opportunities beyond wound and burn and tissue and organ regeneration that we will be examining over time, but we will keep a focus our portfolio growth in key therapeutic areas and strategic partnerships for being high in our radar screen, I've already spoken much about the proven IP estate and the strength of that estate and our sole ownership.

Again, this is very important because these technology projections cover our methods and our devices. And this is obviously also the courier focus that helps us differentiating our products for unmet medical needs, and that's where, again, we are laser focused, if you will.

We have a demonstrated record, a track record and many years of experience in strategic commercial partnerships. So, we have a clear and focus business development effort that's already going on and that's based on experience of myself and others. And we have an established history of success so let me define this, strategic [longitudinal] relationships. And that is having relationships with highly credible partners and very sophisticated partners, both at the development and the commercial stage. Those will certainly be on our radar screen and they already are in discussions with various good companies.

And we also feel we are very well-positioned for government relationships having Robin here who worked with BARDA and its relationships in the whole regulatory group, including the FDA, is certainly helpful to having that kind of expertise in house.

And last but not least is we run a company with a discipline capital allocation process with a very effective management team. We are focused on investment, not expense driven. We're investment driven and we are market obsessive in terms of time to market.

Everyone from here to Germany and around the United States understands that every activity every day must contribute to speed to market. I think, again, and we have all of these investments focused on the business drivers that we pointed out today and the operational efficiency that we demand of our organization.

At this point, this concludes our formal part of our presentation to all of you and I hope you have found it very informative. We had the opportunity and you've had the opportunity to provide questions to us and we would like to respond to, and so, I will turn that over to my colleague, Amit to raise the questions and we will respond, myself, Bob and Robin. Amit?

+++ q-and-a

Amit Singh^ Thank you, Alan. The corporate presentations have concluded and we are now entering the question and answer segment to today's investor forum. Questions will be read aloud by myself and moderated by company CEO, Mr. Alan Rubino.

We will attempt to answer all applicable question, and if we don't want to answer your question, or if you have any additional questions, please feel free to email your queries to us @contact@renovacareinc.com or call us directly at 888-398-0202.

Alan, the first question is, I'm a long time investor in RenovaCare. My question is when the company is planning to move from the OTC board to the normal exchange for better exposure.

Alan Rubino^ Thank you, Amit. Obviously, a good question and one we'd probably would anticipate anyway. At some point when a company elects to raise capital and wishes to seek a traditional financing and uplisting would definitely be a consideration for sure at that time.

Amit Singh^ Thank you, Alan. The second question is, what does the competitive market look like? I see MiMedx, Organogenesis, Fibrocell, and many other, are there any other biotech players using a similar stem cell spray technology?

Alan Rubino^ I'd like to ask Dr. Robinson. I think we're all aware of these, but I think Robin even acutely so. So Robin, maybe you might want to comment on that.

Robin Robinson^ Thank you, Alan. So in 2018 after about a 10-year journey, AVITA was able to obtain FDA approval of their stem cell therapy for burn wounds. It was the first generation and they have done a good job, but we actually feel very strongly that we're the next generation and transformative with our technologies and provide the greater ability to facilitate wound healing. Thank you.

Amit Singh^ Thank you, Robin. The third question is regarding distribution. If you follow the typical model, you will need to develop a sales organization, generate leads, and convert them. What are your plans for creating awareness, educating, and training burn doctor and specialist and getting distribution?

Alan Rubino^ Right now at this point, where we are in development, certainly, the company will review multiple options including commercialization. We can look at commercialization alone or as I mentioned earlier, with a partner, but that's the spectrum of decisions that we would look at and I think all are viable. But we do not need to be making that just at this time as we're, as you know, in the development stage.

Amit Singh^ Thank you, Alan. The next question is, what other products can RenovaCare develop to generate revenue?

Alan Rubino^ I guess I'll take that question. As I've mentioned throughout the presentation, and again with small companies, you want to keep focused. So I want to repeat that our focus is burns right now and that's in the foreseeable future we'll be focused on that.

But as you can see during the presentation, it was commented that there were other areas of consideration that certainly include chronic wounds skin. And, again, possible use in the future in areas of tissue regeneration with other organs.

So again, we will keep ourselves very disciplined and we will look at the (inaudible) the scientific and clinical rationale for those indications to know that we have the best chance to be successful in the clinic and more importantly with the patients.

But I think that, yes, the short answer is yes, we will be looking at these other areas to generate growth, but right now burn and chronic wound would be the initial focus of the company's efforts.

Amit Singh^ Thank you, Alan. The next question is, I see you are developing stem cell technology to regenerate tissues and organ. I assume they too will need to go through clinical trials. Could you please comment on those?

Alan Rubino^ Absolutely. I mean, the basic answer is yes, they will all go through clinical trials, protocols and [what] like would have to be discussed in design with the FDA as the appropriate size or the patient populations, the desired endpoints, primary and secondary.

So yes, all of these would require that type of pathway, similar to what we're doing now with burn, but obviously customized to those areas.

Amit Singh^ Thank you, Alan. The next question is, has there been any work carried out for the tattoo removal process?

Alan Rubino^ At this time, there has not. I mean, there's certainly a lot of conversation about that. We certainly have Dr. Robinson, Dr. Esteban here. We also have a board member, Dr. Lydia Evans that I think could give us directional feedback on whether or not this is an appropriate target for us.

It's certainly a large market as you well know, but we'd have to make sure that we have a product that in ourselves would be very effective in that. And we have not really studied that at this time to be able to make that determination, but it's a good question and we certainly will keep that. It is on our docket as a potential portfolio area.

But again, we would need more information to determine that. You have to have that information before you make an investment in areas like that. You have to have a good idea that you're going to come out successful in the end, but theoretically, it sounds like a very good target to examine.

Amit Singh^ Thank you, Alan. The next question is, at what stage of the FDA approval process is the company technology in?

Alan Rubino^ I think that was addressed, but I'd like to ask Robin to comment again because it's a lot of information we provided today. I think it'd probably be nice to him to just reiterate that again, Robin.

Robin Robinson^ Yes. Thank you, Alan. The CellMist system and electronic SkinGun for burn wounds is at the precipice of moving forward with the beginning of clinical trials next year. And so we're on our major first step in advanced clinical development going forward over the next four years to get pivotal clinical trials in commencing and in submitting our PMA for submission 2024-2025.

Alan Rubino^ Thank you, Robin. Amit?

Amit Singh^ I believe we've got a few more questions coming in. Let's allow them the opportunity to ask their question.

Alan Rubino^ Okay. Sure.

Amit Singh^ Okay. I believe we have one last question and that question is, how do your products match up against AVITA RECELL? Can you be more specific about your advantages? I've been invested in your company since 2017?

Alan Rubino^ Okay. Also, a very good question. We're very keenly aware of AVITA and the RECELL product and I'm sure they are of us. We have a great deal of respect for that product. It was the pioneering first-generation in this category.

And I think, we will always say, positive things because we believe in the technology as they do and we're certainly in the same space, but we do anticipate that there'll be

differentiation. And I'd like to, again, I think Dr. Robin's part of his presentations today, when you saw it spraying on the skin and some of the points that were made there.

And by the way, this slide presentation will be available subsequently on our website. You'll hear that. But I'd like Dr. Robinson to describe this from a clinical perspective, what he believes is differentiation areas will be. Robin?

Robin Robinson^ Yes. Thank you, Alan. Clearly, one of the major things is that the RECELL product from AVITA, which we supported when I was the head of BARDA. The cells actually come from only one layer, that's the epidermal layer and the underside of epidermis. We intentionally actually use both epidermis and dermis for partial thickness and [properly] going to be what's necessary for full thickness burn recovery. And by doing that, we actually get more cells, high viable cells with the way that we have our CellMist system procedure in place.

But also the right kinds of cells, more than just keratinocytes, the melanocytes from the epidermal layer. But we get fibroblasts and other types of [fully] potent stem cells from that dermal layer, which are really important for rapid wound healing. So that's one and is really paramount.

So from the very beginning, we have a really a different product. The second thing is that with the spray gun device that we have, we actually are able then to have the cell suspension not as clumps, but as single cells that are the very fine mist. And that with medical air mixing with that cell suspension that allows them that fine mist to be sprayed onto the burn wound and adhere very quickly and tightly to the burn wounds so that you do not have drips or the liquid of the cells actually running off of the burn wound. And that's really important, not only for the healing of the burn wound, but also to prevent infection. And so that's another, I think, transformative thing that we have with our SkinGun products.

The third thing is that because of the abundance and types of cells that we have, the area in which we can cover is maybe actually more than what you see with the single kit from the RECELL product.

You may actually take two or three kits from their product. We would actually have one. I would say that one of the big advantages both of theirs and ours is this a single day or single afternoon or single warning procedure as opposed to all the other types of skin procedures that you have for burn wounds. And that's for the surgeons and for the patient, especially this is a big advantage and we certainly are in line with that.

And lastly, we think that the SkinGun also allows them the very careful comprehensive area, up to 30% total body surface area can be contemplated very easily with our SkinGun and CellMist technology.

So those are the few things. There are some more that we can get into details about, but again, we think we're the next generation. Thank you.

Alan Rubino^ Thank you, Robin. Very comprehensive and I think very fair balanced. Okay. Amit, any other questions?

Amit Singh^ No other questions. Thank you, Robin. Thank you, Alan. Thank you, Bob. This concludes today's corporate presentation on the question and answer segment. The presentation will be available. Yes, go ahead.

Alan Rubino^ Yes. I just want to make one comment when you complete. Thank you.

Amit Singh^ Sure. This presentation will be available on our company website, located at www.renovacareinc.com. On behalf of the entire RenovaCare team, we thank you for your attendance and participation of today's meeting.

Alan Rubino^ And I just like to add to Amit's comment and, again, I know this has been a longer presentation, but we felt this was warranted because we really want to have more increased dialogue with all of you.

I just want to say on behalf of the management team here, I want to thank Robin and Bob and others who helped prepare this, but certainly I want you all to know that we really do value all of our current investors and including our majority shareholder for your collective support and loyalty and your confidence in where the company is going.

We certainly welcomed new investors that see this is as opportune for them and see the science and innovation is meaningful. And for all others that joined this call, we trust that we're able to give you a much deeper perspective into RenovaCare company, our overall strategy, and our implementation priorities.

So thank you again for all of your attention and your time. Everyone, have a nice day.