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Regenerative Medicine company AMNICELL is using Amniotic Fluid Stem Cells to improve Health and Wellness and in treating Serious Lung Disease such as COVID-19



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“AMNICELL leverages technology in the very exciting field of regenerative medicine by being the first company to use amniotic fluid stem cells to improve health and wellness, including COVID-19 and other serious lung diseases.” Caroline Einaugler

CEOCFO: *Ms. Einaugler, according to your site, "AMNICELL is improving lives through advanced stem cell technology." In what way?*

Ms. Einaugler: AMNICELL leverages technology in the very exciting field of regenerative medicine by being the first company to use amniotic fluid stem cells to improve health and wellness, including COVID-19 and other serious lung diseases. AMNICELL is the first company to recognize the unique capability of human amniotic fluid as an abundant source for novel stem cell products.

CEOCFO: *Has this been looked at before? Was there a lightbulb moment, "We should do this?" How did it come about?*

Ms. Einaugler: It is really fascinating. Medical and scientific research is very challenging, and it takes a very long time and many brilliant people to get new therapies on the market. The idea began with Dr Young working at the NYU School of Medicine, who realized that the fluid around the baby in the womb, amniotic fluid, contained cells that have potential for groundbreaking therapies. The research was conducted on this amniotic fluid during the last ten years and it showed that amniotic fluid from normal full-term cesarean births contains millions of stem cells for possible clinical use. The amniotic fluid, previously discarded as a waste product, can be safely collected, frozen and stored for later clinical use. Therefore, it is really a long process from the idea to actually bringing a novel product to the market.

Right now, we are ready to begin our Phase 1 trial of amniotic fluid stem cells to treat serious lung disease for which there is currently no

satisfactory treatment. Additional clinical trials will be for chronic non-healing wounds like diabetic foot ulcers and war wounds. We expect clinical trials take at least a year for each of 3 phases, and then be able to get FDA approval to bring the new product to market.

CEOCFO: *When do you collect the amniotic fluid? How would you store it? How do we get stem cells from the fluid?*

Ms. Einaugler: At AMNICELL, we have a technique for collecting amniotic fluid and stem cells at the time of scheduled cesarean birth. Because they are natural stem cells we collect and store them frozen after separation from the fluid, and nothing more is needed for clinical use. There are no risks to the mother or baby, and the fluid is considered medical waste and usually thrown out. We foresee the transformative treatment of COVID-19 ventilator patients, respiratory failure from other lung diseases, and non-healing wounds, as well as many other applications for health where there are unmet needs.

CEOCFO: *You are new to the role of CEO at AMNICELL, although you were involved with AMNICELL in the past. Why have you chosen to get onboard and what have you found as CEO?*

Ms. Einaugler: Really, what is amazing is that the potential for stem cells is really unlimited and it is the AMNICELL mission that is so exciting. AMNICELL will be at the forefront of the global expansion of regenerative medicine and typically for AMNICELL, by collecting, storing, and providing amniotic fluid and stem cells for health and wellness. The powerful mission of the company is to develop its innovative stem cell technology platform to advance health and wellness and save lives, and that is just very exciting and drew me to the company. As CEO I find an outstanding dedicated team that makes me proud to have this role at Amnicell.

CEOCFO: *Does the fact that you do not have a scientific background make it harder, or in some ways is it easier, as you can be potentially more objective on the business side?*

Ms. Einaugler: It is both. It is harder in the sense that it harder for me to have the deep understanding of the science, but we have our founder and our Chief Science Officer. Both are distinguished professors and teachers with incredible background knowledge and research experience, so they are there to explain and help me with the science component.

In some ways, it is easier in terms of the fact that I do not feel limited in any way, because I can come up with creative suggestions. Sometimes it does not go naturally with the science, but then as we discuss it, we may be able to turn things in a different direction that we might not have thought of if everyone was completely focused on the science.

It also allows me to look at the science and make sure that it is something that can be translated into something that is easy for everyone to understand. As CEO I built on our achievements so far and I am expanding the scope of our platform, aligning research support via grants, and business funding via investors, and coordinating science and business as we make progress.

CEOCFO: *Does the mother have to agree to you using the amniotic fluid, or because it is a waste product, is it just up to the hospital?*

Ms. Einaugler: The mother has to agree, even though the fluid is waste. Anytime the amniotic fluid is taken from a cesarean birth, the mother is aware and has the consent that we are doing that. We believe there should always be consent.

CEOCFO: *Are there challenges from anyone? Are there challenges to using amniotic fluid? Is it accepted as a good means as opposed to something like aborted fetuses? What is the feeling amongst the medical and the "moral" community about using amniotic fluid?*

Ms. Einaugler: That is one of the benefits of amniotic fluid. It is not, as you said, stem cells taken from a fetus. It is truly just taken from a waste product. That is one huge advantage as the non-controversial way of obtaining stem cells, in contrast to all other means. Neither the medical nor the moral community have raised any issues about amniotic fluid sourced from normal patients at scheduled cesarean births. Their potential for creating therapies for diseases that have no cure at this time is truly amazing. There is Covid -19, ARDS (Acute Respiratory Distress Syndrome), SARS-2 and other serious lung diseases with respiratory failure. Those are just one aspect of the stem cell therapy platform Amnicell is developing. The medical community recognizes that the hope of the future is through regenerative medicine and stem cells. As I mentioned before, from the amniotic fluid, again, it is really just a waste product, a big advantage over other stem cell sources.

CEOCFO: *You mentioned lung disease. How have you chosen what you to try first?*

Ms. Einaugler: I think that we were already looking at lung disease and non-healing wounds, and things like skin related disorders. Because of COVID-19, we did pivot somewhat to focusing more on COVID-19 lung disease. We are hopefully beginning to see some let up of the number of people dying in the United States from COVID-19 and the number of people who are on respirators due to very serious COVID-19 disease. However, new variants continue to emerge, many countries are far behind the US in dealing with the pandemic, and resurgences are occurring in various advanced European countries.

As a result, it is still very timely, and in this country, it is becoming clear that there are likely to be new variants year after year. Therefore, its not just Covid-19. In addition to the COVID-19 lung disease, there is also the existing lung diseases, like the very serious lung disease I mentioned before, the ARDS. The treatment for lung disease alone is likely to help millions of people globally, so the need remains and will persist.

CEOCFO: *Funding is always an issue for companies that are developing, particularly in the medical field. How are you positioned in that regard?*

Ms. Einaugler: We are in the process of looking for additional funding. We have gotten a lot of grants, close to 4 million dollars in grants for the research alone. We have had private investors and are looking for, of course, increasing the number of private investors at this point.

CEOCFO: *What has been the reception from the medical community that are aware of what you are doing?*

Ms. Einaugler: The reception is very positive. A number of research papers have been written on this by our founder, Dr. Bruce Young. The response is really incredible. He has done a number of presentations on the national and international level, about what AMNICELL is doing and research that is going on. It is very exciting, and the medical community is aware of how exciting it is.

CEOCFO: *Are other people starting to look at amniotic fluid now? Has it sort of opened the flood gates? It would seem such a natural idea.*

Ms. Einaugler: AMNICELL is the first company to recognize the unique capability of human amniotic fluid as an abundant source for novel stem cell products. There are not any other companies, that I am aware of, that are using amniotic stem cells for the same kind of research that we are doing, for non-healing wounds and the serious lung disease. Therefore, at this point there is really not a lot of competition. The scientific community has recognized the importance of the previous research and some scientists have been studying these cells, but no companies have a clinical product.

CEOCFO: *How do you spend your time as CEO? What is your focus right now?*

Ms. Einaugler: The focus right now is on trying to raise money, trying to come up with succinct ways to describe what our company does, in a way that makes sense to scientist and non-scientists, working on presentations, and then of course, on the operating and just overseeing what direction the company is going in. There is more mundane things of trying to figure out if we want to stay in the same location that we are in, do we want to move and how will we use the additional funding that we hope to receive soon, with the idea that most of it will be focused on going back into the research, but how else will we spend most of the money, to make sure that the research is effective and that the product can be marketed.

CEOCFO: *What was learned from the early research that might have been unexpected?*

Ms. Einaugler: I think that the early research was actually even more positive than expected. The stem cells have so much potential for so many different ways of being used to help different kinds of diseases where there is very slow progress or no progress and many of the medicines on the market are really just to stop it from getting worse or to keep someone alive, as opposed to really helping them get better.

It became obvious very quickly that, for example, with the non-healing wounds, that even just putting some of these stem cells on the wounds topically had a very quick and rapid effect on healing wounds, which was truly surprising. In the lab, the cells responded so quickly to just being in contact with the stem cells.

CEOCFO: *Will you be pursuing wound care as well now, or is that a little further down the line?*

Ms. Einaugler: Right now, we are really focused on severe lung disease, for which there is no treatment, and the chronic non-healing

wounds will follow soon afterward. Again, there are millions of people, worldwide, that have both of those conditions. Non-healing wounds is actually very pervasive, in addition to the current widespread lung disease.

CEOCFO: *Why should AMNICELL stand out from so many others? Why is the company so important?*

Ms. Einaugler: We are really the only company that is using the stem cells from amniotic fluid for regenerative medicine. Our goals are to improve lives, save lives, and use this technology to cure as many diseases as we can. We are already at the Phase 1 trial level for the COVID-19, and other serious lung disease and we have a very well thought out process for going forward with that. That has already been funded through grants, and we are really just looking for additional monies to keep it going past the next 18 months or so, so that we can move into the Phase 2 trials for the serious lung disease, and then also begin Phase 1 trials for the non-healing wounds.

There are also other applications more long-term for things like cosmetics and creams, that also have a lot of potential and do not require the FDA approval. I am really just repeating the same thing, but AMNICELL, once again, is very unique. It is the first company to recognize the capability of human amniotic fluid at the source for novel stem cell products, and has amazing long-term capability, which is a very exciting situation, that really will do a lot of good for many people and save many lives.

