



Revolutionary Non-Invasive Medical Device that Will Reduce the Incidence of Preterm Births



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CEOCFO: *Mr. Rosenkoetter, the tagline on your site is “Improving Obstetrics, Saving Babies.” How are you planning to do that?*

Mr. Rosenkoetter: We will be bringing to market an exciting new non-pharmaceutical product that will prevent the onset of preterm labor. Annually preterm births result in 1,000,000 infant deaths. Adding to that tragedy, another 2,000,000 infants will be born with serious lifelong disabilities including cerebral palsy, profound retardation, deafness and blindness. Over the last 40 years there has been no improvement in the incidence.

My cofounder, James Olcese, PhD, is one of the leading authorities in something called neuroendocrine systems and circadian rhythms. He knew that the labor process for most deliveries begins at night and he knew that the circadian rhythms were somehow involved. Building on some old research, he conducted breakthrough new research that led to exciting discoveries, regarding a hormone the brain produces called melatonin. It regulates our circadian clock. During the course of a pregnancy, receptors from melatonin start appearing in the uterus. The interaction between the receptors and the melatonin is part of the process causing contractions. That was a new and very interesting insight. Since melatonin increases at night telling us to shut down he posited that if we can down regulate its’ secretion we can impact contractions. The next step in his journey was to take a group of women who were 37-38 weeks pregnant and contracting and expose them to a light source just before going to bed. Lo and behold, their melatonin secretions went down by about 30%-40%, which was remarkable. But what was truly remarkable was that their contractions stopped! They were not diminished they were stopped. (These results were mirrored by a collaborator of Dr. Olcese’s at Brigham and Women’s Hospital in Boston.) The big “so-what” is that if we can prevent contractions in healthy women at risk of preterm birth, we can significantly reduce preterm deliveries and infant deaths.

The embodiment of these learnings is a very comfortable, elegant sleep mask. Women will “tell” the device when she is going to bed. She will put on the mask at bedtime and approximately forty-five minutes later a very low-level blue light will slowly ramp up and hold for a period time and then ramp back down. That will be adequate to regulate the secretion of melatonin and will not disturb her sleep. That low-level blue light will penetrate her eyelids and reach the pineal gland and tell the pineal gland to shut down secretions of melatonin.

To help us advance this science and translate it into a viable therapy we have been working with the Medical College at Florida State University, where Dr. Olcese is a professor, a researcher and clinician at Brigham and Women’s Hospital, a NASA researcher / light expert at Rensselaer Polytechnic Institute and a thought leader from the Toronto Centre for Advanced Reproductive Therapy.

CEOCFO: *How do we know there are no side effects?*

Mr. Rosenkoetter: There is precious little data related to testing pregnant women because everyone is reluctant to do that. However, we do know that the effect of the therapy in the evening is transitional, and auto-corrected the next morning. The woman will wake up in the morning and her clock says, “Okay it is morning, time to get up and get going”. We also know that people that are deprived of melatonin and in a sleep-deprived condition for a time will still maintain their normal sleep rhythms despite the fact that the melatonin is not being secreted. We know from other tests that if someone is deprived of melatonin during pregnancy, the fetus has a normal circadian rhythm within a week of birth. There are no discernable adverse effects. Minor impacts such as a potential loss of sleep in some of the women are trivial when compared to the risk of a preterm delivery.

CEOCFO: *What has been the response of the medical community?*

Mr. Rosenkoetter: I have spoken with a number of normal practicing OB/GYNs and with several key opinion leaders within the area. Their response is just short of a resounding “Halleluiah”. The response of the head of Fetal and Maternal Health at Brigham and Women’s Hospital at Harvard was that if this works they will erect a statue of Dr. Olcese in every labor and delivery room in the world because this is a problem that has been without a solution. The current therapies that they employ are short term and often harmful to the mother and/or the baby or just medieval.

CEOCFO: *Does it matter that you do not know why this happens?*

Mr. Rosenkoetter: We do know why. We know that because we are stopping the secretion of melatonin we are causing the avoidance of contractions. We have proven that at Tallahassee Memorial Hospital and at Brigham Women’s.

CEOCFO: *You have a number of products. What will be available first and what are the differences as you go along in your pipeline?*

Mr. Rosenkoetter: Our first product will be targeted for developed markets. It will have blue light capability and also have an alarm system, so that if an at risk woman rolls over and starts sleeping on her back the alarm will go off, so that she will roll back over. This is because a pregnant at risk woman should not be sleeping on her back. That will be Version 1. Version 1.1 will add additional monitoring capabilities, such as the ability to monitor rapid eye movement, temperature and other bodily functions that the medical community identifies as important. The third version will be specifically tailored for the lesser-developed markets. Right now there are roughly 33 million pre-term women at risk globally. Of that approximately two thirds of that are in developing countries, so our third product is going to be uniquely configured and specifically targeted to those needs.

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CEOCFO: *Are you funded for the next steps? Are you seeking investment or partnerships?*

Mr. Rosenkoetter: Yes, for immediate next steps. We are funded for short term activities, but we are still working to close our Seed Round. That will provide adequate funds to carry us through the next phase of development and clinical testing. We will then be seeking a qualified round, which will take us all the way through to launch. So a short answer is: as with most start-ups we are always looking for funding.

CEOCFO: *How do you personally deal with the frustration, when you have something that obviously could make such a difference, but it takes awhile to get it through the system?*

Mr. Rosenkoetter: Our frustration is the realization that every additional day that we take to get our product to market has real implications for people’s health, and this translates into tragedies and deaths. The offset to any frustration is that we can look to the near future when we will be able to provide a solution, make a difference, and save lives. Those combine to create a tremendous sense of urgency.

Additionally, the anticipated FDA review and approval process is not too painful for a product like ours and we anticipate having US and EU approvals in hand within 5-6 quarters, which ameliorates the frustration as well.

CEOCFO: *What have you learned from past experience about bringing products to market that will help you in this venture?*

Mr. Rosenkoetter: Probably the most important and rewarding learning is that it is going to take more dollars and time than your most conservative plan if you do not have a top-notch team that stays very tightly focused throughout the process. We have that. After that is to always understand the real medical need. There is a great deal of science that does not accurately address the core medical problem. And of course, make sure that you really understand the physician’s and patient’s wants and needs. This is particularly true with products like ours.

CEOCFO: *Why does KynderMed stand out?*

Mr. Rosenkoetter: KynderMed stands out because first of all, it is addressing a tremendous unmet need. It is a market comprised of 33 million women who are at-risk of giving birth preterm and a physician population that has been frustrated by a lack of solutions. So it is a large, emotionally charged, unsatisfied market. We have a solution that will meet that need. From a commercial point of view that is attractive. Moreover, we have the potential to save millions of lives and improve even more. Those are pretty compelling reasons to get involved.