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Issue: February 24, 2025

Alessa Therapeutics – Bringing a New Paradigm to Cancer Treatment with their Proprietary Drug Delivery Technology enabling Early Interception and Prevention in Prostate Cancer with Less Side Effects

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CEOCFO: *Dr. Munster, what is the concept behind Alessa Therapeutics?*
Dr. Munster: As a medical oncologist I have always been aware of the fact that we tackle cancer with medications mainly when it has advanced. We have not made a huge dent in early interception and prevention. The reason for that is that often drugs have a lot of side effects, and for someone who doesn't know if they will get cancer or if their cancer has progressed, it is hard to determine whether they need an intervention.

The concept of Alessa was based on the idea of taking anti-cancer agents proven to be beneficial and treat the organ that is at risk. Our first clinical program was the prostate, and we created an implant that eludes an anti-androgen selectively delivering drug to the prostate. This should spare men at risk for progression and side effects.

CEOCFO: *Why prostate first?*
Dr. Munster: We did not start with prostate first, we started with breast cancer. Our mission was to figure out a new prevention strategy for breast cancer. However, the clinical and regulatory development path for breast cancer prevention, trying to show that we indeed could prevent breast cancer as an end point was long and daunting to any pharmaceutical company investor or even clinician. This makes showing the benefits of a totally new paradigm in breast cancer challenging. It is my goal that if we can show that the prostate cancer strategy is successful, to then go back and move this forward in breast cancer.

CEOCFO: *Would you tell us about your implant - what it is made of and how it works?*
Dr. Munster: What early interception needs is drug release in the organ at risk for a prolonged period of time, and our case that organ is the prostate. We think in prostate cancer drug delivery has to be at least two years so that men do not have to be retreated. That makes a biodegradable material difficult because biodegradable materials only work for three or maybe at best six months. Our goal is to deliver drugs for at least two years.

We have created a non-biodegradable polymer that is mixed with a drug. The way we select the polymer which is an inert material and mix it with a drug is the proprietary technology. Our implant delivers a high burst first and then a steady release of drug. We are confident that we can deliver drug for 2 or more years as similar concepts have been created with an IUD (Intrauterine Device) in women. In women the concept of long-term drug delivery has been quite well established and very well accepted. This IUD can stay in the body for up to seven years. We have somewhat established

a Proof-of-Paradigm that we could deliver for a longer time but also that we have long-term safety with our initial prototype, Biolen. This is an implant for prostate cancer and maybe BPH that contains bicalutamide.

CEOCFO: ***What have you developed so far and where are you in the process?***
Dr. Munster: Because this is a new paradigm and no anti-androgen has been approved as a single agent in early-stage prostate cancer, we started with Bicalutamide, which is an old drug that has been around since the 1980s and approved in 1995, It has been used for different purposes. Bicalutamide in our implant was placed into 17 men who had been scheduled for a prostatectomy, to see if we could have the implant deliver enough of the drug to the prostate but not to other organs. We also wanted to know how far the drug is traveling through the prostate and how much drug is in the plasma. What we found was exciting. We found high drug levels around the implants, and in the tumor. The implants were easy to insert. We inserted up to 16 implants into the prostate and that took about thirty minutes. We further observed tumor shrinkage, proving that we have an effective drug therapy. We measured the tumor shrinkage by getting an MRI before the implant was inserted and then after it was in place for an average of 66 days.

The other interesting finding was that because when we placed these implants, we were initially worried that when we implant these men with 16 implants to a very small prostate, could there be worsening of their benign prostate hyperplasia symptoms measured by IPSS, or that we could we have a negative impact on sexual function. However, we found just the opposite, because we saw tumor shrinkage, and we also saw shrinkage of the non-cancer prostate tissue, which can cause BPH. We actually found that the men benefitted from their BPH symptoms and there was no negative impact on sexual function. These findings could make our implant a promising option for BPH.

"We can deliver an efficacious drug selectively to the prostate without the side effects of oral anti-androgens." Pamela Munster, M.D., Founder/CSO

We have another trial where we looked at these implants in combination with radiation therapy to see if we could spare men who need hormonal therapy systemic exposure. That trial is currently ongoing with 10 patients enrolled. In both trials we found that the plasma levels are very low. For example, the average plasma level for the men getting our Biolen® implant was about 22 nanograms per milliliters. Conversely, the average plasma level for someone getting oral Bicalutamide is 8800, based on what the oral exposure would do.

CEOCFO: ***What has been the response from the medical community is aware of your approach?***
Dr. Munster: People are excited. This is really a first glimpse that we could give an oral anti-androgen in a durable from without systemic side effects and not to have to take a pill every day. If you give oral systemic anti-androgens, you get quite a bit of hair loss and erectile dysfunction. Fatigue is significant. Men have a lot of breast tenderness and breast tissue growth. It is quite appealing that we can accomplish what we set out to do.

CEOCFO: ***You had recent funding, so there is some interest in the investment community. How will you be using these funds; how long will they last you and what has been the response overall from potential investors?***
Dr. Munster: We have very promising early clinical data and are creating two more programs. We will be raising money for a pivotal trial, and we have good feedback from the regulatory agency that we can get to registration with one large clinical trial. The trial will be with about 500 patients.

CEOCFO: ***Why did you step aside from the CEO role now?***
Dr. Munster: I founded this company as a spin-off from UCSF. It was an incredibly rich environment for me. I retained access to my patient care to my development in my NCI-funded lab and running the Phase 1 program. That allowed me to have my foot in the clinic and understand what it means to be a patient. I had breast cancer myself, so I really understand what early interception and prevention means, seeing it from the patient's side. I am hoping to continue this and being able to partner with our new very seasoned CEO. Cam Callagher has brought start-ups to large clinical trials with successful exits. Working with him is both an incredible boost for Alessa and a wonderful opportunity for me to partner with him and learn the intricacy of bringing a startup to the next level. At the same time, I get to work on the third, and fourth product for Alessa.

CEOCFO: ***What if anything might the medical or investment community not recognize about Alessa that they should know?***

Dr. Munster: I don't have to prove that the medication in our implants work, the medical community has already established this. We have to prove that they can get it to the prostate in high doses and keep it there. With the premise that these drugs are efficacious, and we have Proof-of-Principle studies to have high target organ and low plasma levels, the development becomes heavily de-risked. I am aware that tackling prevention and early interception may pose a considerable risk, because it takes a longer time to prove that these strategies work and may require large trials. Systemic side effects may further make it unappealing to high-risk individuals to consider prevention or early interventions. Just looking at the example of tamoxifen. Tamoxifen was never really adopted as a prevention drug, even though Tamoxifen has a 50% reduction in the development of breast cancer. It is quite challenging to take tamoxifen for 5 years because of all its side effects. Our solution could completely remove such side effects and still be as beneficial.

For our prostate cancer trial, we have also had regulatory support for an end-point that is much shorter. Our study will not take ten years, we should have an answer after about 3 years with 500 patients. We have minimal systemic drug exposure, so men will not suffer from androgen withdrawal and don't have to take pills every day. This will also help with therapy adherence. Once the implant is in, it is in place for at least two years. We do not have to worry that after six months people will say it is so much of a struggle, so they do not want to deal with it anymore. With this we overcome three of the major hurdles in the early interception and intervention development.