

Or-Genix Therapeutics Delivers Paradigm Shifting Innovation to the Woman's Health and Dermatology Markets



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CEOCFO: *Dr. Schwartz, would you tell us the concept behind Or-Genix Therapeutics?*

Dr. Schwartz: The concept behind our company is the re-engineering of ageing. For our first line of products, our primary clients were the women who are perimenopausal and menopausal. In their menopausal years they have begun to see unwanted changes to their topical surfaces, like skin, mucus membranes and hair.

CEOCFO: *What is your approach to helping?*

Dr. Schwartz: Our approach is to make women understand how menopause and the changes that occur just before and during the menopause, affect their biology and how those changes affect their overall sense of well-being. To that end, we licensed some very interesting assets from Yale University School of Medicine. These assets enable us to get right to the source of ageing to alleviate those undesirable topical symptoms.

CEOCFO: *Would you tell us more?*

Dr. Schwartz: When women go through menopause they begin to see these unwanted changes to their skin, their skin becomes drier, thinner, increasing redder, sometimes they get pimply break-outs, hair also gets thinner, mucosal membranes such as the vaginal wall and the eye begins to get itchy and less moist. What we found very interesting was that many women did not equate those changes with the loss of their menstrual cycles. We thought that was quite interesting, so we set out to educate them that all of these unwanted changes they begin to see are really due to the decline and subsequent loss in estrogen. Some refer to that as Estrogen Deficiency Syndrome (EDS). What we have been able to do with some of our very interesting ingredients is safely and effectively replace with our proprietary topical active ingredients what nature took away. We do this without using a hormone.

CEOCFO: *What are you using to replace estrogen?*

Dr. Schwartz: We replace it with what can be best described as a non-hormonal estrogen-like surrogate. It is not an estrogen, it is not a SERM (selective estrogen receptor modulator), and it is not a phytoestrogen. It is also not an endocrine disruptor. These chemical entities are completely synthetic, they bind to the estrogen receptor and turn-on all the proteins that are necessary for healthy-looking skin and mucous membranes, while sparing the internal organs of any unwanted exposure leading to side-effects. Furthermore, they are environmentally "green" because of how they biodegrade rapidly to an inactive degradation product. Initially, our primary market was perimenopausal and menopausal

women although we have some interesting new chemical entities in our pipeline addressing other skin problems that will be useful for men and women of all ages.

CEOCFO: *There are a lot of products that claim to help many of the different areas you are talking about; why do your products work, what makes them a cut above the rest?*

Dr. Schwartz: One of the things we learned in speaking to clinicians was that when women walk into their offices, they can tell which women are on Hormone Replacement Therapy (HRT). Their skin looks good, their hair looks good, they look vital and their bone density is good. A well-trained physician can take a look at a woman and recognized she is on HRT. However, the fear of HRT particularly Premarin® and Estradiol creams do not make it safe for women to apply these topically to their face because of the risk of systemic exposure, particularly in those women who are prone to breast and uterine disease.

Our active ingredients are very different. We can apply these to the face and mucosal membranes and not have any unwanted systemic effects. Our products break down rapidly to a single inactive metabolite upon reaching the system thereby avoiding these unwanted effects. That makes us desirably different from anything else currently on the market. Many antiaging skincare products are made predominantly from off-the-shelf ingredients, they supply moisture to the skin and really do not correct the underlying source of the problem. The source of the problem is what hormonal imbalance has created, that is, dry, wrinkly skin and dry and itchy mucosal membranes.

“In short, you have to have a great team and you have to be dogged because there are a lot of people with ideas and not everybody who has a good idea is going to get attention. You have to be determined, resilient, relentless and undaunted to succeed.”- Yael Schwartz PhD

There are products on the market that do work well. The retinoids, for example, work for wrinkly skin and for some breakouts and blemishes but they have their issues as well. Number one, they can be systemic, although systemic exposure is not a real problem with them. However, they do tend to be irritating to the skin. They exert their therapeutic effect by irritating the skin and then you get new skin deposited and restored. They have been around a long time and I think the market craves something new that really gets right to the source of ageing. Then you have the alpha hydroxy acids and those work well. You also have injectables like Restylane or injectable fillers, as we call them, and then you have Botox. Our active ingredients add to that armatorium and they actually get right to the exact source of ageing without being irritating and without requiring injection.

CEOCFO: *Would you tell us about hair growth and products you have for that as well?*

Dr. Schwartz: That is a totally different class of compounds. We have two classes of products, one can be used as a cosmetic for blemishes and hair thinning and the other, we are running up the pipeline, is for prescription use for acne and androgenic alopecia. These all work by counter-opposing the effect of testosterone at the level of the hair follicle and the pilosebaceous unit where the oil glands are and where acne begins. There are compounds out on the market like Finasteride and other compounds that you can apply to the scalp, the problem is that once you stop using them your hair falls out. They do stimulate hair growth to a degree but require continuous use to avoid hair shedding. They also have the unwanted issue of systemic exposure. In the case of acne, the market is huge and underserved with novel, safe and effective drugs that get right to the source of the cause of acne.

So, the root cause of androgenic alopecia and acne is excess androgen sensitivity. In women when estrogen declines during menopause, every woman says their hair is not as lustrous as it used to be, it is not as thick, and they are more prone to blemishes and acne breakouts. Well, there is a physiological reason for that. The reason is that estrogen went away and now the androgens that are made by your adrenal glands are no longer opposed. That is when women begin to see their hair thins and all the sudden their crown looks further back on the forehead, they begin to see thinning at the part line and we believe we can ameliorate that situation with the anti-androgenic assets we have. Their skin gets pimply, too. Our anti-androgenic topical compounds were chemically designed just like our other compounds by virtue of how they biodegrade rapidly after the therapeutic effect is achieved. They are engineered to be applied topically only; they work on a known mechanism of targeting androgen sensitivity at the hair follicle and pilosebaceous unit, all the while avoiding systemic exposure. They will be able to be used by women and men. We have not started full development yet of our prescription product for acne and alopecia but we have done animal studies and formulation work. Proof-of-

concept is very solid and we will be going into clinical trials before too long. We are very excited about that compound, those indications and the associated market values.

CEO CFO: *What has been the response from the medical community?*

Dr. Schwartz: They are very excited about our innovative approach to dermatology. The point of excitement for these clinicians is to be able to rectify what nature does naturally and still spare the system from unwanted side-effects. Or-Genix offers something very exciting to the dermatology community that continually craves innovation.

CEO CFO: *How do you stand out at a meeting or a conference?*

Dr. Schwartz: There has not been a lot new and novel in dermatology for a long time. I am not saying there has not been anything but a lot of focus in the pharmaceutical industry, and understandably so, is in oncology. We are not an oncology company; we are strictly a dermatology company focused on the professional and non-prescription therapeutic space. The amount of novelty is very wanting at these meetings. A lot of what you are seeing new is really reformulations of existing products.

There are some new compounds out there particularly for melanoma and psoriasis, but a good deal of dermatological changes that drive people to consult with a dermatologist has a lot to do with natural ageing and the associated consequences. In that area, there has not been a lot innovation. When I show up at these meetings I am referred to as "Oh, there's that woman with those wonderful safe and effective locally-acting compounds. You should talk to her."

CEO CFO: *Would you tell us about the agreement with Fission Labs?*

Dr. Schwartz: Yes, we are very excited about that. That came to us through our new Chief Business Officer, Cristina Griffin. Christina has worked in the South American and European market for the past ten plus years of her career. She is American but has lived in Europe for quite some time. Christina knew our assets very well and happened to be speaking with the Chief Scientific Officer at Fission, who said "Wow, we would love something for hair thinning and facial blemishes, but for non-prescription cosmetic use." Cristina said "Our CEO happens to be in Spain, let's see if I can make the introduction." The introduction was made, our data was reviewed and that led to the agreement with Fission. I believe their first market is going to be for oily skin and blemishes followed rapidly by a product for hair thinning. They are starting in human proof-of-concept studies very shortly, and we foresee them on the market in about a year and a half. Latin America is a very large and emerging market for skin and hair care.

CEO CFO: *Are you looking for funding, investment partnerships, as you move forward?*

Dr. Schwartz: Yes, in fact we are currently speaking with viable partners for our topical prescription treatments for androgenic alopecia and acne because those markets are quite huge and craving innovation. Unmet need is high. We are always looking for financing, like any small company, you never have enough money to do everything you want to do, so we have had to remain more focused on a couple of areas when, in fact, there are other therapeutic areas we could enter. However, we prefer smart money from those familiar with the women's health and dermatology space. This is a good time to be in business, the economy is very robust.

Any company that tells you they are not looking for partnerships or for money, probably has more money than they need and that would be rare indeed. We do have a partnership for a whole portfolio of these topical anti-aging compounds for estrogen deficient syndrome. We do have one product out on the market currently and I cannot speak to that because that would be up to another company who licensed it from us to talk to you about it. A few months ago, we entered into a term sheet with another US company based on the west coast for a whole portfolio of that same type of compound, for ageing skin. We expect them to launch globally under their own brand probably in a year and a half. We have been doing deals and we would not be doing deals if people did not find our company and our pipeline value-added.

CEO CFO: *What surprised you as the company has grown?*

Dr. Schwartz: I can tell you what has not surprised me, the appetite people have for innovative science and products that will work topically and spare the internal system from unwanted exposure. That was not a surprise to me. What surprised me was how large the appetite was for these types of products.

CEO CFO: *Why pay attention to Or-Genix? Why is Or-Genix important?*

Dr. Schwartz: This is kind of an odd way to put it but the message we have for people is that we are anti-aging engineers with topical, locally acting ingredients that safely and effectively decode dogma regarding how hormonal agonists and antagonists act pharmacologically. It was not an easy hurdle for us. We had many skeptics. Furthermore, a few years ago, we actually made it through a tough economy and stayed alive while other companies were falling by the wayside due to lack of funding. We managed to forge forward and get deals done, nonetheless. Now that the economy is robust, it still takes an ability to sustain the reputation that we are serious people with a serious pipeline of products. I can tell you one of the current partners we have said to me that he sees about thirty interesting deals a month but have not seen anything this interesting, innovative or cutting-edge in a very long time.

The other thing is that people invest in or want to do business with people they like and respect. As is the case with any small company that has a novel idea, not everybody believes the idea and you have to show them first that you offer value. One of the things that I think has impressed people who have now engaged with us is that they like us as a group. They like my resilience and my straight-forward interpersonal approach. They greatly admire my Chief Development Officer & Co-Founder, Craig Abolin, Ph.D. They admire his intellect greatly and his way of explaining how mechanistically our compounds work topically and how they fall apart and spare the system. Regarding our Chief Business Officer, Christina Griffin, they admire her upbeat attitude and her negotiation style of getting deals done. In short, you have to have a great team and you have to be dogged because there are a lot of people with ideas and not everybody who has a good idea is going to get attention. You have to be determined, resilient, relentless and undaunted to succeed.

