

The Owner and Operator of Subsidiary Businesses, Evofem LLC is in the Areas of Women's Reproductive Health, Dermatology and Pain Management, and is the Seventh Best Funded Company in America since 2009

**Healthcare
Drug Development**

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**Sean Edwards
CEO**

BIO: Mr. Edwards has more than 16 years of experience providing legal guidance to public and private companies on issues relating to corporate governance, business strategy and technology licensing. Mr. Edwards joined Evofem as Vice President and General Counsel in 2006. In addition to coordinating Evofem's global operations, Mr. Edwards is CEO of Cosmederm Bioscience, Inc., an Evofem subsidiary. Prior to joining Evofem, he was Director of West Coast Business Development for UTEK, a publicly traded company that specializes in technology licensing and transfer. He is a graduate of Princeton University where he was a recipient of the Alexander Maitland Stewart Scholarship. Mr. Edwards received his J.D. from The University of San Die-

go, School of Law. In addition to being on the Board of the San Diego Coastal Chapter of Young President's Organization (YPO), Mr. Edwards is President Emeritus and current VP of the Princeton Club of San Diego.

About

Cosmederm Bioscience, Inc.:

Headquartered in San Diego, California, Cosmederm Bioscience is a specialty pharmaceutical company focusing on the development of uniquely potent topical dermatological products based on its core knowledge in the fields of neuroscience and immunology. Our family of patented analgesic and anti-inflammatory compounds has led to the development of uniquely effective products in the area of cosmeceuticals and OTC drugs. In addition, we are developing our first and second generation compounds as drug candidates for prescription drugs in the areas of neuropathic pain, atopic dermatitis and other forms of pruritus (itching), thermal burns, ultraviolet burns and pain from viral infection (e.g. Herpes labialis, Genital Herpes and Varicella zoster (Shingles)). Our technology is currently being marketed in medical products, cosmeceuticals and OTC drugs in the U.S., and parts of Europe, Latin America, Asia, and the Middle East.

**Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFO Magazine**

CEOCFO: Mr. Edwards, what is the concept for Evofem?

Mr. Edwards: Evofem Holding Company, Evofem LLC owns and operates two subsidiary businesses.

One is Evofem Inc, which is in the area of women's reproductive health. The other is Cosmederm Bioscience Inc, which is in the area of dermatology and pain management. Both companies have an element of the business that is traditional CPG or consumer packaged goods; products that are sold and marketed in retail chains, drug stores and so on. Both companies also have an element of the business that is traditional pharma drug development.

CEOCFO: Would you tell us about the products available from each of your entities?

Mr. Edwards: In Evofem Inc, in the women's reproductive health area, we have a product called the Softcup™, which is a menstrual collection cup. It is sold in about forty five thousand stores here in the US. It has been available in the US for about a decade. The advantages of the cup are numerous over tampons and pads. The first is that you can wear it twice as long. You can wear it up to twelve hours. Therefore, it benefits women that are active; that are on the go. What we hear from our customers is that they can put it in and forget about their period. You put one in, in the morning and one in at night and you are covered. The other advantage is that when it is inserted properly you cannot feel it. Women that are big advocates of this product include athletes, marathoners and triathletes, because when they put it in they cannot feel the product. It is not like having a pad in between your legs or a tampon that can cause dryness and friction. The other advantage is that we have sold over two hundred million

Softcups now and we have never had one reported instance of toxic shock. Because it collects menses, basically sits inside, encapsulated where the cervix can collect menstrual fluid. It does not expose that menstrual fluid to oxygen. There is no risk of bacteria build up, which is the genesis of toxic shock. The other aspect of that business is a drug that is in late phase clinical development. It is a microbicidal and spermicidal gel called AMPHORA®. AMPHORA is currently in a Phase III clinical trial that is just finishing up. It will be completed in March. This clinical trial is testing only the contraceptive efficacy of AMPHORA. However, the gel was initially developed as a microbicide; meaning it would be a gel that would protect women against sexually transmitted diseases. We anticipate the continued development of the product that will allow us to make claims associated with STD prevention and protection. However, for now, the trial that we are completing will just be for contraception. We think it has an important place in the market, because there are twenty two percent of women of reproductive age that cannot be on hormonal contraceptives. Therefore, AMPHORA Gel represents a significant change in the market as a method of contraception that is non-hormonal and peri-coital, which means you only need to use it right before sex; you do not have to remember to put it in every day. It is also “woman controlled”. She does not have to go see her doctor about it and it is rapidly reversible. Therefore, when a woman chooses to become pregnant she can stop using the product and have the ability to become pregnant right away.

CEO CFO: Do many women know about the menstrual cup? Is that still kind of below the radar?

Mr. Edwards: The menstrual cup is more of a niche product as it compares to the other products in the category. Although we have been around for a decade it is still somewhat of a novelty. We have had a fair amount of marketing spend over the last several years. We have done

national print ads in women’s magazines and U.S. magazine and those types of outlets. We have a “smallish” but growing and very loyal user base. There are many women that tell us, “Since I have tried this product I will not go back.” It really represents the only novelty in feminine hygiene since the advent of the tampon, which was over seventy years ago.

CEO CFO: What is happening on the Cosmederm side?

Mr. Edwards: Cosmederm has three different business segments. The first is the legacy portion of the business, which is “cosmeceuticals”. These are physician dispensed anti-aging products. They are not prescription, but they are dispensed under the supervision of a physician. The next is a topical we just launched in the U.S. and China as a mass market OTC drug for anti-itch called TriCalm. This is available nationwide in CVS and

“Since 2009 we have received one hundred and forty five million dollars in outside institutional capital. That makes us roughly the seventh or eighth best funded company in America during that time period.”- Sean Edwards

Walgreens. We believe it is a superior option for people that are looking for solutions to treat itches. Historically, there has not been much innovation in this category. There is hydrocortisone, which has mild efficacy and takes a long time to work. There are things like Benadryl® (Diphenhydramine), which are anti-histamines, which work well in some areas of itch, but not on others. For example, Benadryl will not work on atopic dermatitis or eczema sufferers. Our product works on contact within seconds. There was an article that was recently published in one of the leading dermatology journals. It was a study that was done by one of the World’s leading itch researchers, that showed that TriCalm was significantly superior in reducing the severity of itch and the duration of itch, when compared against hydrocortisone and diphenhydramine. And that, to us, was a significant event, obviously because it shows the superiority of the product.

CEO CFO: What is the science? What happens when you are putting on the ointment? Why does it work?

Mr. Edwards: TriCalm works by targeting the nerve subset in the skin that is responsible for transmitting itching and any type of irritation; any type of burning or stinging or itching. Those are all communicated by one nerve subset in the skin called Type C fibers or nociceptors. TriCalm attaches to that nerve subset to inhibit that type of sensory irritation or itching. In the areas of our cosmeceutical product, for example, it allows us to deliver highly potent products and minimize irritation. Our products contain high concentrations of alpha-hydroxy acids (AHAs) which have shown to be very effective at reducing signs of aging. Typically, when you have high acid concentration at a low PH the product will become irritating. You add our technology to it and they become non-irritating. Therefore, you get better products, faster results and a more satisfied consumer, ultimately. The last area of the technology that we are exploring is in topical prescription drugs. We are just beginning the clinical development program for our first drug candidate and

will be beginning Phase I human trials next month. We are looking at targeting things like neuropathic pain; for example, diabetic neuropathy. We are also looking at targeting the pain and pruritis that is suffered by cancer patients that are undergoing radiation therapy. We think these areas are applications of our technology for which they are very well suited.

CEO CFO: Have your choices been opportunistic, as far as what products you are working on or is there a master plan of how, what, where and why?

Mr. Edwards: As it relates to how we came to own these two businesses and in disparate fields; one is in women’s health and the other is dermatology, yes. It is very much opportunistic. What we are looking for are products that represent an innovation in their category; better products to meet solutions that are currently not being met for the

consumer; whether it be for feminine hygiene or for itching and pain related episodes. Therefore, from that standpoint we are opportunistic. A recent alliance is more strategic. We were able to join forces, through a Strategic Alliance, with a non-profit called WomenCare Global. WomenCare Global has a unique model for a non profit in that they are sustainable. They have distribution in one hundred and eleven countries. They distribute products related to women's reproductive health and contraception and are helping in the distribution of our Softcup product. The reason why the alliance with them is important is because we see AMPHORA as a game changer; especially in its ability to potentially protect women against different STDs, including HIV. As a mission of our company we very much want to make sure that this product is available to women in the developing areas that need it most. By joining forces with WomenCare Global we can insure that happens through their distribution network. As I mentioned, they have this hybrid model where they sell these products in the developed world at a profit and then use that profit to sell the same products in the developing world at a loss. Therefore, their profit making activities subsidizes their philanthropic activities in underserved areas with limited access to healthcare.

CEO CFO: How do you get the public to believe the superiority of TriCalm; so many products make inflated claims?

Mr. Edwards: That is a great question. One comment, with respect to the recent published paper; most studies that are referenced in advertising are internal studies done by the company. Oftentimes they are consumer preference studies. We survey ten consumers and six of the ten say they like our product better. Those are not really compelling to the eyes of the consumer. The study that was done on our product was done by an outside entity with which we have no connection. It was done by one of the leading itch researchers in the world, a gentleman by the name of Dr. Gil Yosipovitch. He found that our

product was simply more effective than the other available OTC products. Therefore, it is our job to make sure that that message is communicated to the public. In addition what we urge people to do is just try it. We are sampling the product heavily through physicians, through pharmacists and also through the national parks service this summer. We firmly believe, without hyperbole, that if you try our product you will not buy another anti-itch product, because it just performs that much better.

CEO CFO: How do you reach potential customers?

Mr. Edwards: Currently, we have a national TV ad campaign that we are undertaking. We are spending millions of dollars in media on national TV ads. We have done national print ads. We are doing, again, this nationwide sampling program, reaching out to possibly over fifteen thousand physicians that run across specialties from dermatologists to pediatricians to allergists and immunologists. We are also reaching out to five thousand pharmacists and giving those professionals the education that they need on our product and the science behind our product that would allow them to recommend it in good conscience to their patients or consumers.

CEO CFO: How is business?

Mr. Edwards: Business is good! We just launched the TriCalm product earlier this year in March. Therefore, as with any new product, especially one that is going up against the big boys in the industry, we have our work cut out for us. However, we are very optimistic and the reception of the product, so far, has just been phenomenal. The feedback that we get from our consumers on a daily basis is, "Thank you, thank you, thank you! I have been suffering from 'you name it' condition for years and have not found anything that relieves the itching and your product worked! Thank you for this product!" That is really gratifying.

CEO CFO: As CEO, how do you stay focused when you have several irons in the fire? What is the key to running

a successful company with a broad reach?

Mr. Edwards: That is an excellent question! I think that from a very fundamental standpoint, you look at the different segments of the business and you look at what the market opportunity is for each of those segments. You make sure that you are spending your time on those aspects of the business that hold the biggest value. For us, our drug development activity is really important. We think that having a topical product that is safe and effective at treating different types of neuropathic conditions represents a really valuable opportunity. We think, likewise, that there is a very big opportunity in the OTC anti-itch space in the US, which is a close to four hundred million dollar a year industry. Also, it not just me doing all of this; we have a CEO of Evofem Inc., Sandra Pelletier, that is handling the day to day operations of that business. If you hire good people then you can execute on your vision.

CEO CFO: Why should investors and people in the business community pay attention to Evofem? What sets Evofem apart?

Mr. Edwards: I think we have flown under the radar a bit over the last few years. Since 2009 we have received one hundred and forty five million dollars in outside institutional capital. I think that makes us roughly the seventh or eighth best funded company in America during that time period; therefore I think there is a lot of belief from our investors, our shareholders and our board members. The promise of the technologies that we have is not just that they are novel, but also their efficacy has either been proven superior or, we expect, will be proven superior. The markets that our technologies are addressing are huge and are currently underserved by existing drugs. That is what excites us coming to work every day. That is what excites our investors and shareholders. I would think that that is why you should pay attention to us. You are going to hear some big things from us in the coming months as we finish our Phase III trial of AMPHORA and continue to grow the Cosmederm business.



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