

Ophthalmic Devices and Therapeutics for Commercial and Business Lines

Healthcare

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Michael A Ross
CEO

BIO: MICHAEL A ROSS, MD— As skilled physician with both clinical and pharmaceutical industry experience, Michael Ross brings over 30 years of extensive experience in clinical practice, regulatory and FDA approvals, research, business development, M&A and JV activities and numerous university appointments. He is currently President and Chief Operating Officer of Euclid Systems, an ophthalmic biotech in Virginia. Prior to this he has been the President of E-P Therapeutics, a pre clinical oncology company; President CPL Inc., the North American division of Cadila Pharmaceutical Ltd. As President of CPL Inc., Michael was in charge of all aspects of North American operations and has been the force and face of all new products, joint ventures and research. Dr. Ross

practiced in the DC area for 27 years before entering industry. He served as an elected member of the INOVA Executive Committee from 2003 -2007. He serves on the CDC committee for prevention of breast and cervical cancer and was elected to the board of the Generic Pharmaceutical Association. He is board certified by the American Board of Obstetrics and Gynecology, and currently holds 3 professorships in OB-GYN and Pediatrics, and sits on the boards and advisory boards of multiple healthcare companies.

About Euclid Systems Corporation

Euclid, founded in 1995, first developed and brought to market a standardized Ortho-K lens design and manufacturing process. Euclid was the first company to apply for FDA approval, and the Emerald lens was approved by the FDA in 2004. The Emerald lens has obtained regulatory approval from the appropriate governing bodies in multiple international markets.

Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFO Magazine

CEOCFO: Dr. Ross, would you tell us about Euclid Systems Corporation? What is the concept behind the company?

Dr. Ross: Euclid is an ophthalmic device and therapeutic company. There are currently three business lines in the company. One of them is commercial and two of them are not. The commercial line is a very special type of contact lens called an Ortho-K or orthokeratology lens. This is a lens that is worn at night. It reshapes the cornea. It is not worn during the day and you see perfectly. However, seeing

perfectly is only the side effect. The main purpose of the device is to control the progression of the myopia. Therefore, our primary target is children. If you were a child that needed glasses you started wearing them around the age of six, eight or ten years old. Then every year you end up changing your glasses because your eyes get worse. This particular product stops the progression. Therefore, we like to get kids when they are young, so that if they are a small myope they will never become a high myope. In addition to which, obviously, they do not wear glasses, they do not wear contacts during the pollen season; they only wear them at night. There are two other business lowlines, one of which is a drug delivery system. It is a drug delivery platform. The current research is focused on treatment of glaucoma. Glaucoma is a very, very common cause of blindness. The problem with glaucoma is not the medicine. It is that patients may not take their medicines or more commonly, since many of the patients are elderly, they do not put them in frequently enough or they do not put them in properly in their eyes. Therefore, we have developed a drug delivery system that can be inserted into the lining of the eye and deliver glaucoma medications for six months consistently. That is one and that is preclinical at this point. The other product line is more exciting, which is a biological galacorin. Its properties are to stabilize and strengthen collagen. There is lots of collagen in the eye, including the cornea which is made up of layers like saran wrap of collagen. This molecule can be applied topically to the eye and it has a number of indications. The one that we are working on first is a disease called Keratoconus. That is

a disease of the weakening of the cornea, where you get a bulging in the cornea. The best way that I can compare it is if you have every run your tire into the side of a curb, then you come down the next morning and notice that there is a big bulge on the side of your tire. This bulge is a weakness and that is what happens in the eye. The only permanent treatment for that is corneal transplant.

CEO CFO: Would you please explain how you reshape a cornea?

Dr. Ross: The contact lens is a Gas permeable contact lens. It does two things. It puts pressure on the eyes to flatten the cornea if you are myopic. However, it also has some very special effects by having multiple zones of focus. The medical term is "we have midperiphery defocusing". We believe that is the cause of myopia getting worse. Therefore, the eye basically grows in the proper manner and does not elongate. With people that have myopia the tendency for the eye to elongate from the front of your eye to the back of your eye. That particular process is what causes the long term complications of being near sighted, which are glaucoma, cataracts and retinal tears and blindness. Therefore, the contact lens; by using this special defocus and by pressing on the right places on the cornea, stops this elongation of the eye, as well as making you see normally.

CEO CFO: Are children able to tolerate it well?

Dr. Ross: With no question! Parents always underestimate their kids. Probably the best thing that I have seen was; there has been a big push lately about these tamper proof bottles for kids and they recently did a study with a bunch of tamper proof bottles and a group of three to seven year olds. Most of them opened the bottles in under thirty seconds. You may think that kids have trouble, but we six year old kids in the contact lenses and they have no trouble whatsoever. It is not an issue. They clean them

and they take them out. It is not a problem.

CEO CFO: Are these customized to an eye? Are there a variety of shapes and a variety of types?

Dr. Ross: Absolutely. Each of our lenses is customized for each eye.

CEO CFO: What is the population that is using them now? Who should be and how do you go from one to the other?

Dr. Ross: Our primary target is children under twelve years of age. That is because, within reason, we can make anyone see normally during the day. However, the real therapeutic point is to stop the nearsightedness from getting worse. We want to catch them when they are kids.

CEO CFO: What is the population of kids in the US that could be helped?

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How do you find them? How do they find you?

Dr. Ross: They primarily find us through their optometrist. However, we only sell ten percent of our product in the US. We actually sell twelve percent by dollars. However, ninety percent of our product is sold ex-US and our largest market is actually China.

CEO CFO: Is this a well known product to all optometrists and ophthalmologists?

Dr. Ross: It has been around for a long time, but expertise is not in all hands. The actual process dates back to the late 1970s and early 1980s. However, it has hit a number of speed bumps. Obviously, Lasik or laser refractive treatment has spent tons of money in advertising and no one really cared about using non surgical ways of treating your eyes. Therefore, it slowly caught on. It is interesting

that in South East Asia the knowledge base of our product is much greater than it is in the US. It has just spread primarily by word of mouth there. Our market in China is currently growing. This year it will a one hundred percent increase over last year. Currently in the US and China the market for laser surgery is decreasing. In the US and in South East Asia laser procedures are decreasing. One of the beauties of our product is that one of our products that is in development is using the biologic that I told you about in combination with the lens and you get a permanent or near permanent non surgical vision correction. We have to patients in Mexico in our early pilot study that had our corneal reshaping lenses for three months. They then had these drops of the fixative placed in the cornea. They wear their contact lenses for another month and then they throw them out and they have perfect vision. They have not used anything for five years now. Therefore, the end play is to get kids in these lenses when they are young and let their eyes grow; kids' eyes continue to grow until they are eighteen. Then offer them surgical if they want it, but also offer them a non surgical eye correction.

CEO CFO: Are there other companies? Are there competing products?

Dr. Ross: There are. In the US market there is probably one other competing product with a company called Paragon. In South East Asia there are a number of competitors, but we are the only product in the marketplace that is manufactured in the US and has both US and Chinese FDA approval. South East Asia being what it is, the products on the market are not very competitive. However, we are currently known as the premiere OrthoK brand in China and in Taiwan. We are opening up some other markets in South East Asia. We sell product in Japan, Korea, Australia, New Zealand, Russia, Kazakhstan, and the UK. However, the premier product in this market is the Euclid product. The only major competitor that we have is a Japanese company

called Alpha. Certainly, in South East Asia there is still a lot of post war overlay and the Chinese do not like to buy Japanese. However, there is a strong desire to buy US made devices and pharmaceuticals. They just do not trust products that are manufactured in China.

CEO CFO: Do you sell either with partners or distributors in the other countries?

Dr. Ross: That is an interesting question. Currently, like many other pharma companies, we sell through distributors. One of the reasons is that you become “arms length” from the person dealing with the hospital. Foreign Corrupt Practices and Foreign Corrupt Practice Act violations are a big deal. Therefore, you want to be away from the end user. Therefore, we currently sell through distributors. That being said, one of the reasons that we could not talk this afternoon was because I was on the phone with London much of the day. We are going to be opening our own retail centers in China, so that we can directly sell our lenses, with the proper conditions and everything, in vision care centers in China. The way to look at it as I explain it to people would be this. Under Armour made a great product, but when we started out Under Armour sold to Dicks Sporting Goods and similar places. They obviously made a profit on the shirts, but who made the largest profit on the shirt; Dicks Sporting Goods. They may have bought the shirts for five dollars from Under Armour and they sold it for forty dollars in the store. The same thing happens with our lenses, almost in the same ratio. Our distributor and the doctors that fit them make the vast majority of the profit on our products. We want to be able to participate in that end user and also control our brand. Therefore, just like Under Armour started opening retail stores, we are opening retail stores. However, they are not stores; they are vision care centers. They will exclusively sell our lenses. We have a partner that I cannot tell you about. We have a Chinese partner that was bought by a very large multinational company and they decided that they want us to be their partner in China.

We are really excited about it. We hope that by the beginning of the year we will open our first clinic in the first quarter of 2014.

CEO CFO: Are these permanent lenses or do they need to be changed?

Dr. Ross: They are worn at night and then they take them out during the day. The ratio is about two to one. Therefore, for every hour that you wear the lenses at night you get two hours during the day of normal vision.

CEO CFO: As a child grows do they need a different size lens?

Dr. Ross: Usually not; for the reason I told you. Occasionally they change. However, most of the time they change lenses just because their old lens has gotten crummy and they get the same one. That is because, the beauty of the product is it controls the near sightedness and it controls the shape of the eye. Therefore, most people wear the same size for long periods of time. We recommend they change it out every other year, but many even wear them for longer. We do not currently seek to get reimbursed for it. It is normally a “patient pay” item. We want to stay as far away from reimbursement as we can. Actually, many optometrists look at this as a way of getting away from the “cut throat” markets for contacts and other things; the soft contacts that they are dealing with and contracts with insurance companies. That is because this is a “fee for service” business for them.

CEO CFO: Would you tell us a little more about the topical product that you are working on?

Dr. Ross: The topical product is a natural product called Decorin. We have biologically engineered it to create the core protein. We have the only manufactured product in the world and worldwide rights to all applications to the eye. The applications are anything where collagen needs to be strengthened in the eye so Keratoconus is the target of our first Clinical Trial. We will also be using it in combination with our lenses. It can also be used either pre or post laser corrected vision to strengthen the eye. That is because all laser procedures weaken

the cornea. It can also be used in some applications to treat glaucoma. We also believe that it has applications in treating wet and dry AMD. Therefore, it is an interesting product. However, as you know, developing biologics is very expensive. We have our first clinical trial on the product. It should be starting at the beginning of next year.

CEO CFO: How is business these days?

Dr. Ross: Business is growing like crazy! We have changed our model for sales in China. We are signing up larger distributors. As I said we expect our sales to come close to doubling in South East Asia this year. The rest of our markets where we do business, like the US and Japan, are growing about twenty percent year over year.

CEO CFO: How do you control all the rapid growth that is coming?

Dr. Ross: We can easily keep up with demands. We expand our production locally. We are lucky in that our production is extremely scalable. We have very, very high speed, exact lathes that cut the lenses. It is extremely easy to put new rates in production if you have the floor space and we just expanded our base of operations here. In terms of delivery, we are thinking about ways of cutting down the delivery time substantially to Asia. Even though I told you that our lenses are custom, they are custom to a grade. There are about four hundred and sixty various combinations. Like anything else there is a bell shaped curve, particularly in a particular ethnic group. Therefore, we are definitely putting in a forward dispensing inventory someplace in South East Asia, most likely in cooperation with UPS or FEDEX, who have these type of facilities in place and it is easier to use than to develop our own. We are also enlarging our marketing and sales team in China. We are also moving away from many smaller distributors in China, who do not do much business. We are moving towards provincial distributors, which is much easier for us to deal with. Therefore, instead of having one hundred and fifty “cats to herd”, you have twenty of fifty “cats to herd”. By and large, the “bigger cats” are much

more professional and easier to deal with.

CEO CFO: Why should Euclid Systems Corporation stand out for investors and people in the business community?

Dr. Ross: A few reasons. Number one, we are a rapidly growing company. We have excellent technology in our pipeline, including some other types of lenses. We have decided that, like Willie Sutton used to say, "When you rob banks you go where the money is." The disease is much more prevalent in South East Asia than in the US; about double. Most of the data now shows that ninety percent of college students in China are currently myopic.

Therefore, the market is huge. Plus there are things that Chinese families will spend money on out of their pocket and since most families have one child that means that they have six parents to take care of them; one mother, one father and four grandparents. Therefore, the two things that they will spend out of their pocket for in the healthcare arena are, believe it or not, dental care and eye care. Everything else goes to education. Therefore, the market is right. There is a lot of disease there. Our brand reputation is huge. The deals that we are signing for these clinic operations are with some very, very well known folks. Therefore, we

are just rapidly growing. We have just reached that inflection point where we can do some clinical research on our biologic. Our drug delivery system is now in trials. It is a fun point. The product is made in the US. Therefore, we export it. It is just a very exciting time for the business. The State of Virginia loves us! We export and we manufacture in the country. If you look at what everyone is complaining about it is people that are selling products but manufacturing in China. We do no manufacturing in China. Our sales pitch is "We are manufactured in the US" and they love our product.

