

THE WALL STREET TRANSCRIPT

Questioning Market Leaders For Long Term Investors

Cytomedix, Inc. (GTF)



MARTIN ROSENDALE was appointed Chief Executive Officer of Cytomedix, Inc., effective July 1, 2008, after having joined the company as Chief Operating Officer in March 2008. He has more than 24 years of experience in specialty medical markets, utilizing his background in science, health care and engineering. Prior to joining Cytomedix, Mr. Rosendale was Chief Executive Officer of Core Dynamics, Inc., where he managed a research and development program based in Israel, and initiated US commercial operations for the company's cryobiology and cell lyophilization technologies. In this role, he established a relationship with the U.S. Department of Defense, managed multiple strategic collaborations and facilitated the sourcing of product ingredients from China. In addition, he has held leadership positions in multiple companies: ZLB Bioplasma, Inc., where, as General Manager, he led the company from early launch phase in 2001 to establishment as a market leader by 2004; North American Vaccine Inc., where he directed North American sales and played a vital role in international marketing efforts; Senior Vice President of Sales and Pharmacy Services for SangStat, Inc., where he facilitated the successful launch of two novel drugs for solid organ transplant. He also spent 10 years at the American Red Cross, where he was appointed National Sales Director and successfully launched numerous bio-pharmaceutical products. Mr. Rosendale has served on the Boards of the Transplant Recipients International Organization and the American Red Cross Biomedical Services, San Jose Region. He has also published articles in *Selling Power*, *Journal of Corporate Management* and *Journal of the American Society for Microbiology*.

TWST: May we start with a short history and overview of Cytomedix?

Mr. Rosendale: Cytomedix is a biotechnology company based in Rockville, Maryland. Our focus is in the area of advanced tissue regeneration technologies and related products. Our first product is the AutoloGel™ System, which received market clearance by the FDA in September 2007.

We launched our product in January 2008. The launch is a deliberate and strategic program. As part of our marketing strategy,

we have identified specific territories with large markets in wound care. We have recruited sales managers who have a very entrepreneurial spirit. These sales managers have the skills to grow with the company and manage other salespeople in the future, but also have the desire, willingness and passion necessary to be our frontline today while we are building the company and the organization.

The AutoloGel System is a point-of-care system for the management of chronic wounds. We start with a sample of the patient's own blood. From that blood, we separate the plasma and

platelets to create a formulation that is used to manage the patient's wounds. This formulation contains the proteins and key growth factors from the plasma and platelets that are necessary to facilitate wound healing. In addition to the AutoloGel System, we anticipate that there are future product offerings in related areas, such as hair growth and hair transplantation. In hair transplantation, hair follicles are extracted from one location and transplanted to another. Wounds are created at the donor sites and around the transplanted follicles. The enriched environment provided by AutoloGel may assist the survival of follicles and the management of the wounds. I anticipate that there will be opportunities to incorporate the AutoloGel System in other regenerative medicine procedures, such as stem cell and biomaterial transplants.

Beyond our work in chronic wounds, we have identified compounds with related properties such as angiogenesis, the production of blood vessels, and anti-inflammatory properties. We recently announced that we are developing a peptide, CT-112, which is an

and other wounds that can be difficult to heal. Some of the patients who we have worked with have had wounds for two, three, even five years without healing.

The AutoloGel process, or the science behind it, begins by extracting the plasma and platelets and then activating those platelets. The system creates a cocktail, if you will, of the necessary proteins and growth factors that are required to facilitate healing. By managing the wound with the AutoloGel System, we are able to facilitate wound closure utilizing the patient's own blood.

TWST: What is the extent of the indication for which the FDA has granted you approval?

Mr. Rosendale: We actually have a very broad indication for the safe and rapid application of AutoloGel or platelet-rich plasma to the wound. It covers a broad variety of wounds including exuding wounds such as diabetic foot ulcers, venous ulcers, and surgically or mechanically debrided wounds. Most chronic wounds fall within the scope of the indications for use.

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anti-inflammatory peptide that may be active for the treatment of inflammatory diseases such as rheumatoid arthritis, Crohn's disease, tissue reperfusion injury and other related medical conditions. We also have other therapeutic products in our pipeline.

TWST: Would you explain the science behind the AutoloGel process?

Mr. Rosendale: Basically, the AutoloGel system takes advantage of the patient's own biological systems for healing. In the healing process, there are a number of complex processes that are necessary to facilitate complete healing of a wound. In the case of the AutoloGel System, we are talking specifically about chronic or hard-to-heal wounds, such as diabetic foot ulcers, venous pressure ulcers,

TWST: What is your strategy to gain market traction, and what is the size that you are looking at?

Mr. Rosendale: In the US, we estimate the overall market for wound care to be approximately \$2.2 billion. As I mentioned earlier, our launch of this product is a very strategic and deliberate rollout. Our initial focus is in the areas where we believe early acceptance is likely. We have focused on long-term acute care hospitals, the U.S. Department of Veterans Affairs, and public health services groups like the Indian Health Services. These are mostly in-patient situations where cost benefits are pronounced. We estimate that this subset of the overall chronic wound care market represents about \$500 million of that \$2.2 billion market.

TWST: When do you expect to get the third-party reimbursement clearance from the CMS?

Mr. Rosendale: In 1992, CMS issued a non-coverage determination for platelet-rich plasma products used to treat wounds in the way that we are using the AutoloGel System. We asked CMS to reconsider that decision based on our clinical data. We were disappointed with their decision to uphold the original 1992 non-coverage determination. However, we have continued our dialogue with CMS, and we are encouraged by their apparent interest and desire to keep the dialogue open. CMS has requested more clinical data supporting our original clinical trial. We will continue to work with them, provide the necessary data and strive to reverse the non-coverage determination. Medicare beneficiaries represent a moderate portion of the overall market. I understand it is about 25% of the total wound care market, possibly more in out-patient environments. There is a large market without Medicare reimbursement. We have already seen success with Medicaid in a couple of states across the country. We have had some success with other third-party payers, and we continue to approach and work with those payer organizations to facilitate payment for the AutoloGel System. I anticipate that we will continue to get reimbursement outside of Medicare and, at the same time, we will be collecting the data and the information intended to convince CMS to reverse its non-coverage determination.

TWST: Would you comment on your agreements with other pharmaceutical companies and the prospects there?

Mr. Rosendale: There are a number of companies that use platelet-rich plasma and platelet products for the benefit of the growth factors that are derived from those platelets. Some large orthopedic and cardiovascular companies are using platelet-rich plasma or selling products that produce platelet-rich plasma. We have licensed those companies based upon our patent, which covers the use of platelet releasates or platelet proteins for these purposes. Those licensing revenues will continue through November 2009.

In a randomized controlled clinical trial on diabetic foot ulcers, our proprietary formulation demonstrated complete wound closure in approximately 81% percent of the majority of wounds treated, versus 42% in the control group. An 81% wound closure rate stands out in the published literature. This formulation is protected by other patents that we have elected to keep proprietary to strengthen our market position

TWST: Have all the issues that were pending because of patent litigation been settled?

Mr. Rosendale: Yes. Of course, you never know when another company or individual may want to get into the field, but currently the issues are settled, and we are receiving royalty payments for each of those cases.

TWST: Would you comment further on the pipeline of opportunities you outlined earlier for the concept that you use in AutoloGel?

Mr. Rosendale: One of the things that attracted me to Cytomedix in the first place was the AutoloGel System and the technology behind it. Having spent 25 years in biologics, I'm very familiar with the complexity of living systems. The AutoloGel System applies the benefit of multiple proteins and multiple growth factors to facilitate healing and tissue regeneration. There are a number of other potential future applications that will benefit from this technology. As I have mentioned, we already have patents in the area of hair growth and hair transplantation.

We are also considering strategic collaborations with companies developing other biological products that may benefit from a delivery system that incorporates the proteins and growth factors found in AutoloGel, or possibly a storage system for a biological product that would benefit from these proteins and these growth factors. To be more specific, stem cells and other soft tissue biologics may benefit from the proteins that are found in AutoloGel

TWST: What is the competition to AutoloGel in the wound care market, and how do you compare your pricing?

Mr. Rosendale: It is a relatively crowded market. There are a number of companies producing devices, therapeutics or other products for wound care. Companies have come and gone. The dynamic nature of the market, and the fact that it is so crowded is an indication to me that it is a market with a significant unmet medical need.

The market is segmented into low cost devices that manage the wound environment passively by absorbing exudate, maintaining a moist environment and keeping the wound clean and covered. The tremendous growth area is in active technologies that physiologically change the wound environment to trigger a biologic response. While these products tend to be more expensive and more controversial, they represent the category the AutoloGel System competes in. As far as delivery of growth factors, there is nothing else that offers the full complement.

As I mentioned, many of these patients have wounds that do not heal for months or years. Unfortunately, some even require limb amputations to avoid loss of life. Such a large unmet need has attracted many market entries.

Some companies have entered the market and failed. Others have thrived. Overall, it has created a marketplace that is somewhat skeptical, which creates both a challenge and an opportunity for us. The challenge is to overcome that skepticism through the presentation of good solid data. I believe the opportunity is to set the standard for the quality of clinical data and its presentation.

TWST: What is the cost comparison between your treatment and that of the competition?

Mr. Rosendale: After we completed our clinical trial for our FDA clearance, we commissioned an economic analysis from a consulting group out of Washington, DC, that has a very robust computer model for pharmacoeconomics. They started with our clinical data from the diabetic foot ulcer trial and collected published literature from competing products, other devices and therapeutics for wound care, that had completed similar studies in the area of diabetic foot ulcers. They used the data to perform a five-year economic analysis and comparison.

The economic analysis determined the AutoloGel System results in lower costs over five years as compared to other therapies, and the benefits of the AutoloGel System dominated other therapies when considering quality adjusted life years, a measure of utility. We believe we are in a very good position with the benefits of the AutoloGel System.

TWST: Is Cytomedix pursuing strategic partnerships and collaborations with other pharmaceutical companies?

Mr. Rosendale: If you look at my history, you will see that I've always believed strategic collaborations are important, and they are particularly important to smaller companies like Cytomedix. So the simple answer to your question is, yes, we are pursuing strategic collaborations. We have some very strong intellectual property, not only for AutoloGel and the formulations we are using, but, as I mentioned before, we have opportunities with some therapeutic products, some peptides for anti-inflammatory applications, as well as angiogenesis. So it just makes sense for us to pursue strategic collaborations.

TWST: Would you comment on your own history and the management team that supports you?

Mr. Rosendale: I have more than 24 years of experience in biologics, mostly in the area of plasma biologics, plasma proteins for

the treatment of hemophilia or immune deficiency, and other immunology related products. I spent 10 years with the American Red Cross, where I first entered this marketplace and learned most of what I know about blood and plasma products. Prior to joining Cytomedix, I was the CEO for a company called Core Dynamics. We were focused on the cryopreservation and lyophilization of biological products. Our research and development facility was just outside of Tel Aviv, Israel. I built the commercial structure for the organization here in the US.

Prior to that, I was the General Manager for ZLB Bioplasma, another biologic therapeutics company located in Glendale, California. We opened ZLB Bioplasma in 2001, and by 2004 we had taken 20% of the market in the US. We achieved \$175 million per year in revenues, and the company was merged with Aventis Behring. It is now known in the U.S. as CSL Behring.

We have a very strong management team and Board of Directors at Cytomedix. We have focused on bringing people into the organization who have strong experience in their particular field of expertise, whether it is sales and marketing, clinical services or finance, and also have significant experience in either wound care, biotechnology or related fields. As a result, we have a very effective management team. The team provides access to a robust network of industry contacts. David Hotchkiss, our Vice President of Sales and Marketing, has more than 20 years' experience in sales and marketing. Much of that experience is in the fields of wound care and biological products.

Carelyn Fyelling, our Vice President of Professional Services, is a registered nurse and certified wound care nurse. Carelyn has been involved with this product and products like it for many years. She is a tremendous asset to us in the field. Our Chief Financial Officer is Andrew Maslan. Cytomedix is a publicly traded company listed on the American Stock Exchange. Andrew handles all of our finance, corporate governance, Sarbanes-Oxley and SEC reporting requirements, allowing me to stay focused on strategic collaborations, business development opportunities, and moving the company forward commercially. We have a very strong management team and a strong Board as well. Our Board consists of industry professionals with broad executive experience, providing us a strategic advantage

TWST: Would you outline your priorities for the next 12 to 24 months and your strategy on how to capitalize on the opportunities that you presented earlier?

Mr. Rosendale: My highest priority is the sales of the AutoloGel System. As I mentioned earlier, we launched that product in January of this year. The single most important milestone that investors and others will be monitoring is the sales of the AutoloGel System. So my priority, working with David Hotchkiss, is to initiate commercial contracts, facilitate payment and reimbursement opportunities, and move the sales of the AutoloGel System forward.

Beyond that, the CT-112 anti-inflammatory peptide is another priority for the company. We have entered into a consulting agreement with a leading biochemist who is reconstructing the history of the product for us and helping to determine the development and regulatory strategies. With a number of potential applications, CT-112 provides an opportunity here not only for strategic collaboration but also to develop products ourselves. We have also retained the services of one of the original inventors of the CT-112 peptide who is assisting us with this effort.

immediate goals. As we look to enter into strategic collaborations, we will have opportunities to bring in capital from other sources through those collaborations. One of my responsibilities as CEO is to find available capital and insure good cash flow going forward. We constantly analyze the cost of capital versus the benefit of accelerating the achievement of strategic milestones.

TWST: What should shareholders look for in terms of the strategic change of Cytomedix?

Mr. Rosendale: The biggest difference will be the commercial focus. In the past, the company has done a fantastic job meeting the regulatory requirements, getting the product cleared by the FDA and making sure that we have a sound product to bring to market. Now it is time to focus on the commercial development. Investors and others should be looking for commercial accomplishments, modest sales growth for the AutoloGel System and the strategic collaborations that we have been discussing during this interview.

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While the highest priority is advancing sales of the AutoloGel System, we will continue to focus on the further development of the CT-112 peptide and other strategic opportunities in areas such as hair growth and hair transplantation, and additional applications of the AutoloGel System. For more information about our progress in these areas, readers can look to our public reports, press releases and announcements.

TWST: How does the balance sheet look to you in terms of accomplishing your goals?

Mr. Rosendale: Financially, the company is in a solid financial position with adequate cash on hand for the next 12 months and a debt-free balance sheet. I invite investors and others reading this article to read our 10-Q and 10-K filings to see our financials and review our commercial strategy. From the perspective of resources to move forward, I believe we are in a good position to accomplish our

TWST: In your communications with your shareholders and the financial markets, what are some of the most common misperceptions you feel about your company?

Mr. Rosendale: The biggest misperception that I have seen out there is the belief that we are a company with one product. If I can get one message out to shareholders and potential shareholders right now, it is that we have a good pipeline. As I mentioned earlier, we have the AutoloGel System, for which there are numerous applications, as well as other important peptides in development. The fact is, we have a pretty solid and sound product pipeline.

There is another common misperception out there with respect to CMS. The AutoloGel System is not currently reimbursed by Medicare. The misperception here is that Medicare means everything for the company. That is not the case. Medicare represents

a sizable portion of the market, but there is a large market beyond Medicare. So while we intend to facilitate a reversal of the non-coverage determination, there is enough room in the market for us to succeed in the meantime.

TWST: Does Cytomedix have analysts following on Wall Street?

Mr. Rosendale: Not really. We have spoken to analysts and some have shown interest. However, no analysts are specifically following us at the moment. That may change as we demonstrate success.

be a result of an intense focus on therapies with sound pharmacoeconomic benefits

TWST: Do you have any final thoughts?

Mr. Rosendale: Only that the management team, shareholders and I remain very optimistic about the AutoloGel System and the products that we are bringing to the market. One of the questions that I am asked often is, why I joined the company. My reasons for joining are based on my experience in biologics and understanding of the therapeutic potential of these products. Our healthcare system is evolving. Some of the newest and best prod-

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TWST: How do you communicate and address these issues with your shareholders?

Mr. Rosendale: Our shareholders have been loyal supporters of us and the patients we serve. It is important to me to be very open with my communication and communicate frequently. I issued a shareholder letter recently, and will continue to issue similar communications in the future. As we make progress with our commercial strategy, conference calls and press releases will be important as well. I plan to maintain these lines of communication. In addition, we are working with an outside investor relations firm based in New York, which is assisting us in this area.

TWST: Would you sketch a long-term vision for Cytomedix?

Mr. Rosendale: My long-term vision is to achieve a leadership position in the field of advanced tissue regeneration technologies. Cytomedix will continue to develop and market products that support the needs of patients with debilitating and life-threatening conditions. Our clinical success will result from the logical application of sophisticated biological therapies to treat complex clinical problems, and our commercial success will

ucts that will be coming to market will be biological products. Some will be stem cells and cellular therapy products, and others will be more complex tissues, possibly even engineered organs. We fit well into that future.

TWST: Thank you.

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SAFE HARBOR STATEMENT

This interview contains forward-looking statements that are intended to fall within the safe harbor rule for such statements under the Private Securities Litigation Reform Act of 1995. The information contained in the forward-looking statements is inherently uncertain and Cytomedix's actual results may differ materially due to a number of factors, many of which are beyond its ability to predict or control, including among others, market opportunities available to the Company, its operating and financial goals for fiscal year 2008, its ability to grow its sales, its ability to access all payment pathways including Medicare reimbursement, its positioning going forward, the outcome of development or regulatory review of CT-112, commercial success or acceptance by the medical community, and competitive responses. CT-112 was introduced as a therapeutic candidate with an FDA Pre-IND meeting in 1995. It is uncertain whether the Company will obtain the funds necessary for development, or whether current market conditions will support a renewed effort to develop CT-112. These forward looking statements are subject to known and unknown risks and uncertainties that could cause actual events to differ from the forward-looking statements. More information about some of these risks and uncertainties may be found in the "Risk Factors" section of the Company's public reports filed with the Securities and Exchange Commission. Except as is expressly required by the federal securities laws, Cytomedix undertakes no obligation to update or revise any forward-looking statements, whether as a result of new information, changed circumstances or future events or for any other reason.