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Questioning Market Leaders For Long Term Investors

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COMPANY INTERVIEW

JAMES R. MUSICK

Vitro Diagnostics, Inc.

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Vitro Diagnostics, Inc. (VODG)



JAMES R. MUSICK, President, Chief Executive Officer, Chairman of the Board of Directors and Principal Financial Officer of Vitro Diagnostics, Inc., earned a PhD degree in Biological Sciences with a specialty in Neuroscience from Northwestern University. He joined Vitro in 1988 and directed all operations involved in the establishment of a diagnostic product line targeting a niche market. He was also responsible for the development and initial commercialization of the fertility drug VITROPIN™ as well as the cell immortalization program of the company. He is an inventor or co-inventor of all issued and pending patents owned by the company. In 2000, he orchestrated the sale of the diagnostic operating division to Aspen Biopharma, Inc., allowing the company to focus on development of its core technology of cell line generation while establishing and commercializing the initial cell line products for research applications.

SECTOR – BIOTECHNOLOGY

(AJY609) TWST: May we start with a short history and overview of your operations?

Mr. Musick: Vitro Diagnostics operates under the name, Vitro BioPharma. We are a biotech firm committed to “Harnessing the Power of Cells.”

Our current focus is the development and commercialization of stem cell technology for use in diabetes research and treatment. We have generated over 30 different adult human pancreatic stem cell lines based on our prior research and development activities. We previously developed cellular immortalization technology, which is also a property of stem cells.

Our technology is exclusively focused on adult stem cell lines and we’re not involved with embryonic stem cells. Our business plan includes an initiative to commercialize products for use in drug development and diabetes drug discovery where we identified a niche market.

We’re also interested in developing and commercializing products to treat animal diabetes and as a longer-term goal, we’re interested in developing and commercializing and gaining regulatory approval of stem cell-based treatment of human diabetes.

Our company’s technology represents a platform with broad applications to several medical markets. However, our present focus is on targeting a niche market within pharmaceutical drug development that does not require FDA pre-market approval. Our financial projections show some additional losses prior to turnaround to profitability within the second year of product launch.

TWST: What is the main difference between adult stem lines and embryonic as they pertain to what you are doing?

Mr. Musick: Basically, embryonic stem cells are derived from embryos, whereas adult stem cells are derived from non-embryonic tissues.

Our stem cell lines are derived from pancreatic tissues themselves.

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TWST: What are the main advantages and disadvantages that you see?

Mr. Musick: Adult stem cells are more readily differentiated into fully differentiated cell types as opposed to embryonic stem cells that have pluripotentiality, which is the ability to be differentiated into any cell type. But in order to differentiate the embryonic stem cell lines into, say, human pancreatic beta islets, the differentiation process is more complex since these cells need to be directed to other cell types prior to differentiation into beta islet cells.

TWST: What impediments are you encountering as far as commercialization is concerned?

Mr. Musick: We have completed our research and development stage where we have demonstrated self-renewal of our stem cell lines, meaning operational immortality resulting in a potentially infinite supply of stem cells to support our manufacturing needs. And we have also demonstrated our abilities to differentiate our stem cell lines into terminally differentiated beta islets that are essentially identical to native islets.

The main current objective and obstacle for us is commercial-scale manufacturing. We have an

ongoing program utilizing state of the art manufacturing techniques to deal with this issue and we are making solid progress here. We believe that we will achieve commercial-scale manufacturing in the near future.

TWST: Are there recent clinical trials showing effectiveness of stem cells in the treatment of diabetes?

Mr. Musick: Probably the largest database that we have now is from a procedure known as the Edmonton Protocol. This protocol has been around for nearly 10 years now and over 300 patients have been treated by taking human beta islets that are derived from pancreas glands of organ donors. Initially the islets are purified from pancreatic tissues, characterized and subject to additional procedures prior to transplantation into select patients with Type I diabetes. In general the results have shown that about half of these patients no longer require insulin injections, whereas prior to transplantation they required anywhere from four to six insulin injections per day. There is also a reduction of common diabetes side effects, such as cardiovascular complications. However, there are some problems with the classic Edmonton Protocol. The procedure also requires immunosuppressive therapy, which diminishes the function of the beta cells within the islets and many of these patients must revert to insulin therapy to control blood glucose. These studies do provide evidence suggesting that transplantation of islets will be effective in ameliorating many of the complications associated with Type I diabetes. And we now know that islets may be derived from human stem cells.

TWST: Will the adult stem cell therapy be a stand-alone solution?

Mr. Musick: One of the quests these days within this industry is to develop other methods of immunosuppression besides the drugs that are cur-

rently in the Edmonton Protocol that have deleterious effects on beta cell function. There's a lot of exciting work being done selectively targeting the elimination of the immune rejection of beta cells. And that would be a necessary treatment for our material to be used in therapeutic applications. However, it should be noted that our business plan basically includes predominantly a non-therapeutic target market for initial commercialization.

The development of stem cell-derived beta islets for therapeutic treatment of Type I diabetes is a longer-term objective of the company. The typical development pathway is long and expensive, perhaps up to 10 years and \$0.5 billion to \$1 billion. Our immediate goals are to take our product into non-therapeutic research and drug development markets to generate revenues while we are moving in the direction of developing therapeutic products.

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TWST: Would you comment on this non-therapeutic strategy of enhancing revenues?

Mr. Musick: This is a key component of our current business plan. Basically, we have identified a target market within the pharmaceutical manufacturing sector and in biomedical research where we will target the use of our products in acute and chronic toxicology testing together with functional tests of beta cells, allowing determina-

tion of the impact of new drug candidates on human pancreatic endocrine function. We believe that our stem cell-derived beta islets will allow determination of the possibility that a particular drug candidate may induce diabetes or impact the endocrine function of pancreatic beta islets.

Our target market is new drugs that are going through pre-clinical trials, which is a substantial market. We estimate that market to be on the order of \$50 to \$100 million per year. Currently, toxicological testing is occurring primarily by animal studies. We believe, as others do, that in the future the toxicological testing will involve cellular systems and particularly stem cells derived into terminally differentiated cell types in order to more thoroughly investigate the safety and efficacy profile of new drugs.

As you know, there are safety problems that occur with some new pharmaceutical agents. For example, Vioxx, has been pulled from the market because of safety issues that were not discovered during the development process. So we think that there's a substantial need and market for improved safety and efficacy testing during pre-clinical development of pharmaceutical agents. Furthermore, drug discovery is another target that we are pursuing within this sector; that is companies developing drugs, etc, who require model human pancreatic beta cell systems in order to test various candidate substances for efficacy. This often involves what is called high-throughput screening wherein considerable amounts of the model cellular system are consumed to identify lead compounds.

TWST: And you said that this will not require FDA intervention?

Mr. Musick: Right, FDA pre-market approval is not required in order to take the product to the marketplace since these products are used for testing of new drugs. However, we believe that

in terms of replacing the use of whole-animal toxicology studies with stem cell-derived human pancreatic beta islets, that we will be required to submit a validation package to the FDA to more completely penetrate this market.

Our initial target markets are in research and high-throughput screening, with subsequent application to toxicological determination of pre-clinical drug candidates following the submission and approval of our validation package to the FDA. And we also plan on implementing a process whereby our products are used in various studies that become published and that database then provides a further validation and substantiation of the use of our products in toxicological testing.

TWST: How far along are you in terms of commercialization?

Mr. Musick: Right now we are involved in a beta testing program whereby we have identified a group of about a half a dozen companies that we provide product to in exchange for them providing us with the results of their studies. And we have just begun this process so it's somewhat in its early stages. For example, there is a company that is involved in high-throughput screening of various compounds and they desire to use stem cell-derived beta islets for that work. Another group that we are targeting in our beta testing program would provide us with a detailed biochemical analysis of the status of our stem cell-derived beta islets and a comparison to native islets that are derived from the human pancreas gland.

TWST: What are you estimating as far as revenues are concerned from these programs?

Mr. Musick: Our early estimates are fairly modest in terms of our projections. Again, we think that the market is fairly substantial. This product is not yet available, so if we are successful

in the timely development of our commercial manufacturing process, we could be first to the market and see modest gains initially and then a fairly strong capture of this market as we accelerate our marketing program. Right now we have a team of marketing professionals who are affiliated with the company as consultants who have a great deal of experience in marketing products to the pharmaceutical industry. So we think that after the first year we will see a very aggressive push to capture a majority of this market.

TWST: What are your thoughts regarding strategic partnerships?

Mr. Musick: Strategic partnerships are important to us. We have a program going right now to outsource some of the technology that the company has developed in the past. We have other technology related to the production of a follicle-stimulating hormone, a fertility drug. We're working to outsource that technology through an out-license arrangement with another company who would become a strategic partner. We would transfer our technology and provide technical support for the manufacturing of that particular product.

Also, we're interested in potentially acquiring companies that may have synergistic products and technology to our goals, for example, for targeting stem cell-derived human beta islets for use in drug discovery and development. There are many other cell types besides beta islet cells of value in drug development including, for example, nerve cells, cardiac muscle, liver cells, etc. So we're interested in the possibility of acquiring other stem cell companies, building our company and its revenues through selective acquisitions.

TWST: Are there any other revenue producing opportunities of note?

Mr. Musick: We have some products on the market right now, but they're generating low levels of income. The enhanced revenue prospects right now are the stem cell-derived beta islets and out-licensing of our FSH technology. As we develop further, another area we are interested in pursuing is an exciting aspect of stem cell technology whereby adult cells may be re-programmed to become pluripotent (meaning the capacity to be differentiated into any of the cell types of the body). This technology may also obviate some of the ethical controversies regarding embryonic stem cells, by essentially enabling their generation from adult cells. And we have reason to believe that our cells may be suitable for some of that work. And given that we're successful in converting adult cells to pluripotency, that then increases the revenue potential for the company substantially.

TWST: You recently raised additional financing from private placements. Would you comment on how you intend to allocate those resources?

Mr. Musick: The primary allocation of those resources is for use in the implementation of our business plan and the majority of those funds are being allocated to product development. We are acquiring equipment and building a new laboratory facility as we speak that we anticipate will be fully online and operational by approximately the end of June. And so we are emphasizing the improvement of our capabilities with regard to manufacturing and in-house analytical capabilities through the acquisition of appropriate instrumentation and build out of our facility to allow us to implement these capabilities.

TWST: Are you now in the position to manufacture adult stem cells to meet your needs?

Mr. Musick: Yes, we have numerous adult stem cell lines that exhibit immortality. So we can readily expand these cell lines to generate as many cells as needed for particular uses. Right now that's not an issue for us.

TWST: What would you consider as the strengths and advantages of your management team?

Mr. Musick: I think there is a great deal of prior experience in similar industries that we are targeting now that is relevant to the non-therapeutic applications that I have previously mentioned. I and another member of the Board of Directors have both been involved in a similar venture in the 1990s with Vitro, when we developed a diagnostic product line that targeted a niche market and developed manufacturing, quality control procedures, regulatory operations while also implementing a direct marketing program that also involved selected use of distributors.

We also have other individuals who are not yet management who complement our current business objectives. Dr. Joe Nieuwma is on our Scientific Advisory Board and he is a pharmaceutical toxicologist with many years experience in this area. He provides a great deal of assistance to us in terms of business development and developing our marketing and distribution plan for the initial launch of our stem cell-derived beta islets.

Another aspect of our work is to determine the ability of our stem cell-derived beta islets to reverse diabetes in animals. Dr. Kupfer, who recently joined our team, was the former technical director of the beta islet transplantation program at the Barbara Davis Center for Childhood Diabetes here in Denver. She has considerable expertise in that area. We now have a protocol under review for detailed studies along these lines. I think we have an exciting team with considerable expertise in the

primary areas of need with regard to the implementation of our business plan.

TWST: Do you feel you are reasonably well understood by the financial markets now?

Mr. Musick: I think we are reasonably well understood. In terms of the valuation of the company, at this particular point in time our current market cap is about twelvefold higher than its 52-week low, but it's also about twentyfold less than its historical high. So I think that basically we are an undervalued issue, probably due to the general economic conditions on the one hand and also, we have been in R&D for some time and we haven't had substantial revenues for some time. I think those are factors that affect the current valuation of the company's stock.

We believe that revenues and earnings growth is a key element to an improved valuation and that's our current primary operational goal. We believe that there are limited obstacles to sharp increases in revenue and we believe that we can achieve a turnaround within the second year following launch. We then hope to see rapid earnings growth thereafter that would sustain profitability and also fund development of products targeting therapeutic applications in animals. Our initial non-therapeutic target market does not require FDA approval, as I mentioned previously.

TWST: What is the timeline on introducing a therapeutic product for treating diabetes in animals?

Mr. Musick: We would certainly need to have our current pre-clinical protocols completed and then extend those studies further. I think the timeline that we are looking at in terms of getting into trials would be approximately two years, given availability of adequate resources.

TWST: As a small company, how do you get your message out to shareholders and potential shareholders?

Mr. Musick: We've tried to improve our public relations program by more regular releases of information from the company. We're also interested in trying to promote some local interest in our company. There's a possibility that we would seek assistance from outside professionals in the implementation of a more widespread program to increase awareness of the company to potential investors.

TWST: What keeps you occupied on a daily basis?

Mr. Musick: I have the responsibility for all operations of the company. We're a fully reporting public corporation. I am also the Chief Financial Officer for the corporation so I have SEC reporting responsibilities. We actively pursue working capital and I attempt to keep capital flowing into the company. I coordinate the technical operations of the company on a day-to-day basis and now I am responsible for the build-out of our new manufacturing facility in Golden, Colorado.

TWST: When do you intend to reach out again to the capital markets for further financing?

Mr. Musick: We have current financing through a private placement with group of investors. We have two rounds out of four completed now and we're doing all that we can to complete the third and the fourth rounds of that particular financing. There are some other opportunities available to the company for capitalization that could match the funds that the company has recently raised. As we develop to more advanced stages, we certainly are interested in a follow-on offering that could be of assistance in raising substantially more capital that would be needed to support some of the therapeutic developments and acquisitions that I have mentioned previously.

TWST: What is your current burn rate?

Mr. Musick: We've increased our spending as we accelerate the commercialization of our stem cell-derived islets and build-out our new manufacturing facility. Still our burn rate remains modest, about \$15,000/month.

TWST: Do you have any final thoughts?

Mr. Musick: I think we have competitive advantages that are attractive to the investment community. And one of them is that we're at an advanced stage of product development and our R&D is complete. We have an initial target market where pre-approval by the FDA is not necessary and we currently have available resources that are needed to manufacture and distribute our products. We have access to several human adult stem cell lines, and we've demonstrated the capacity of these stem cell lines for differentiation into functional beta cells.

We're currently developing state-of-the-art manufacturing processes that are fully scalable and capable of operation to demanding FDA standards. We're in the final stages of construction of a modern extended facility that is suitable for our current manufacturing operations and will also support our future expansion. We have a seasoned management team that's experienced in prior ventures targeting similar niche markets. The company has further opportunities to realize growth in synergistic markets through targeted acquisitions.

TWST: Thank you (WT)

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