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Questioning Market Leaders For Long Term Investors

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CEO/COMPANY INTERVIEW

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GalaGen, Inc. (GGENC)



HENRY J. (HANK) CARDELLO joined GalaGen, Inc., as President in January 1999 and was appointed Chief Executive Officer in March 2000. Mr. Cardello previously was President of Marketing Ventures America (MVA), a new-products marketing firm specializing in commercializing consumer-based nutritional products. During his 10-year tenure with MVA, corporate partners included such well-known names as The Pillsbury Company, Hormel Foods and The Quaker Oats Company. Mr.

Cardello is the former President of Sunkist Soft Drinks, Inc., a unit of Cadbury Schweppes Plc, where he led a major restructuring that substantially increased profitability and firmly positioned Sunkist within the soft drink industry. Prior to Sunkist, Mr. Cardello served as the Director of Marketing for Coca-Cola USA. Under his leadership, Diet Coke became the third largest selling soft drink in America. Mr. Cardello also held several brand management positions with Anheuser-Busch, Inc., and General Mills. Mr. Cardello received a Bachelor of Science degree in Engineering from Lehigh University and a Masters of Business Administration from the Wharton Graduate School of Business at the University of Pennsylvania.

SECTOR – FOOD

(LAJ612) TWST: Could you start us off with an overview and profile of GalaGen?

Mr. Cardello: GalaGen actually was started in 1987 as a division of Land O'Lakes, the dairy cooperative. The purpose of the company was to take its specialized technology and a dairy product called colostrum, which is the first and most highly nutritious part of milk, and convert it into different pharmaceutical types of applications. In 1992, it was spun off from Land O'Lakes as an independent company called GalaGen, with the mission of delivering pharmaceutical or therapeutic type benefits based on colostrum technology.

In 1996, the company went public as a pharmaceutical company, primarily addressing AIDS-related disease problems, such as AIDS-re-

lated diarrhea. Shortly thereafter, drugs combining AZT and protease inhibitors were introduced into the market by other firms. The result was a lessening of secondary AIDS infections tackled by GalaGen's products.

The company decided, given the competition, that it would instead pursue what is called the functional foods market. Functional foods are products that contain an ingredient that delivers a health benefit. For instance, a juice product with added calcium would be considered a functional food. The company felt that, after having invested over \$50 million in its technology, that functional foods would be the quickest route to market and would be the best non-drug applications for its technology. A non-drug application was preferable because drugs are a highly expensive and time-consuming en-

deavor for a small company to pursue. The goal was to license our technology to major consumer products companies.

TWST: Is that when you became involved in the company?

Mr. Cardello: Yes, in the first quarter of 1998, I got involved with the group. My background is primarily in marketing consumer-packaged goods. Over the last decade, I've had my own company and have been successful in forging alliances with major consumer products companies such as Pillsbury, Quaker Oats, and Hormel, just to name a handful. I joined GalaGen first as a Consultant to advise the company on how to take its technology and forge alliances with large consumer product corporations. At the end of 1998, the company asked me if I wanted to come on full time and run the business, which I did because I saw great potential in the business.

TWST: What has been your strategy in shifting from a pharmaceutical to a functional foods emphasis?

Mr. Cardello: Our strategy since the end of 1998 has been to take this wonderful platform technology derived from colostrum and put it into applications that help consumers stay healthy. We do this by forming alliances with major consumer products companies, consumer food beverage and supplement companies, and other consumer products corporations. Right now, we're probably considered the poster child of the functional foods industry for our success in forging alliances with major consumer products companies.

I've already defined a functional food as one that contains one or more ingredients that enhance the health benefit of the basic food. Just for dimension, the functional foods category is a little over \$20 billion, according to market estimates, and is growing in double-digits. It's expected to double within the next five years. Large companies have finally figured it out and they're starting to jump in there. They're looking for corporations such as GalaGen that have proprietary technology, in order to put that technology into their existing trademarks and create the next generation of new businesses.

TWST: What does the agenda look like for the company over the next 12 to 18 months? What events and activities are anticipated and what accomplishments would signify success for the company in that time frame?

Mr. Cardello: Our primary focus, as I just mentioned, is to forge alliances with major food and beverage companies. I'd like to give you a quick recap of the alliances we have now, at least the major ones. We have an alliance with Wyeth-Ayerst, a division of American Home Products, for a very unique application for infant formula and nutritional worldwide. We also have a partnership with Novartis, which is the parent company of brands such as Gerber and Ovaltine, and also has a huge pharmaceutical business.

Last summer, we announced a deal with Estée Lauder. After thorough testing, Estée Lauder concluded that our colostrum is superior to other substances that they were evaluating for collagen

Highlights

GalaGen is a leading provider of functional food products. CEO Henry J. Cardello describes them as foods that contain an ingredient that delivers a health benefit. The company decided that functional foods would be the quickest route to market and would be the best non-drug applications for its technology. The functional foods market is currently over \$20 billion a year, and expected to grow in double digits. Large companies are looking for businesses like GalaGen that have proprietary technology to create the next generation of new businesses. The company has a very full pipeline and is working in alliance with numerous corporations including international companies.

production, which is linked to anti-aging benefits, and also superior to competing colostrum products. They chose to go with our colostrum product versus not only other colostrums, but also other substances that have been known to have certain benefits for anti-aging.

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We also maintain relationships with Lifeway Foods, which is 20% owned by Dannon, for a yogurt-type beverage. It’s actually a kefir-based beverage, which Lifeway is selling here as well as in Eastern Europe.

We have two deals with Hormel HealthLabs, which is a subsidiary of Hormel. The first is a licensing agreement for a business that produces elemental enteral nutrition products. These products ensure that critically ill or severely injured patients consume adequate nutrients, thus reducing complications and helping to avoid prolonged hospital stays. This product does not use our colostrum technology, which is why we licensed it to Hormel. Secondly, we have a product called Vistrum™, a clinically-tested, cultured dairy beverage, developed to improve the gastrointestinal health of patients in hospitals and nursing homes. We are working with Hormel on this product in order to take advantage of their excellent distribution channels in these markets. We anticipate that Vistrum will be in test markets in the second quarter of 2001.

We also have a nutritional supplement on

the market, called Proventra™, being sold by GNC under its PharmAssure line of products, a line of 39 different items.

TWST: What is your business model?

Mr. Cardello: The reason we are pursuing a strategy of effecting these alliances with these major corporations is their capability to create a potentially huge end-business. For instance, Novartis has a marketing organization and trademarks in place, and a network and marketing budget to create a significant opportunity for us as the supplier of a key ingredient.

In forging these alliances, the ideal model is a combination of licensing fees, a supply agreement that provides operating margin to GalaGen, and royalties. In some cases, we do have milestone payments, so that if the business is successful and it attains certain sales levels, we receive additional one-time payments.

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TWST: How are you making the reinvestment, or do you see more extensions of the current science that you’re using? Are you looking to bring in through mergers or acquisitions other similar science technologies that can be licensed and distributed the way you’ve just described?

Mr. Cardello: Yes. I used the term platform technology earlier. By platform technology, I mean that there are multiple benefits that one derives from using our particular kind of colostrum.

I'm very specific on that because our proprietary technology allows us to concentrate our ingredient to an extent that it opens the door for more applications than other colostrums. There are other companies that can make pills. However, when you start getting into beverage products, snack bars and cereal products, if the colostrum is not concentrated enough, you have to throw in so much powder for it to be effective that the product is unpalatable or just doesn't work. Our competitors do not have the ability to concentrate their colostrum products to the extent we do.

Our other advantage is that we have developed through the years the knowledge of how to treat the cow in such a way that the colostrum that comes from the cow delivers specific benefits. These properties may act against targeted germs or bugs, or against certain conditions. So we have a two-pronged attack. One is our broad-spectrum colostrums, which primarily are geared toward enhancing immunity, and that's really the primary focus of the company right now. We are working on putting this ingredient into beverages, juices and dairy products, cereals, etc. where it can provide a deliberate immune benefit to a mainstream consumer audience.

We also have the capability, with our special know-how, to create products that address certain health conditions. For instance, we already are doing things for oral health, to address tooth decay and to combat candida or yeast infections in women. We have seen anti-cancer benefits in studies against colon cancer and melanoma. So we have a number of secondary benefits that we can deliver. Therefore, while we're focusing on delivering the immune benefit via alliances with consumer companies, on a parallel path, we've selected a handful of additional benefits that we will be delivering to

other corporations for incorporation into some of their products.

With so much opportunity for this platform technology, we are not actively pursuing the acquisition of other technologies. Do we keep our eyes open? Of course we do. Is it the number-one strategy? No. Right now, we're very focused on getting the applications potential of our technology platform into the market.

There is an adjunct capability to this. We hold patent rights to the combination of colostrum with probiotics. An example of a probiotic is the acidophilus culture in yogurt. When you combine colostrum with probiotics, there are some indications that they deliver an enhanced benefit — a one-plus-one-equals-three type of immune benefit. We hold the patent rights to that combination and we are exploring that on a parallel path to what we're already doing.

So, to answer your original question, we certainly have plenty to keep us busy for a while. I'd rather keep the company focused on what we can do best.

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TWST: Give us an assessment of your top management team. With what's ahead as far as a schedule and opportunities, do you have

the bench strength and the skill sets necessary to meet those challenges?

Mr. Cardello: Definitely. If you look back at the company in its pharmaceutical heyday, it was composed very heavily by PhD-type scientists and a few MDs. What we have now is much more of a balance between the business side and the scientific side. We need the scientific underpinnings because we're dealing with proprietary science here. That's important to us. What I've done is brought in additional marketing people to complement my own background, people out of Quaker Oats and General Mills, because these are the kinds of companies we're forging alliances with, and that's very critical to the success of our company.

Frank Kuhar joined the company a little over a year ago as Chief Financial Officer. Frank has background from Ernst & Young, GE Capital and other more entrepreneurial ventures, so he brings corporate and entrepreneurial experience.

I think the senior management is well-rounded. Bob Hoerr, our Chairman and Chief Technical Officer, has not only a PhD in nutrition but also is a Medical Doctor and has regulatory experience as well. He heads up a group called the Research Based Dietary Ingredient Association, or the RDIA, which just last week held a major conference that involved the FDA. He's President of the RDIA, and GalaGen is taking the leadership role in establishing the gold standard or the Good Housekeeping Seal of Approval for these functional food ingredients so the public doesn't have any perceptions that there's fairy dust out there.

We are interested in having legitimate science behind what we sell, so senior management is well balanced in terms of our skill sets. We have continuity in our R&D and also our manufacturing area, where the people who not only devel-

oped the science but also developed the proprietary manufacturing processes are still with us, providing their expertise. That is a point of difference for us too.

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TWST: At this point, how can the investment community better understand GalaGen? Are there any legacy or baggage issues that still come through the door but should be left outside?

Mr. Cardello: First of all, one of the things that we've learned in dealing with our corporate partners is that we have to buy into their strategy 110% and keep it confidential. They do not want to reveal the details of what they're doing with us in order to keep their competitive advantage.

However, that means we cannot be highly specific in terms of the application or the specific product line we are working on with any major company. I think that negatively impacts the way the financial community sees us. If we could just lay it all out, I believe we would be perceived more positively, but it's just a question of how much information our partners are willing to share with the market. If we had a major company like a Novartis or a Wyeth-Ayerst that wanted to be very specific about the products and trademarks where they will use our products, I believe that the market would feel very differently about GalaGen. But, again, they don't want to give anything away. Why tell their major competitor what they're up to?

TWST: What would be the essential message today that convinces an investor to buy in?

Mr. Cardello: We have proprietary technology and we are the poster child for forging alliances with the major companies. Those alliances are going to be the machines to grow this business and I think that's a message that has to be out there. We're in a leadership mode in terms of our visibility on the regulatory side. We have the team to do it and we also have a very loaded pipeline. We are working with quite a number of major corporations. Actually, we just added up the dollar amount of revenues of these companies — not our revenues, but the revenues of the companies that are in our pipeline right now and have expressed interest in discussions with us about our technology — and it exceeds \$200 billion.

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We are talking with the major players. If someone can see that this is the right strategy and that we really have a live pipeline, then it's just a question of their understanding competitive advantage and the lead-time it takes these companies to get a product out there. That's the kind of investor that is right for this kind of business.

TWST: Are there any thoughts or issues you normally include or present that we've not covered?

Mr. Cardello: We've talked about the technology platform and our ongoing R & D. The alliances are the key. To help us in effecting these alliances, we use a unique concept-packaging model that helps increase corporate interest in us. Before we approach a company, we understand its

margins, its organizational structures and its trademarks, and we actually create a business plan for that company. We don't walk in the front door and say, “Here's a hot new ingredient. Do you want to buy some?” We look at it from their viewpoint and won't even go see a company unless we know we can help them build new franchises.

TWST: What's the international impact that you have today, and how is that international presence and impact changing or evolving?

Mr. Cardello: Actually, two of our major partners are very strong internationally. Wyeth-Ayerst, of course, is a worldwide player in the infant nutritional and formula arena. Novartis, which is a Swiss-based company, has lots of strength outside the US. Therefore, while we don't have much of a presence internationally right now, we do anticipate that down the road. We are not looking at our business purely from a domestic standpoint. However, we are concentrating here because most of the large consumer products companies have a significant presence here in the United States.

TWST: Thank you. (DA)

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