

THE WALL STREET TRANSCRIPT

Connecting Market Leaders with Investors

ADVENTRX Pharmaceuticals, Inc. (ANX)



BRIAN M. CULLEY was appointed Principal Executive Officer of ADVENTRX in February 2009 and Chief Business Officer in January 2007. Mr. Culley joined the company as Vice President, Business Development, in December 2004 and was appointed Senior Vice President in January 2006. From 2002 until 2004, Mr. Culley managed all strategic collaborations and licensing agreements for Immusol, Inc., in San Diego, where his most recent title was Director of Business Development and Marketing. From 1999 until 2000, he was a Licensing and Marketing Associate at the University of California, San Diego, Department of Technology Transfer & Intellectual Property Services. In addition, from 1996 to 1999 he was a Research Associate for Neurocrine Biosciences, Inc., where he performed drug discovery research. Mr. Culley

has over 15 years of experience in the biotechnology industry, including deal structure and negotiation, licensing, due diligence, market and competitive research, and venture funding. He received a master's degree in biochemistry from the University of California Santa Barbara and an MBA from The Johnson School of Business at Cornell University with an emphasis on private equity and entrepreneurship.

SECTOR — BIOTECHNOLOGY

TWST: Please give us a brief history of ADVENTRX.

Mr. Culley: The company is in the midst of a restart, so in many ways it has a very short history. In prior years, ADVENTRX was engaged in developing a traditional new chemical entity, but that program faced many difficulties and was extremely expensive. We believed, both fundamentally and in light of the current environment, that our stockholders would be best served by pursuing a faster, lower-cost, lower-risk drug development strategy. We're still addressing cancer, but we've moved away from high-risk programs to focus on improving already-approved drugs. In particular, we leverage our proprietary emulsion technology to reformulate existing drugs without changing their underlying pharmacokinetics. The drugs we are focused on today were acquired in 2006.

TWST: What are your leading therapies?

Mr. Culley: We currently have two programs, both of which are new formulations of cancer chemotherapeutics. One of them is a new formulation of vinorelbine, a drug commonly used to treat breast cancer and non-small cell lung cancer. This product candidate, known as ANX-530, was designed to reduce phlebitis, a severe injection site reaction, which is a common problem with off-the-shelf generic versions of vinorelbine. Our formulation was designed to reduce this side effect without affecting the underlying

pharmacokinetics or efficacy of vinorelbine. The other product that we are developing is ANX-514, which is a detergent-free formulation of docetaxel. Docetaxel is widely known by its brand name, Taxotere, and is used to treat solid tumors such as breast, lung, prostate and gastric cancers. A big problem with Taxotere is that it's formulated with detergent, and the detergent can cause side effects such as hypersensitivity reactions. To mitigate these side effects, physicians often pre-treat patients with steroids, but these have costs and themselves have side effects. Our formulation, known as ANX-514, is completely detergent-free, so we obviously wouldn't expect to observe any of the side effects which are caused by detergent. We're trying to provide alternatives to currently available chemotherapies but without starting from scratch and reinventing the wheel, so to speak.

TWST: Where is each of those in the pipeline?

Mr. Culley: ANX-530 is our most advanced program. We have successfully completed a clinical bioequivalence study and scaled up manufacturing, and we are now preparing to submit an NDA to the FDA later this year. So we are hopeful of having our first product approval next year. We also conducted a clinical study with ANX-514, and we're currently going through that data in order to determine what the next steps are for that program. We're hopeful to have ANX-514 on the heels of ANX-530 as our second commercial product.

TWST: What makes ANX-530 different? What is the technology behind it?

Mr. Culley: Our nano-emulsion technology associates non-toxic ingredients with an underlying drug. For ANX-530, those non-toxic ingredients are designed to protect the vein at the site of injection. So rather than having a high concentration of raw drug exposed to your vein and causing swelling, discoloration and pain, the drug is associated with our formulation, meaning there is less exposure of the vein to the drug. After the drug is administered and is into the patient's central circulation, the emulsion breaks down, allowing the drug to be taken up by tissues and tumor cells. Essentially, the drug can get to the tumor site without corroding the vein along the way. So in some ways, it's a delivery mechanism.

TWST: You said you are hoping to get an NDA at the end of this year. What happens after that?

Mr. Culley: Our business model is both reproducible and scalable. We have a number of opportunities to apply our formulation technology to drugs that are already approved and to develop new versions of drugs with improved side effect profiles. As we grow, we're interested in applying this technology to a third, fourth and fifth drug. In addition, we are looking to identify other technologies that fit within our strategy of getting products approved through bioequivalence studies.

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TWST: Where did the technology for these therapies come from?

Mr. Culley: It was developed by a private company called SD Pharmaceuticals. Initially, ADVENTRX licensed ANX-530 from SD Pharmaceuticals, and we were impressed with our early studies on this product. We were so impressed, in fact, that we decided to acquire the whole company, which included eight different development programs. This being biotech, not all of those programs have panned out, but two of them in particular — ANX-530 and ANX-514 — are very promising.

TWST: Your clinical and regulatory strategy is a bit different from those of other biotechs. Would you tell us about that strategy?

Mr. Culley: Conventional drug development requires a Phase I, Phase II and two large Phase III studies. That process is very time consuming and extraordinarily costly. However, it is also possible to get your products approved through a single bioequivalence study, which may involve as few as 30 patients, and is obviously much faster and less costly. Our strategy is to identify these opportunities, get our products approved through this regulatory path and ultimately to make investments in differentiating our products against the generics. In addition to being faster and cheaper, this strategy involves far less risk than the traditional regulatory path.

TWST: You also have a detailed commercialization strategy. Would you tell us about that as well?

Mr. Culley: We have a two-pronged strategy for ANX-530. First, we expect to have a conventional field force of sales reps calling on physicians. But in addition, we also plan to engage distributors and Group Purchasing Organizations. We plan to contract with these groups

to create awareness of the potential non-clinical benefits of our products versus the generics, such as pharmacoeconomic benefits. Depending on the nature of the underlying market, this particular supply channel is an efficient way to get product to end users. We're also interested in working with groups that understand the potential benefits of our products. One example of this is the Oncology Nursing Society. Their members have a keen awareness of the side effects of chemotherapy, and we think that there will be strong interest from that group in our products once they are available. We have conducted extensive market research on both products, and these studies strongly suggest that oncologists and other medical professionals will have a preference for our reformulated drugs. And finally, both of these drugs address a large, proven market. Sales of vinorelbine have been growing steadily since 2007 and Taxotere sales in the U.S. are approximately \$1 billion.

TWST: Like other companies, you have felt some pain from the economic downturn and tightening of credit. What adjustments have you had to make to continue moving forward?

Mr. Culley: There are two important changes that we've implemented. First, we have gone to a highly outsourced business model. We retain a small number of full-time employees and contract for most of our development activities. That provides us with tremendous financial and operating flexibility, and we're able to attract experienced advis-

ers at very reasonable rates. Second, we've had to be realistic about raising capital. I'm never pleased about raising money at low valuations, but the capital markets have been so selective that in some ways, raising money as a small-cap biotech firm is itself an imprimatur of high value and a testimonial to our business.

TWST: You recently announced a stock sale that will prove you with about \$11.3 million. Would you tell us about that?

Mr. Culley: This was our fourth financing since June, the other three were much smaller. With this latest round, we believe we have the funds to get us deep into 2010 and through an important milestone — the FDA decision on ANX-530. So via this financing, we have eliminated a substantial amount of financing risk, which is something that investors are paying a lot of attention to. And being able to raise capital on four separate occasions in a difficult market reflects positively on our strategy, our product candidates and our core formulation technology.

TWST: How would you like to see the company evolve over the next couple of years?

Mr. Culley: We're strongly committed to creating value for ADVENTRX stockholders. That might mean we will be acquired or will remain as an independent business, and we will make those determinations as we grow, but we will always make the decision that we believe maximizes our value on a risk-adjusted basis. We know that focusing on products that are desired by patients and doctors will naturally create a high-value company, so we are open-minded as to the ultimate outcome. We have and will continue to entertain credible discussions concerning partnering and acquisition, but in the meantime we will move forward on the regulatory and commercial plan I've described and build the business with both long- and short-term value in mind.

TWST: What makes ADVENTRX a good investment?

Mr. Culley: As investors begin to return to the micro-cap markets, I think that ADVENTRX offers them a lower-risk regulatory path, shorter timelines to major value-creating events and hopefully a good return on their investment. Our shares are widely held with significant trading volume, and we have an easy-to-understand story within a complex biotech space. I also think that much of our success next year will be driven by execution rather than by clinical risk. So as investors look at the health care sector, ADVENTRX is well poised to offer a comfortable place to make an investment in what is still a time of considerable uncertainty.

TWST: Tell us about your background.

Mr. Culley: I'm fortunate to have spent many years on both the research and business side of this industry. The first half of my career was spent conducting academic research and working on drug development for a biotech company, and I have a master's degree in biochemistry from UC, Santa Barbara. The second half of my career was spent as a Director and Vice President of business development, and I have an MBA from Cornell University. Being able to jump with facility between business and science has proven invaluable to me in my current role.

TWST: Is there anything that you'd like to add?

Mr. Culley: I think ADVENTRX is going to have a bright future. We're delivering on our goals, we're realistic about the challenges

we face, and our recent financing success demonstrates our ability to adapt and thrive in difficult environments. We've moved away from high-risk, new chemical entities and costly in-house R&D activities and are focused on a business model that we believe will deliver high-value branded products with a limited investment and fairly short timelines.

TWST: Thank you. (LMR)

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