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With A New CEO And A Strong Balance Sheet, ADVENTRX Pharmaceuticals (NYSE Amex: ANX) Is Being Rebuilt And Could Have Its First Approved Product Next Year

Healthcare
Biotechnology
(ANX-NYSE AMEX)

ADVENTRX Pharmaceuticals, Inc.
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Brian M. Culley, M.A., M.B.A.
Chief Executive Officer

BIO:

Brian M. Culley was appointed Chief Executive Officer in February, 2010, Principal Executive Officer 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. At Immusol, Mr. Culley negotiated a discovery, development and commercialization deal with Novartis Pharma AG worth up to \$78 million. From 1999 until 2000, he was a licensing and marketing associate at the University of California, San Diego Department of Technology Transfer & Intellectual Prop-

erty Services, and from 1996-1999 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 Masters 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.

Company Profile:

ADVENTRX Pharmaceuticals is a specialty pharmaceutical company whose product candidates are designed to improve the performance of existing cancer treatments by addressing limitations associated principally with their safety and use.

ADVENTRX currently is focused on commercializing two late-stage product candidates in the U.S., ANX-530 (vinorelbine injectable emulsion) and ANX-514 (docetaxel lyophilized emulsion for injection), both of which are reformulations of currently approved products.

Interview conducted by:
Lynn Fosse, Senior Editor

CEOCFO: Mr. Culley, you are new at the CEO position at the company, what is the plan as you take over leadership?

Mr. Culley: I had been working for ADVENTRX as head of business development for approximately four years and Chief Business Officer before I took over as CEO. We conducted a series of layoffs following the deprioritization of one of our development programs and the finan-

cial turmoil of 2008 and 2009. Consequently, I am tasked with rebuilding the company, and currently we are doing so with a focus on new formulations of previously approved chemotherapy drugs.

CEOCFO: What is your plan for the types of drugs you are looking at?

Mr. Culley: We take drugs already approved by the FDA, modify them in some way to improve their profile and then we seek to re-launch them with the new profile back into the market.

CEOCFO: How do you decide which therapies deserve focus?

Mr. Culley: We look for opportunities where we can apply a proprietary emulsion technology to improve the safety or use of a drug. For example, the widely-used chemotherapy drug vinorelbine causes inflammation and pain at the site of injection. By using our emulsion technology, we seek to reduce that painful and avoidable side-effect. Another drug, Taxotere, is formulated with detergent to help it dissolve, and that detergent is associated with serious side effects. We have a detergent-free formulation of that drug, which should reduce the incidence and severity of side effects associated with the detergent.

CEOCFO: What is the science behind what you are doing that makes it different?

Mr. Culley: The science behind our emulsion formulations is very understandable, but it involves precise manipulation at the nano-scale. Think of an emulsion as being like salad dressing. Salad dressing is a combination of oil and vinegar and when shaken these ingredients form tiny droplets. We do the same thing, but with chemo drugs. We force

these drugs into tiny oil droplets, which changes how the drugs are initially presented to the body and provides us an opportunity to address limitations of existing formulations. An important difference, and much of the science and art between what we do and salad dressing, is that oil and vinegar will separate over time. With our emulsion formulations, we keep the two phases stable for an extended period, which is critical from a commercial standpoint.

CEOCFO: What are you working on today, and where is it in the process?

Mr. Culley: For our most advanced drug program, a drug named Exelbine, we are anticipating that we will submit a request for marketing approval from the FDA in the fourth quarter of this year. If submitted in Q4 and approved on first-cycle, we would have our first approved drug sometime in the second half of 2011. In addition, we have a second development program and we expect to meet with the FDA later this year to discuss results from a completed clinical study. Following that meeting, we should have insight into the timeline for submitting our second NDA.

CEOCFO: Are you working on general or specific types of cancer?

Mr. Culley: The drugs that we are reformulating are most widely used in lung cancer and breast cancer and to a lesser degree prostate, head and neck, and gastric cancers. In other words, we're going after some of the largest and most common solid tumors.

CEOCFO: Once the FDA becomes involved, what is the timetable?

Mr. Culley: We are developing branded drugs that have a target review period of approximately ten months, so we could expect to be cleared for commercialization approximately ten months after submitting an NDA.

CEOCFO: What is the financial picture like for ADVENTRX Pharmaceuticals today?

Mr. Culley: We have a strong balance sheet today. We've raised approximately \$30 million this year through two equity

financings with institutional investors. To put that in perspective, our operating expenses were about \$2.4 million for the first quarter of 2010. As you can see, we are judicious with our cash and always seek to deploy it intelligently. The company employs a small number of critical full-time employees and utilizes a large number of consultants and other vendors who are highly specialized for the tasks that we need to have completed. We outsource many of our operations to folks that provide us with turn-key solutions. For example, we have an important alliance with a manufacturer in Italy, which allows us to access 150 skilled people on a fractional basis for the manufacture of clinical material and ultimately, commercial product.

CEOCFO: Is the investment and medical communities paying attention?

Mr. Culley: We were able to raise \$30

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million in what is still a difficult financing environment, which speaks to investment community interest. In addition, we have a broad and international investor following. At last look, we have approximately 20,000 beneficial holders, and we have robust trading volume for a small cap company. As for the medical community, I think everyone in that arena pays close attention to late-stage cancer companies like ours, so I think the answer to both questions is yes.

CEOCFO: Do you see partnerships down the road once you get closer to commercialization?

Mr. Culley: Yes. We already have a partnership with a major South Korean company in which they have purchased rights to develop and commercialize one of our drugs in that country in return for certain milestone payments and royalties. We are interested in identifying and contracting with other companies that would take on similar regional licenses, as well as with companies that could be partners

in commercializing our products in the U.S., and we frequently have discussions with such companies.

CEOCFO: There are many companies in your field; why should ADVENTRX stand out to potential investors?

Mr. Culley: ADVENTRX stands out among its small cap peers because we expect to submit an NDA, the final regulatory hurdle to drug approval, this year. There is only a limited amount of work remaining before we submit that NDA, and we have both the financial and human capital to get there. So when I look at the cash that we have on-hand, the late-stage of development for our drugs, and the market capitalization of the company, I believe that there is a disconnect between our fundamentals and our value. I feel there is a compelling opportunity for stockholders to own part of a company that is relatively close to having an ap-

proved drug and then generating revenues either directly or from partner royalties.

CEOCFO: Do you have other drugs in the pipeline?

Mr. Culley: We plan to. We are often asked, “When your drugs get to market, what’s next and how will you continue

to grow the company?” We are certainly interested in acquiring and developing additional assets, which is something we are focused on in 2010.

CEOCFO: Final thoughts, what should people remember most when they read about ADVENTRX?

Mr. Culley: I believe ADVENTRX has done a terrific job deploying its stockholders’ investments carefully. Not long ago, the company was in a difficult financial position with few options, but we focused on our core business and we believe we have made an extraordinary amount of progress in a short amount of time. And we’re always looking for new ways to increase the value of the organization and to bring new medicines to market for the benefit of cancer patients around the world.

Readers are reminded that this interview includes forward-looking statements and all forward-looking statements involve

risks and assumptions that, if they materialize or do not prove accurate, could cause actual results to differ materially

from the forward-looking statements. Readers are therefore advised review the Company's most recent annual report on

Form 10-K for a full discussion of these risk factors.



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