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Successful Phase 3 Development of Clarus's Oral Testosterone (T) Replacement Product CLR-610 will be a Major Advance in Treatment Options for Men with Low T

Healthcare
Drug Development

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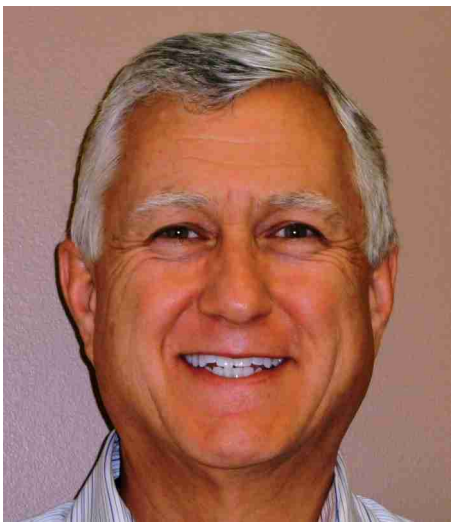

Dr. Robert (Bob) Dudley
CEO

BIO:
Robert E. Dudley, Ph.D., has served as Clarus' Chief Executive Officer, President and Chairman of its board of directors since February 2004. Dr. Dudley has significant development, regulatory and commercial experience in the testosterone (T) replacement field. During his tenure as an executive at Unimed Pharmaceuticals, Inc., he led the discovery, development, FDA regulatory approval and launch of AndroGel®, the first T-gel product, which today remains the market-leading T-replacement therapy over a decade after its launch. Prior to founding Clarus, Dr. Dudley served as President, Chief Executive Officer, and Director of Anagen Therapeutics, Inc., from 2001-2003. He served as President, Chief Executive Officer and Director of Unimed Pharmaceuticals, Inc., from 1999 to 2001. From 1994 to 2001, Dr. Dudley held several senior-level executive positions at Unimed Pharmaceuticals, Inc., a public company acquired by Solvay Pharmaceuticals in 1999. Dr. Dudley received his B.S. in Biology from Pepperdine University, Seaver College, his M.S. in Biology from University of New Mexico, and his Ph.D., with honors, in Pharmacology and Toxicology from the University of Kansas School of Medicine. Dr. Dudley is also a board-certified toxicologist.

About Clarus Therapeutics:
Clarus Therapeutics, Inc. is a privately held pharmaceutical company focused on the development and commercialization of CLR-610, our oral testosterone (T) replacement product that is in Phase 3 clinical testing. If approved by the Food and Drug Administration (FDA), CLR-610 will be a first-in-class oral T-replacement therapy in the United States. CLR-610 contains a T prodrug, namely, T undecanoate (TU) that is absorbed via the intestinal lymphatic pathway (thus by passing the liver) and acted upon by natural substances in the body to release T.

Interview conducted by:
Lynn Fosse, Senior Editor

CEOCFO: Dr. Dudley, Clarus is developing a unique oral testosterone (T) therapy; would you tell us what you are actually doing in that direction?

Dr. Dudley: To begin, I have been in the T-replacement field for almost 20 years. I have had the good fortune to invent, develop and commercialize AndroGel®, which is today the #1 prescribed T-replacement product in the world; but there has always been a large gap in the treatment options for men with low testosterone in that there was not a good oral option. When we founded Clarus, our sole purpose, and where we have spent 100% of our time, has been to develop a safe and effective oral T delivery method that will make it much easier for men to begin and stay on therapy.

CEOCFO: What is the current method? What is being used now, and why is your solution better?
Dr. Dudley: The number one T products on the market today in terms of sales are the topical T-gels and they are driving a market approaching $2 billion annually with a strong double-digit compound annual growth rate. By far, the most prescribed T-gels are AndroGel®, marketed by Abbott and Testim®, a product from Auxilium. Then there are a few other minor gels including an underarm T-lotion launched about a year ago by Lilly. The gels comprise probably 85% of the testosterone replacement market today. Then there are some injectable products that are cheaper, but obviously not very user-friendly. There has been a single T-patch on the market for a long time but its sales have pretty flat. Injectable (deep muscle) T products are still used principally because they are cheap.

CEOCFO: What has been the barrier to developing an oral therapy, and

what have you figured out that others have not?

Dr. Dudley: There are two principle barriers when it comes to development of an oral T product. First, when you take drugs orally, they typically are absorbed into the portal circulation and then directly into the liver where drugs, including T, are extensively metabolized. To overcome this, you would have to give very, very large amounts of T that are not likely to be liver-friendly nor cost effective. Next, efforts to change the testosterone molecule so that it still acts like testosterone but avoids liver metabolism have resulted in products that are toxic to the liver. One of these actually made it to market, namely methyl testosterone, and remarkably it is still on the market in the U.S., despite its association with liver injury. In fact, methyl-T has been removed in several countries around the world due to safety concerns but, as I said, not in the U.S. In my view, methyl T is a very poor T-replacement alternative. The approach that we have taken is to use a T prodrug; a slightly modified version of testosterone that is not liver toxic. We have hooked a fat molecule on to T so that the body views it as a dietary fatty acid – just like any other fatty acid. This T-prodrug is absorbed principally through the intestinal lymphatic system -- a parallel absorptive system for fats that avoids the liver. When you do that, you can get very good blood levels of T after the fatty acid part of the molecule is naturally cleaved off by enzymes that are present in the body. It is a very eloquent way of getting testosterone into the blood stream. But the other key is how this is formulated and our proprietary formulation is a critical success factor.

CEOCFO: Where are you in the development process?

Dr. Dudley: We are in Phase 3 testing right now but we will not have all of the safety and efficacy data from this trial until the spring of 2013. We have reported that the 90-Day efficacy data is quite strong and meets the current FDA guidelines for T-replacement products.

CEOCFO: What is the prevalence of low testosterone, and how do we know it is a real problem not just a current catchall fad?

Dr. Dudley: The prevalence of low T in the U. S. is remarkably high, particularly when you include in this category 'the aging male'. Based on published epidemiology data, you are looking at probably prevalence numbers anywhere from 13 -15+ million men who actually have clinically relevant low T levels. You layer on to that several million men in disease categories, that is, men who have chronic disease; for example, renal disease, cardiovascular disease, and in particular, type-2 diabetes and its precursor, metabolic syndrome. There are probably 30 – 50% of men with type-2 diabetes that have low T levels. Regarding the second part of your question, "Is it a fad?" my answer is 'no'. What has occurred over the last 15-20 years has been an appreciation within the medical community that there are a lot more men who may benefit from T therapy than had been previously appreciated. This, along with greater awareness among men about the importance of maintaining normal T levels and the symptoms associated with low T, has dramatically increased the number of physician visits by men to determine if they do in fact, have low T, and what treatment options are available. That is really what has been driving the market; greater awareness on the physician and general male population level, and evidence that you can safely give testosterone to these men and improve their symptoms.

"Our continued successful development, anticipated FDA approval and launch of CLR-610 will represent a major advance in the treatment options available for men with low T; and that is a great place for Clarus to be."

- Robert E. Dudley, Ph.D.

CEOCFO: Are there potential side effects or a downside to this therapy?

Dr. Dudley: Yes, four primary side effects come to mind. First, an increase in red blood cell count (the medical term is hematocrit) can occur and if this gets too high, your blood can become sluggish which increases the risk of stroke. However, in my experience, this is very rare when T replacement is properly managed. Another side effect is fluid retention and you have to watch for that in individuals with heart, liver and/or kidney disease. Third, some men may experience an increase in breast tissue since some of the T is naturally converted to estrogen. Last but not least, an increase in prostate size or stimulation of an already present but undetected prostate cancer can occur. Consequently, men on T therapy need to be regularly monitored for side effects. Overall, when men have low T and the therapy is appropriate—that is T is replaced to the normal range, it is generally quite safe.

CEOCFO: Has the medical community been paying attention to Clarus?

Dr. Dudley: Yes and no, we purposely have flown below radar detection until we had something substantial to talk about and that is now. When we announced our preliminary Phase 3 data a little bit earlier in the fall, people might have known we were out there but perhaps did not appreciate how far we have moved the ball down the field. For those people, they now see that we are real and likely to be the company that brings a true oral T replacement product to market before other companies that are far behind us.

CEOCFO: What have you learned in the past in bringing products like this to market that you utilize or will be utilizing at Clarus that will help make a difference?

Dr. Dudley: As I noted earlier, my experience in having developed and launched AndroGel® will serve Clarus very well. Certain market dynamics have obviously changed from when we launched AndroGel®. For instance, AndroGel was launched only to endocrinologists and urologists but today the bulk of the prescriptions—probably 55-60% -- are coming from primary care physicians. What you see is an evolution within the prescribing universe. Primary care physicians are more comfortable with diagnosing low T and putting their patients

on appropriate therapy. For us to tap into this broader market with a product that our market research shows would be very well accepted given the ease of delivery, in many ways makes it much easier than when I introduced AndroGel®.

CEOCFO: What is the basic plan for commercialization? Will you be partnering, will you be going it alone; what have you decided?

Dr. Dudley: We have not decided anything yet. We are looking at various options that run the gambit from going alone, to partnering, to making ourselves open as an acquisition target. I would say all of those are things that are on the table right now.

CEOCFO: Will your current funding take you to where you need to be, or will Clarus Therapeutics look for funding as you go to commercialization?

Dr. Dudley: We are well funded now. Before we commercialize we would need to increase the level of funding. For now, our focus is the completion of Phase 3 development.

CEOCFO: Why should investors and people in the business and healthcare communities pay attention to Clarus Therapeutics today?

Dr. Dudley: There are some very good reasons to pay attention to Clarus. First, we have now demonstrated that we have a patent-protected product that is well in front of competitors and is likely to be first to market – just like AndroGel was with respect to T-gels. For people really in the know, our oral T product has the potential to be an absolute game changer. Secondly, the team here has a proven track record; several of us were involved in AndroGel® from the get go. We know this market and we know what it takes to successfully commercialize CLR-610. Third, the demographics of the market are such that you are seeing a compound annual growth rate for T replacement products in the U.S. that is increasing around 25-30% per year. That is a pretty attractive market in which to step in, again, with what we believe will be a real game-changing product.

CEOCFO: What should people remember most when reading about Clarus Therapeutics?

Dr. Dudley: It is an exciting and really interesting time for the T-replacement market. Our continued successful development, anticipated FDA approval and launch of CLR-610 will represent a major advance in the treatment options available for men with low T; and that is a great place for Clarus to be.

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