

Oral Testosterone Therapy for Hypogonadism



Will Robberts
Company President

About TesoRx Pharma, LLC.

TesoRx is a specialty pharma company developing the only bio- identical oral Testosterone therapy (TSX-002) to treat hypogonadism in men ("Low-T"). In early studies, TSX-002 has shown efficacy and a very strong safety profile. The compound is Phase 3 ready and has already met FDA endpoints in earlier studies. TesoRx intends to obtain FDA approval and launch TSX-002 by 2016. It is based out of Menlo Park with laboratories in California and a manufacturing facility in Clearwater, Florida.

Interview conducted by: Lynn Fosse, Senior Editor, CEOCFO Magazine

CEOCFO: Mr. Robberts, what is the concept at TesoRx Pharma?

Mr. Robberts: TesoRx is developing an oral Testosterone therapy using breakthrough technology that solves a complex problem that has been around for many decades. Currently, no oral testosterone has been approved by the FDA in the US to treat low testosterone, also known as Low T. Gel products and depot injections are currently the standard for treatment - even though they have significant drawbacks in regards to

safety and convenience. It is estimated that seventy percent of these patients would switch from the current treatments to a safe and convenient oral treatment if it were available. TesoRx intends to meet this massive need with the first pure Testosterone treatment that patients can take orally.

CEOCFO: Would you give us just a little background on low T? Why is it a problem? Why is it becoming more in the consciousness of people as well?

Mr. Robberts: Low testosterone, also known as Hypogonadism, is a very real disease that has been around for a long time. However, it is only in the last ten years or so that awareness has really picked up around this disease. The market is currently \$2.3 Billion in the USA alone and growing at more than 15% per year. Studies have shown that approximately thirty nine percent of men in the USA over forty five suffer from low testosterone. Of these patients, only a meager twelve percent currently receive treatment. More than ninety percent of these patients that are currently receiving treatment are using the gels and depot injections, even though there are significant safety and convenience issues with these treatments. The higher prevalence in use of the topical gels led the FDA in 2009 to place a black box warning on gel products due to the risk of secondary exposure since it is possible that one person can transfer Testosterone to another. For patients this is quite serious especially as it can potentially transfer to spouses, children or even grandchildren. Testosterone can actually be toxic for children under a certain age. Patients are also recommended to keep their shirts on after they have applied the gels and patients have complained odor and skin irritation. Depot injectables are no better: they are very painful and they normally require doctor's visits to administer. They have also been known to cause spikes in testosterone levels after administration. Despite these existing products having significant drawbacks, they are still being used by many patients because there is no safer or more convenient alternative that currently exists. With only a small percentage of men with low Testosterone being treated currently, we believe a safe and convenient oral treatment will further increase awareness and treatment rates among men with low Testosterone.

CEOCFO: What has been the challenge in creating an oral drug? What have you figured out at TesoRx that is allowing you to do so?

Mr. Robberts: Testosterone is a very difficult substance to dose orally. It is a poorly soluble hormone and a challenge to solubilize for oral delivery. In addition, it undergoes high first-pass metabolism, i.e. it is taken up by the liver and completely metabolized, providing no therapeutic benefit to the patient. TesoRx gets around these very basic problems with an enteric coated capsule that passes through the stomach intact and then breaks up in the intestines, where the contents are released, forming a complex that is easily absorbed by the lymphatic system. Once absorbed, the complex breaks up, releasing pure testosterone in the systemic circulation of the patient. TesoRx's novel formulation delivers bio- identical testosterone directly to patients with low Testosterone that increases Testosterone levels into the normal range. This technology is a big breakthrough as we know of no other company that has been able to dose pure Testosterone orally.

CEOCFO: *What is the science?*

Mr. Robberts: That earlier piece was really the basics of the science. To go another level down, TesoRx has developed a proprietary pro-liposomal formulation of Testosterone that allows for safe absorption of pure Testosterone into the body. When our enteric-coated capsule disintegrates in the intestines, the formulation is hydrated by the fluids in the intestines and spontaneously forms liposome T-complexes, which again are familiar substances to the human body. It is then absorbed through the lymphatic system and circulates through the body until it ultimately metabolizes via the liver, the same way that normal Testosterone would be metabolized.

CEOCFO: *Where are you in the development and regulatory process?*

Mr. Robberts: We are currently completing our Phase 2 clinical studies and have already shown that we can meet the FDA's primary endpoints. We plan on starting Phase 3 later this year under a 505(b)2 regulatory pathway, which is much less onerous than the standard registration process followed by new drugs based on new molecular entities. We will be meeting the FDA at the end of Q3 in an End of Phase 2 meeting, finalize our protocol and commence our pivotal Phase 3 study before year-end.

CEOCFO: *Are other companies working in a similar approach that might ultimately come into play when you are ready to market?*

Mr. Robberts: There are other oral products in development, although there is not one that doses pure testosterone like TesoRx does. Most of these products are based on adding fatty molecules to the Testosterone molecule to form Testosterone Undecanoates. Testosterone Undecanoate products have been available for many years overseas but have never been approved by the FDA due to concerns about liver toxicity. These treatments also require that patients have high fat meals with every dose to achieve absorption, which will clearly be problematic for many patients that have dietary restrictions or eat healthily. There is also a product that stimulates the body to produce more testosterone, but the trials for this product have excluded patients over the age of sixty and patients with a higher body mass index. We do not see this product addressing the bulk of the market, given that age is the number one driver for low Testosterone. Based on our Phase 2 trials, we believe that our product will have a much better safety profile.

“TesoRx is creating a breakthrough therapy that addresses a massive unmet need - to provide a safe and convenient oral treatment for patients suffering from low Testosterone. Unlike any other product, it will dose bio-identical Testosterone orally which delivers many safety benefits to patients over currently available treatments and those in development.”

- Will Robberts

CEOCFO: *Would you tell us what you and the team have learned from previous ventures that have been most helpful in the science part and also in the business and regulatory areas?*

Mr. Robberts: We are very fortunate in having a CEO, Dr. TR Thirucote, who has previously been involved with taking numerous drugs from bench to market. He has more than thirty years experience in the industry. In his last venture he was pivotal in bringing a drug called SPRIX™ to the market from conducting early studies all the way through obtaining FDA approval and scaling it for commercial release. We are fortunate to have a very experienced CEO and a very experienced team. The inventor of our product is Dr. Guru Betageri from Western University of Health Sciences in Pomona, California. Dr. Betageri is known as a key thought leader on liposomal drug delivery and our compound, TSX-002, is the result of many years of hard work in his laboratory. He has spent the last fifteen years perfecting this technology and we are delighted to finally bring it to market. We are very serious when it comes to drug development and have a team with strong scientific and regulatory experience who want to see this product be made available to patients!

CEOCFO: *Is the delivery method applicable for other conditions, other drugs?*

Mr. Robberts: Our technology could represent a breakthrough for drug delivery and can serve as a platform for poorly soluble molecules that can't be delivered orally. We are open to exploring the dosing of other drugs as well, especially with a view to not just the US market, but also internationally.

CEOCFO: *Are you funded to get through the next steps or will you be seeking funding or partnerships?*

Mr. Robberts: We are funded well into our Phase III studies by existing investors and would entertain a strategic pharmaceutical partner to be involved in our Phase 3 study and ultimately, in taking the product to the widest market possible.

CEOCFO: *Different conditions, different types of pharma or different types of healthcare are in favor with investors in different points in time. Is low T something the investment community and the medical community are paying attention to right now?*

Mr. Robberts: Very much so. The Low-Testosterone market has grown from a very small market 14 years ago to \$2.7 Billion in 2013 internationally. The US still represents the bulk of this market at \$2.3 Billion and is showing signs of further growth. There is such great anticipation of the next generation of oral Testosterone treatments that two companies have already gone public, primarily on the basis of having oral Testosterone products in development. Both of them were well received by investors and we will certainly be open to that road if the market conditions were advantageous.

CEOCFO: *What is the end plan for you?*

Mr. Robberts: Ultimately, we believe the product will benefit greatly from the reach of a strategic partner, such as a larger pharmaceutical company, when it comes to the commercialization of TSX-002. That being said, given the strength and the depth of our team and the quality of our platform technology, we are prepared to scale the business so we could sell and market the product ourselves.

CEOCFO: *Why does TesoRx Pharma stand out in a crowded healthcare?*

Mr. Robberts: TesoRx is creating a breakthrough therapy that addresses a massive unmet need - to provide a safe and convenient oral treatment for patients suffering from low Testosterone. Unlike any other product, it will dose bio-identical Testosterone orally which delivers many safety benefits to patients over currently available treatments and those in development.

BIO: Willem A Robberts C.A. (SA), M.Comm(RAU) — Company President

As a C-Level Executive, Robberts has been an integral part of the accelerated growth of numerous companies in the industries of biotech, software and professional services. Prior to TesoRx, Robberts was the COO of Softline AccountMate Software (acquired by Sage Accounting), President of LiveNote Software (acquired by Thomson Reuters) and served as the Senior Vice President of Esquire Deposition Service (bought by HIG), leading over 50 offices across the country. Will began his career with KPMG Corporate Finance, where he focused on M&A transactions, divestitures, fundraisings and IPOs in the technology and media markets.

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