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**Drug Delivery Company, TheraKine, Ltd. is focused on developing an Injectable Sustained Release Technology that would allow any Biological Drug to be formulated for Months of Stability and Controlled Release and then Delivered Locally by Placing the Drug in the Target Organ or in a Bolus for Systemic Delivery**

**Healthcare  
Drug Delivery**

**TheraKine, Ltd.  
245 33rd St.  
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**Stan Yakatan  
CEO**

**BIO:**

After 40 years as a successful CEO, entrepreneur, and operational manager, Stan Yakatan has dedicated the last 15 years of his career to sharing his experiences with management teams interested in building technology-based companies. His experience as an executive is far reaching; he has served in an Executive capacity with: New England Nuclear, El DuPont, ICN Pharma, New Brunswick Scientific, Biosearch, and Katan Associates.

These experiences have provided

him with management skills and a corporate finance acumen that he enjoys sharing with others.

He has founded or co-founded in excess of 15 companies in the United States, Canada, Israel, France and Germany and in many cases served as the initial CEO, and Chairman of these companies. He currently sits on the board of directors of several public and private companies and has advised several of the world's leading venture capital firms including TVM (Germany), Ventana (USA), MSP (USA) and Biocapital (Canada). During the decade of the 1990's Biocapital was the most successful health care venture capital fund in Canada.

From 2002 to 2008 Stan served in a business development capacity for the XL TechGroup. XL Tech Group systematically discovers unmet business needs, then creates, selects, and develops new technology businesses, and scales them to liquidity. Stan assisted XL TechGroup in the development of its business model, and advised on the overall capitalization strategy for XL Tech Group. In the aggregate, XL TechGroup and its related companies raised in excess of \$300.0 million.

Stan has served as a Senior Advisor in Life Sciences to numerous State, Provincial and Federal government agencies. These roles have been largely in an effort to assist in the development of government incentives and initiatives to foster and develop regional Life Science clusters. These efforts include work in Canada from

1993 to 1999, Israel from 1999 to 2001, and Victoria, Australia from 2002 to 2008.

Stan has completed and advised on numerous acquisitions and corporate finance transactions raising in excess of \$1.0 billion dollars in the public and private capital financing markets. He is a frequent speaker at financial and biotechnology conferences throughout the world speaking on topics including, "Capital Raising for the Technology-Based Start-Up" and "The Need to be Global in the Quest for Capital and Partners". Rick Biondi, Editor of Lab Business Magazine stated, "Mr. Yakatan is a venture capital raising Guru and it is part of his genetic makeup."

Stan founded and served as the Executive Director and Chairman of Biocomm, in Melbourne, Australia, the first of its kind regional business development agency and early-stage capital pool. Stan currently is Chairman of the Board of Mercury Therapeutics, Inc. developing new AMP kinase based drugs for the treatment of diabetes and cancer and sits on the Board of Directors for Phenomenome Discoveries, Inc., a novel biomarker company. Recently Stan was appointed to the Teaching Faculty at Skolkovo School of Management in Moscow.

Stan currently serves as CEO of TheraKine, Ltd., a privately held company with a novel drug delivery technology for biologics and small molecules that address drug delivery challenges in multiple therapeutic areas.

## **About TheraKine, Ltd.:**

TheraKine's toolbox of sustained release technologies allows custom tunable formulations with weeks to months of predictable release. Tunable release makes it possible to satisfy any therapeutic need - linear, burst release, and decay release can be combined if required. The technologies have been validated with monoclonal antibodies, antibody fragments, receptor antagonists, and other large molecule drugs as well as class small molecules. Significantly, the bioactivity of the source drug is well preserved through the entire release duration.

**Interview conducted by:  
Lynn Fosse, Senior Editor  
CEOFCO Magazine**

**CEOFCO:** Mr. Yakatan, would you tell us about TheraKine? What is the basic concept?

**Mr. Yakatan:** The basic concept is a drug delivery company with some very novel approaches. It can deliver biologicals, it can deliver small molecules, and the technology allows them to be applied or injected directly at the site where their therapeutic effect is needed. We can extend the life of virtually any drug up to six months in a single injection with any desired dose and release.

**CEOFCO:** What are the current delivery methods?

**Mr. Yakatan:** Let me try to put it in a concept that makes sense. The problem with most biological drugs is that they have to be injected or infused repeatedly, and depending on the drug, daily or weekly injections are pretty much the norm. This limits the potential indications of many drugs. It is also very inconvenient for the patient, and very expensive for the healthcare system. We undertook the development of an injectable sustained release technology that would then allow any biological drug to be formulated for months of stability and controlled release, locally, by placing the drug in the target organ or in a bolus for systemic delivery.

**CEOFCO:** What have you figured out that others have not?

**Mr. Yakatan:** In simple forms, we figured out a way to take an existing drug and extend its life, whether it is hydrophobic or hydrophilic. We can then place, for example, a six months supply of the drug directly into the body and have it released exactly when it needs to be. What is unique is that we use physics, instead of modifying the drug chemically: we mechanically form biopolymers or biopolymer derivatives using only already approved additives. Then we modify those carefully under controlled conditions. Then we create a number of cycles of pressing and kneading that transform the mixture of ingredients into a polymer elastic body of high stability.

**CEOFCO:** Whatever is happening in the body is not going to affect that release mechanism?

**Mr. Yakatan:** Not in any way shape or form. That is because that everything we use, beside the drug itself that gets added to our material, is generally accepted as safe, or what the FDA calls GRAS, Generally Recommended As Safe. Therefore, we do not affect any of the bodily functions, at all. By injecting directly into a site we also avoid all of the systemic side effects that are caused by most drugs.

**CEOFCO:** What was the biggest stumbling block in figuring this out?

**Mr. Yakatan:** The easiest way to answer that is; think about making a croissant. When you make a croissant it is folded and folded and folded many, many times. To get the therapeutic to be evenly distributed through our matrix, we had to develop folding and blending processes that gave the right properties. That took a couple of years to actually figure out and then refine to develop a patented methodology that was repeatable.

**CEOFCO:** Has the medical community been paying attention?

**Mr. Yakatan:** One of the reasons why I got involved with TheraKine is that for about the last four years it has really been an R&D project, and it has been focused on a particular drug in the ophthalmology area that is used for age related macular degeneration. That drug required quite frequent in-

jections in the human eye. The company undertook an R&D project to figure out how we could improve that interval from every few weeks to many months. As a result of that work that was done was very internalized. It has never gone out to the market place for capital. It has done most of its work on an R&D grant. When I found out about this technology about four or five months ago I said, "Maybe I should come out of retirement", and to; in answer to your question, make the medical community aware of this. We went to the Biotech Showcase in

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**- Stan Yakatan**

San Francisco and we had forty-five companies who were interested in learning more about the technology. Therefore, in the last three or four months, more people have known about the company than in the past four of five years.

**CEOFCO:** What are the next steps? What is your plan?

**Mr. Yakatan:** We are focusing on continuing to develop the technology and broaden its base. We are now in the process of looking at how we can do peptides and other drugs. We are looking at how we can expand other activities. We have undertaken a pro-

gram where we are actually doing a feasibility study on several products to determine whether or not our technology has impact there. We would like to find one partner in 2013 where we can demonstrate the performance of this product, all the way through animal trials. We want to get a drug master file on our matrix filed with the FDA. We are currently doing a small capital raise to facilitate those activities.

**CEO CFO:** Will you need to bring other people on board, or are you able to man the whole effort?

**Mr. Yakatan:** Yes, we need to bring more people on board. We have a limited staff right now. The company itself is made up of five or six people, including myself. By the end of the year I would like it to be at ten.

**CEO CFO:** You have, as you mentioned, a long history in the industry. What are the most important things that you have learned over the years that will be applicable as you go forward with TheraKine?

**Mr. Yakatan:** I think the key, especially in this type of technology, is being able to demonstrate the improvement that it brings to existing molecules. We are not a drug company, so we are not out developing our own drugs. We are taking other peoples drugs and we are making them work better and safer. You have to be able to really demonstrate that, and sometimes that is more difficult than developing a drug.

That is because you can promise everything in developing a drug, but once your technology does not work in this space you are done. We have just

begun a program of really trying to demonstrate that what we have is what we say we have. If you are familiar with drug delivery, some things work and some things do not work. This, to me, is extremely revolutionary, and that is one of the reasons that I got involved with the company.

**CEO CFO:** What makes you so sure?

**Mr. Yakatan:** The early data. We have demonstrated this already in a major drug that is used in macular degeneration; AMD as it is referred to in the medical community. In addition, we have already demonstrated it in a series of monoclonal antibodies. We have also demonstrated it to the Air Force. We are working with them on an ophthalmology project. I would say that the early data that was generated while the company was focusing on R&D has absolutely convinced me, and is starting to convince others that this really does work.

**CEO CFO:** What are you going to do in the next two months?

**Mr. Yakatan:** In the next two months we are beginning a program to determine the feasibility of this technology with two peptides that have revenue in the multi-hundreds of millions of dollars. They are now given on a single injection basis quite frequently, and if we can demonstrate the expansion of that, that will be another milestone. We also have begun a large animal study program in Oregon to demonstrate the feasibility of this in particular diseases, both human and animal. We are moving forward with at least six large pharma companies that have expressed interest in learning more about our technology.

**CEO CFO:** You mentioned a small raise. Is drug delivery in favor these days? It seems that the investment community runs in cycles.

**Mr. Yakatan:** Biotech is like fashion. One year miniskirts are in, another year ankle length skirts are in, skinny ties, and so on. I think drug delivery has always been in vogue. The problem with drug delivery is that everyone and their mother claim that what they have can do things, and people do not have enough data to demonstrate that they can do it. That is why I have decided to go out and just raise enough money to achieve one or two milestones, demonstration of this in particular feasibility in certain compounds, maybe one biological, and begin the animal trials. Then, once we can demonstrate, not only the feasibility and the proof of principle, but also the fact that our claims are all validatable, then we will go out and get a large amount of capital.

**CEO CFO:** Why does TheraKine stand out for investors and people in the business community?

**Mr. Yakatan:** We stand out because we have one of the most novel and interesting technologies in drug delivery. We have the only system that doesn't damage biologic or sensitive drugs. We have the only tunable, targeted drug delivery technology for injectable drugs. We can also develop it for ointments and creams as well, but right now we are focusing in the injectable area.



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