

TheraKine's newsletter
for investors, advisors,
and interested parties.



Changes

Scott Hampton, Founder and C.O.O.

If the first rule for success in academia is "Publish or perish," the first rule in BioTech is "Patent or perish." To this end, TheraKine's focus for the last year has been on animal trials, technology development and patents. We have been, and continue to be, working on a number of new filings designed to expand our portfolio basis. Some of these patents are of interest to certain pharmaceutical companies, while others are for novel formulation methods that are being developed in our new Berlin laboratory.

In October of last year we founded TheraKine BioDelivery (TKBD), a wholly owned subsidiary of TheraKine. TKBD will be the technology arm of TheraKine, with laboratory and offices in Berlin. Andreas Voigt, PhD and formulations expert, has joined us as Senior Scientist and Director of TKBD. Dr. Voigt will be directing all development activities in Berlin, from the selection of scientific staff to the planning and execution of all projects. Having our own facilities

In This Issue:

- *Introduction to our new team members*
- *The partnership market and opportunities*
- *Announcing our new technology arm: TheraKine BioDelivery GmbH, Berlin*
- *EpiKine™ USAF Trial Update*
- *OptiKine™ Akita Dog Safety and Tolerability Study Update*

will enable us to move through the commercialization process much faster.

Through TheraKine BioDelivery, we now qualify for a variety of German and Berlin-area grants and incentives, which we are currently pursuing. This non-dilutive long term funding was one of the key factors in our selection of Berlin for the technology arm of the company. Another factor was the location of the new TKBD office and laboratory in the Adlershof district — the science and technology hub of Berlin. The area provides

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countless advantages, including access to almost every supporting resource we might need, the availability of many talented scientists and technicians, and relatively low costs for space. The location has also allowed us the opportunity to collaborate with The Charité, one of the largest university hospitals in Europe, connected to Universitätsmedizin Berlin and Humboldt University.

In the last year, we have transformed TheraKine from a virtual firm into one that has resources and talent dedicated full time to the realization of our goal: creating drug delivery systems that will keep millions of people from losing vision.

Growing the Team

Jerry Seelig, Senior Advisor for Business Development

Over the past six months TheraKine has added three wonderfully talented people to our team. The Board of Directors has two new members: Thomas Bliss, who is also our new CEO, and C. David Adair, M.D. In Berlin, Andreas Voigt, PhD, formerly of Capsulation, has joined as Chief Scientist of our new development entity, TheraKine BioDelivery GmbH.

In early 2009, Tom Bliss joined TheraKine as acting CEO and was named as the permanent CEO and Director later in the year. Tom has vast experience on the business side of BioTech, from his time working both for big pharmaceuticals and as an advisor to, and participant in, a wide range of entrepreneurial efforts. Tom has held senior licensing and acquisition positions at Amgen, Baxter Bioscience and Johnson +Johnson.



Tom Bliss

C. David Adair, M.D. joined the TheraKine Board of Directors in 2009. David is an investor in the company's angel financing round and has assisted the company in attracting multiple investors. David is board certified in both Maternal-Fetal Medicine and Obstetrics and Gynecology. He is a well-recognized expert in both fields and has established one of the South's largest Maternal-Fetal Medicine groups. David serves as a senior faculty member and clinician at the University of Tennessee's Knoxville and Chattanooga medical campuses.



Dr. David Adair

In addition to being a clinician and academic, David is also an equally successful entrepreneur. David founded Glenveigh Medical where he currently serves as Chief Science Officer and Chairman of Board. Glenveigh Medical is the parent company of Glenveigh Pharmaceuticals, Glenveigh Surgical, and Glenveigh Research. All three subdivisions are engaged in the development of devices, therapeutics, and diagnostics in the area of Maternal-Fetal Medicine. Ther

Our second Andreas, Andreas Voigt, PhD (or "AV," as we call him) is an international expert in the field of Layer-by-Layer (LBL) encapsulation technology. AV's success with LBL

attracted us to Capsulation Pharma AG, who TheraKine contracted for OptiKine research and development from 2007 to 2009. AV was a Founder, Director and Chief Science Officer of Capsulation. A few months after leaving Capsulation, in the fall of 2009, AV joined TheraKine to establish and direct TheraKine BioDelivery GmbH.

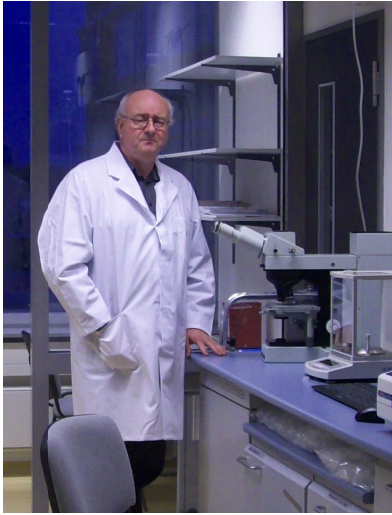
Disease or Condition	Product	Patients
Corneal injury	EpiKine Topical Eye Drops	1.1 million
LASIK, PRK, and other LVC		1.5 million
Uveitis and related diseases	OptiKine Injectable sustained release Implant	450,000
Diabetic Macular Edema		3.6 million
Macular Degeneration (AMD)	AngioKine Injectable sustained release Implant	16.0 million
Diabetic Retinopathies (DRP)		5.3 million
Total USA		28 million

TheraKine's Partnership Potential

Tom Bliss, C.E.O.

Following the JPMorgan Health Care Conference in January, it has become clear to TheraKine that there are a variety of interests in drug delivery to the back of the eye beyond our original recognition. These interests can be broken down into roughly three types: first, there are companies with a presence in ophthalmological market that want to expand the utility of the existing standard of care. These companies are interested in improved administration such as kinetics adjustments and sustained release. Second, there are companies with novel therapeutics willing to take on the challenge of taking multiple variables simultaneously through the regulatory process. These companies are convinced of the value proposition of their novel therapies and believe the known elements of TheraKine's delivery system will result in superior therapeutics. Finally, there are the companies with a similar vision to TheraKine, ones interested in bringing known, validated mechanisms to diseases of the eye.

As a development-stage company, TheraKine, like most BioTech companies, has limited functionality and resources. Large biopharmaceutical partners have entire departments dedicated to the characterization of a drug candidate, its safety, or lack thereof, and the understanding of its absorption, distribution, metabolism and excretion. Without Drug Metabolism and Pharmacokinetics (DMPK), Analytical, or Toxicological departments, TheraKine has been able to gather only limited information on our pipeline products. TheraKine currently lacks some of the information large biopharmaceutical companies consider essential in advancing a drug candidate into human clinical trials. Even in the instance of approved drugs, such as anti-TNF mAb and TheraKine's known excipients, this information is seen as a requirement



Dr. Andreas Voigt in the new TheraKine BioDelivery lab in Berlin

because of the novelty of the combination. As a result, partnering discussions are caught in the middle of testing EpiKine™ and OptiKine™ and potential partners' desire for the more complete data they're accustomed to before beginning human clinical trials. The solution to this balancing act has been the feasibility study. Currently, TheraKine has twelve such discussions ongoing, ten of which are with leading

biopharmaceutical companies and two with development-stage companies. These studies will accomplish two things. First, they will provide TheraKine with near-term operating income. Second, they will further validate TheraKine's approach by providing the data required by large biopharmaceutical partners.

Initial discussions have shown that there is a desire by numerous parties to partner with TheraKine in gathering this data. Early feedback indicates that our potential partners have a unified interest in being able to deliver to the back of the eye with TheraKine's unique delivery approach. It is also apparent that a large part of TheraKine's appeals lies with the fact that each delivery system is custom-designed to the therapeutic. For partners, TheraKine's system offers unique design, functionality and intellectual property solutions.

TheraKine BioDelivery

Andreas Voigt, PhD Senior Scientist, TheraKine BioDelivery GmbH

In October 2009, TheraKine BioDelivery GmbH (TKBD), the technological development arm of TheraKine, was founded in Berlin, Germany. TKBD's primarily goals are: 1) laying the foundations for structure and formulation routes and 2) expanding the intellectual property of TheraKine's focused product developments. To achieve this, TKBD has established an office and laboratory in Germany's largest science and technology park, the Wissenschafts- und Technologiepark in Adlershof, Berlin.

The new TKBD laboratory's main purpose is to develop finely tuned sustained antibody delivery systems. The laboratory will form the central experimental unit in a network of corporations within the US, Ireland and Germany. Due to its location in Berlin's science and technology district, TKBD has accrued a strong relationship with the development department for microparticulate carrier at The Charité, one of the largest university hospitals in Europe. The Charité's development department will conduct diverse biological tests of proprietary TheraKine formulations such as release characterization of

active antibodies. These formulation activities are built both on TheraKine's existing achievements and innovative methods.

The year ahead will be a busy one for TKBD. We recently filed a series of applications for research and development grants with Investitionsbank Berlin (IBB) and other German sponsorship organizations. The grant money is geared to support the antibody formulations. Further development of formulations and optimizations of existing technologies is progressing nicely in the Berlin lab. TKBD also anticipates the creation of substantial new Intellectual Property for the continued strengthening of TheraKine's IP basis.

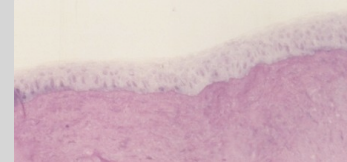
EpiKine's™ USAF Trials

Phillip Buscemi, OD, Head of Marketing

Last year TheraKine, in partnership with the United States Air Force (USAF), conducted a study on one of the formulations of EpiKine™. EpiKine™ is a topical drop or gel in a timed-release format that is designed to help control corneal wound healing after refractive surgery. EpiKine™ does this by limiting the effects of Interleukin 1 (IL-1), a cytokine that is part of the body's inflammatory response during corneal healing.

EpiKine: is a topical formulation of anti IL-1

Treated Cornea



Clean, healthy boundary, no haze/scar

Vs.



"Foam," voids, debris and collagen

The USAF study was a test of EpiKine's™ efficacy at improving corneal wound healing after refractive surgery, as compared to commonly used steroids. These steroids are the current standard of care for controlling inflammation and helping manage outcomes after refractive surgery and corneal injury. They can, however, have significant side effects, including increased intra-ocular pressure causing glaucoma, cataracts and increased risk of ocular infection.

Aberrant healing is such a considerable variable in the outcome of refractive surgery. Controlling healing will increase predictability of the procedure and is necessary for some of the newer treatments that are being developed. The armed forces

and the Air Force in particular, would benefit greatly by being able to perform refractive surgery on their war fighters. The Air Force spends tens of millions of dollars training each pilot. If a pilot's refractive error changes, causing less than optimal vision, this substantial investment can be lost.

The EpiKine™ study began by performing PRK, a refractive surgery that does not cut a flap in the epithelium like LASIK, on both eyes of the test subjects (rabbits). For seven weeks following PRK, Interleukin-1 inhibitor (IL-1ra) eye drops in different concentrations were applied to the subject's eyes at regular intervals. The animals were treated with 10 mg/ml, 5 mg/ml, or 1 mg/ml four times a day. The other eye of the test subject was treated with a steroid eye drop.

The researchers used a Scheimpflug Camera to record the reflectivity of the cornea. This was a test for corneal hazing—an unwanted side effect of the healing process. The higher the reflectivity, the more haze, and the more haze, the worse the healing. The Scheimpflug Camera readings then were compared to histological sections of the corneas.

The results showed that the two lower concentrations of EpiKine proved to be as effective as steroids in controlling the inflammatory response without any side effects. These results confirmed both the initial USAF study and an earlier EpiKine™ study at the University of Crete School of Medicine. It is these series of tests that leads TheraKine to believe that EpiKine™ will one day supplement, if not replace completely, topical steroids used for corneal wound healing.

The one surprising aspect of the test was that the higher EpiKine™ concentrations were less effective than the lower concentrations. The reasons for this are not yet clear, though the high efficacy of the lower concentrations is potentially beneficial. The lower the amount of drug required, the lower the cost and the greater the ease in packaging the formulation in TheraKine's timed-release delivery technology.

TheraKine hopes to continue studies with our researchers in Crete and the USAF. We are attempting to organize a multi-centered study to provide a larger group to achieve higher statistical reliability of our results and to collaborate on different techniques employed for analysis.

OptiKine™ Study and Developing Biologics

Andreas Reiff, MD, C.S.O.

TheraKine's study on the safety and tolerability of intraocular anti-Tumor Necrosis Factor (TNF α) in an OptiKine™ formulation, done in Akita dogs with canine uveitis, is moving forward successfully. Six dogs (seven eyes) have been injected so far, with observation periods averaging about nine weeks (range: 3-16 weeks). Preliminary results suggest that the system is well tolerated, and no safety concerns have been observed. Even though the injected eyes already had permanent vision loss, some of them had residual inflammation, which was resolved after the injection of the polyelectrolytes. Post injection, there was no evidence of either increased intra-ocular pressure (IOP) or retinal toxicity (as measured by fluorescein angiography).

Treated Eye	F/U in weeks*	ACD by slit lamp		IOP (OS/OD)	
		Base-line	Last exam	Base-line	Last exam
OS	6	Normal	No cells/flare	9 mmHg	7 mmHg
OS	10	2/4 cells	2/4 cells, no flare	6 mmHg	14 mmHg
OD	14	normal	No cells/flare	6 mmHg	6 mmHg
OS	16	normal	No cells/flare	4 mmHg	8 mmHg
OD	4	2/4 cells	1/4 cells, immature cataract	16 mmHg	13 mmHg
OD & OS	3	1/4 cells	No cells/flare	66/13 mmHg	3/17 mmHg

*At time of last exam

A quick update on the latest biologics: Certolizumab, an anti-TNF α fragment, was recently approved as the fifth anti-TNF α agent for Crohn's disease and rheumatoid arthritis. Centocor's intravenous golimumab, a fully human anti-TNF α antibody is in phase III and is expected to replace its internal competitor Remicade in the near future. Roche's tocilizumab, an inhibitor to the interleukin (IL-) 6 receptor, has also received its approval for rheumatoid arthritis and is rapidly moving phase III trials in periodic fever syndromes including systemic arthritis. This drug will open a new alternative strategy for patients unresponsive to anti-TNF α treatment.

Since IL-6 is stimulating IL-1 and TNF α production, it may also play an important role in the treatment of inflammatory eye diseases. Similarly, Genentech's ustekinumab, an IL-12/23 inhibitor, has been approved for the treatment of psoriasis. The IL12/23 pathway is critical in the development of VKH-syndrome, another form of autoimmune uveitis.

Co-stimulatory molecule inhibitors such as BMS's abatacept, which has been approved for arthritis, is evolving as a successful drug in patients with systemic lupus and renal involvement. While multiple new targets continue to be identified, small molecule, intracellular cellular signal inhibitors such as JAK and STAT inhibitors are rapidly moving through clinical trials in rheumatoid arthritis and preliminary results suggest that this new generation of "biologics" are at least as effective as classical biologics but can be given orally.

