

# ITEK prescribes path to success for drug delivery breakthrough



The commercialisation company  
of the University of South Australia

## CASE STUDY

### **Business name**

**LipoCeramic™ Technologies**

### **Industry**

**Pharmaceutical**

### **Executive summary**

Innovative drug delivery technology is on the threshold for huge worldwide sales due to a long-term partnership between researchers at the University of South Australia's Ian Wark Research Institute and the university's commercialisation arm, ITEK

### **Business opportunity**

ITEK is working closely with the University of South Australia's Ian Wark Research Institute to commercialise an innovative drug delivery technology with huge potential for worldwide sales.

Led by the institute's Professor Clive Prestidge, a research team over the past six years has developed a unique mechanism for administering poorly soluble drugs to patients.

Called LipoCeramic™ Technologies, the drug delivery system increases the body's ability to absorb poorly soluble drugs. This bioavailability is increased by administering the drug in a nanoparticle-coated capsule with a matrix structure that provides a much larger surface area than traditional tablets.

Poorly soluble drugs comprise about 40 per cent of formulations produced by the multi-billion-dollar global pharmaceutical industry. Increasing the absorption rate of these drugs represents a huge commercial opportunity through reviving previously abandoned drug formulations, re-inventing end-of-life products into new formulations and improving the viability of new product lines.

The name "LipoCeramic" is derived from "lipo", which describes the fat or oil that active drug compounds are dissolved in to assist absorption, combined with the "ceramic"-like qualities of "nanoparticles".

Professor Prestidge said the LipoCeramic™ breakthrough had the potential for significant success in the global pharmaceutical industry. "Big Pharma has a long pipeline of new molecules," he said. "Introducing a new chemical entity to market can cost \$1 billion. Some of these compounds fail

to get to final phase because of the solubility challenge – they have good efficacy but poor delivery. This innovation can keep that pipeline flowing."

### **ITEK's role**

ITEK became involved with the LipoCeramic™ breakthrough in 2002-2003 when the research was in its early stages. Since then, ITEK has assisted the research team to gain funding and investment of nearly \$1 million to take the innovative drug delivery technology from concept to a viable commercial opportunity.

As well as \$200,000 in direct funding from ITEK to develop basic prototypes, ITEK has leveraged other grants including \$100,000 from BioInnovation SA, \$200,000 from an NHMRC Development grant and \$300,000 from an ARC Discovery Grant.

ITEK has also invested an additional \$130,000 to assist the research team to establish patent protection for the Intellectual Property (IP) it has developed. As a result, the University of South Australia has filed four patent "families" based on the LipoCeramic™ breakthrough. A patent "family" is a series of applications for patents in multiple territories based on a core set of Intellectual Property. Three of these applications are in the National Phase in Australia and other countries while the fourth is in the preliminary PCT (Patent Cooperation Treaty) phase and scheduled to enter the National phase in the third quarter of this year.

ITEK has also assisted LipoCeramic™ Technologies to identify opportunities in the global pharmaceutical market and develop a commercialisation strategy to capitalise on its innovation. For example, in March 2006, ITEK commissioned the Australian Institute of Commercialisation to prepare a thorough market research report on the drug delivery market. As well as direct investment, access to grant funding and patent funding, ITEK has facilitated introductions for LipoCeramic™ Technologies to potential commercial partners and assisted its team members to attend key industry conferences and events.



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**Professor Clive Prestidge**  
*Ian Wark Research Institute  
University of South Australia*

Professor Prestidge said ITEK’s initial involvement was purely to protect the IP. “This was critical in terms of financial support and liaison with patent attorneys,” he said.

“That process has cost more than \$100,000. That direct support has been absolutely critical: Otherwise we wouldn’t have been able to protect the IP. As the whole business opportunity developed, we benefitted greatly from the support of ITEK in terms of looking at commercial opportunities, defining business cases and helping attract additional funding.”

### **Business benefits**

One of the biggest challenges faced by LipoCeramic™ Technologies is the size of the commercial opportunity it faces. As well as a global market with hundreds of billions of dollars in sales annually, the innovation addresses multiple business opportunities within each market segment.

ITEK has assisted LipoCeramic™ Technologies to protect its IP – essential for commercial viability – and to plan a roadmap with multiple paths to successfully commercialising its innovation.

Current commercialisation options for the technology include direct licensing of its technology to drug delivery and drug discovery companies; creation of a contract research organisation to provide a service-for-fee and / or license-for-use for pharmaceutical companies seeking to improve the solubility of their existing drug formulations; and creation of a start-up company to fund and progress several promising reformulated drug candidates to market.

ITEK has provided the business skills, access to professional services and the commercial “sounding board” that has enabled LipoCeramic™ Technologies to develop a business plan that pursues each of these approaches concurrently to maximise its chances of success.

ITEK has assisted the research team to identify a path that involves partnering with larger companies in order to develop specific applications of the LipoCeramic™ technology as a way to build both credibility and market presence for its innovative approach.

Professor Prestidge said the LipoCeramic™ breakthrough offered a “truly platform technology”. “The poorly soluble drug market is worth multiple tens of billions a year,” he said.

“This means we need to target carefully and requires lots of reviewing. ITEK has helped all the way through by searching for opportunities. As the technology has become more mature, ITEK has funded consultants in the drug delivery area, reviewing the technology with a view to its commercial opportunities. ITEK has spent significant funds on identifying a guaranteed accurate regulatory pathway for this technology.”

### **Future opportunities**

LipoCeramic™ Technologies has developed a commercially promising solution to a well recognised problem within the global pharmaceutical industry. While many companies may discover drugs that succeed in producing the desired effect, poor solubility often undermines the commercial viability of these compounds.

In the US alone, the 2007 drug delivery market was worth more than \$40 billion, with oral drug delivery accounting for 55 per cent of the total. A key factor for growth in the pharmaceutical industry is strong demand for reformulating and optimising both new and old drugs.

In these competitive markets, LipoCeramic™ Technologies has developed a new delivery system with the potential for strong impact if it gains visibility with major pharmaceutical firms.

Professor Prestidge said ITEK’s involvement had contributed significantly to building the business viability of LipoCeramic™ Technologies. “Our chances of success are very high,” he said.

“ITEK’s involvement has been vital in terms of making it successful and taking the technology to market. It is also assisting us with the critical steps of establishing the best possible structure for commercialising this complex technology, assisting to raise funds and putting in place the right business team. “Over the past five or six years, we’ve had more than half a million in investment from ITEK. Early stage financial support is vital. Without ITEK’s assistance, we would not be where we are today.”

To learn more about ITEK, visit [www.itek.com.au](http://www.itek.com.au)