

Executive Summary

- **Clinical Stage Reformulation Company**
- **Commercialising Versatile Encapsulation platform**
- **Founder & Inventor is Clive Prestidge**
- **World Class Team**
- **Global Regulatory and Marketing Approach**
- **Technology is Safe and Effective**
- **Human Trials Started in Q4'10**

Executive Team

CEO
Gregor Rozenberg PhD BSc(hons) FilKand GAICD
 Gregor was the Senior Investment Manager at Queensland BioCapital Fund from 2003 to 2008. QBF is a \$100m closed-end biotech focused venture fund and a subsidiary of QIC and \$80Bn funds manager. Gregor has more than a decade of international financial and business management experience and has for the last eight years been managing companies as part of venture fund management. Prior to that he held business development related positions in novel technology companies in UK and Australia. He has held academic positions at Imperial College University of London and University of Cambridge UK and is a graduate member of the Australian Institute of Company Directors. Dr. Rozenberg Board experience as a Director and Observer include; Cellix Pty Ltd (Sydney AUS), Columna Pty Ltd (Sydney AUS), Gelesis Inc. (Boston US & Rehevoot IL), Protagonist Therapeutics Inc. (Brisbane AUS & Silicon Valley US), Satori Pharmaceuticals Inc. (Boston US), Tokai Pharmaceuticals Inc. (Cambridge US), Xenome Pty Ltd (Brisbane AUS & San Diego US) and Advent Pty Ltd (Melbourne AUS). He is also Senior Advisor with a New York based healthcare investment bank and founding managing director of Rozenberg & Co a biotech and venture consulting firm specialising in providing strategic regulatory and clinical advice. He obtained BSc (hons) from Lund University Sweden, was an Erasmus scholar at Debye Institute Utrecht University Netherlands and received PhD from Queen Mary College, University of London UK.

CTO
Clive Prestidge Prof. PhD BSc

Clive is the University's professor of Colloid and Pharmaceutical Science and Sector Coordinator for Bio and Polymer Interfaces Research at the Ian Wark Research Institute. He leads a wide range of research projects concerned with the application of colloid and interfacial chemistry in pharmaceuticals and biointerfaces. A major research interest is in nanoscale drug delivery systems, which includes nanoparticles, dendrimers, liposomes, porous silicon and emulsions. Clive has authored over 95 refereed international journal articles and textbook chapters, 60 international conference papers (many as an invited speaker) and over 70 major reports to industry. He acts on the advisory boards and as a referee for major international journals, a reviewer for National research granting schemes and is a consultant to both private industry and government bodies. Within his research portfolio, Clive has taken a leadership role in a number of major collaborative projects in association with the national and international agencies, the ARC, and University researchers from Australia and overseas, and has attracted competitive research grants worth more than \$7M. Some of his commercial interactions include a strategic partnership with pSivida Ltd to develop commercially viable drug delivery systems for protein therapeutics and poorly soluble drugs based on porous silicon; and also with Mayne Pharma Ltd (Hospira Ltd) and Starpharma Holdings Ltd to develop novel pharmaceutical products.

Company Overview

Ceridia Pty Ltd is an Australian based clinical stage reformulation company. Researchers at The University of South Australia have developed a revolutionary drug delivery technology that has the potential to reformulate and significantly improve the delivery of poorly soluble drugs. Lipoceramic nanoparticles are made of *GRAS* and *Inactives* approved components, simple to manufacture, can be seamlessly integrated within existing processes and are easily transferable from one company to the next. The technology is presently involved in a first-in-man Phase 1 safety study with data and results to be published in January 2011.

Versatile Platform

THE FOCUS

- Generics, Super Generics, Improved Chemical Entities and New Pharmaceutical Products
- Patent extension through reformulations
- New delivery mechanisms and repositioned old drugs
- New indications
- Product combination introductions

ADVANTAGES

The LipoCeramic™ nanoparticle encapsulation platform technology solves solubility problems for an incredibly wide range of drugs. The technology possesses a useful combination of competitive advantages over other drug delivery technologies. These advantages include:

- Enhanced pharmacokinetics and bioavailability
- Improved drug stability
- Enhanced dissolution of poorly soluble drugs
- Low cost of high purity raw materials
- Single, ambient and cold temperature processing
- Surfactant and solvent-free
- Scale-up and manufacturing readily facilitated
- No capital equipment expenditure requirements

Regulatory Advantages

New Chemical Entities	Pre-Clinical 3 Years	Ph1 Clinical 1 Year	Ph2 Clinical 2 Years	Ph3 Clinical 3 years	New Drug Application FDA Review 2-3 years	FDA Approval	12 Years
Improved Chemical Entities				Bio-equivalency 1-2 years	Abbreviated NDA FDA Review 1-2 years	FDA Approval	2-4 Years

Market Advantages

	Generics	Improved Chemical Entities	New Chemical Entities
Cost	Low	Medium	High
Time	Quick	Quick	Long
Reward	Low	Medium	High
Regulatory	Short	Medium	Long
Benefits	Cost	Clinical & Cost	Clinical
Patents	No	Yes	Yes

CERIDIA Pty Ltd

PO Box 546, Salisbury South, ADELAIDE, SA 5106, AUSTRALIA

t: +61 412 911 404

e: gregor.rozenberg@gmail.com

w: www.ceridia.com.au

Directors and Officers

Non-Executive Director

Graham Smith MBA BEC

Mr Smith is the CHIEF EXECUTIVE & MANAGING DIRECTOR of ITEK the commercialisation arm of University of South Australia. His previous position was Chief Executive of The Katolyst Group, an organisation specialising in improving the development and commercialisation capabilities of New Zealand industry, Universities and government owned research laboratories.

Prior to this Graham was a senior manager for the AgResearch Group, the largest government owned research organisation in New Zealand, where the emphasis was on working with scientists and academics to develop and commercialise new technologies and products. Graham has also worked for major food companies in Australia in the dairy, soft-drinks and sugar industries. He has led teams that researched, developed and launched over twenty food products, rationalised supply chain management systems and introduced new technologies into food factories. He has also worked for an international marketing & advertising company in a variety of roles in Australia and overseas. Graham holds a Bachelor of Economics Degree from the University of Adelaide and a Master of Business Administration from the University of South Australia.

Company Secretary

Mark Bruce MSc BSc GAICD

Mr Bruce is responsible for the evaluation of new technology and research opportunities, IP management and commercial development. He has progressed opportunities into novel applications prior to engaging in licensing, partnering and spin-out strategies. Mark has played an integral role in the development of small business units and spin-out companies. Mark holds a Bachelor of Science and a Master of Science and Technology Commercialisation from the University of Adelaide. He is also a Graduate of the Australian Institute of Company Directors.

CFO

Bruce Tilbrook CPA GAICD

Bruce is responsible for commercial management and corporate governance of the ITEK group of companies. He is a graduate of the Australian Institute of Company Directors and is currently a non executive director of 3 start-up companies in the ITEK portfolio. He also manages the ITEK Catalyst Fund which provides pre-seed funding for ITEK approved projects. His past experience includes senior commercial roles in the transport, retail and manufacturing industries, management consulting in M&A and business planning and franchising services.

Vision

- To commercialise clinically proven drug reformulation technology

Mission

- Turning generic drugs into value added super-generics through the generation of added IP, prolonged exclusivity and by improved clinical profile

Expenditure to date

- Total of US\$1.5m invested to date on technology by ITEK and BioSA.
- IP estate consisting of 4 families in all important regulatory domains.

INTELLECTUAL PROPERTY

On-going development of the technology has created a patent portfolio that covers the preparation of the delivery system, drug release properties, and specific applications for oral and dermal delivery. There are currently four patents with 20 plus years of protection ahead of it which includes two national phase patent applications active in Australia, Japan, Europe, USA, and Canada, in addition to patents 3 (a PCT application) and 4 (a provisional application) that cover specific embodiments of the underlying platform.

PARTNERSHIPS

Collaborations have been established with several world class clinical research centres including the Royal Adelaide Hospital, several local and global pharmaceutical companies including partnerships on both the manufacturing (Australian-based FDA Approved) and the selling side (US-based Generic manufacturer). In addition, a dozen compounds are being reviewed and evaluated as potential product collaboration programs.

Opportunity

Ceridia Pty Ltd is a spin-off which has been established as the Lipoceramic commercialisation vehicle. The company has successfully leveraged grant funding, is expanding and developing several lead candidates and is being managed by an experienced management team.

Nearly 40% of all new chemical entities are lipid and poorly soluble. While these drugs have efficacy and safety, their performance is far from optimal in terms of bioavailability and dose variability. Even at a late stage, many novel development programs are abandoned due to poor solubility of the therapeutic and difficulties with acceptable delivery parameters within a biological system. Solving these issues leads to better therapeutics with lower doses, fewer side effects, and greater control.

Partnering opportunities exist for pharmaceutical companies looking to solve formulation and solubility problems, improve skin physiology and create significant product advantages in the market. Co-development, joint venture and investment are being sought.

Summary

Market Opportunity

- Global generics market will be ~US\$150 billion by 2015, Teva 2010
- 39% of total product launches from 50 top manufacturers between '02 and '05 were reformulations
- Global generic products generated US\$83 billion (>70% of total drug sales), IMS 2009
- The oral drug delivery segment – the largest in the drug delivery market – is expected to reach \$71.3 billion in 2013, with a compound annual growth rate of 10.6%.
- To address poorly soluble formulations in an unmet medical need

Technology

- Reformulation and dry powder encapsulation of lipophilic drugs
- No excipient related SAE - safe
- GMP compliant manufacturing facilities through partnering
- Cost effective process and no organic solvent are used.
- Very adaptable process requiring no specialised equipment.

Regulatory Path

- POC human clinical study initiated.
- Components are GRAS annotated and most registered as Inactives by FDA.
- Registration is the same as per the original drug mixture e.g. 505(b)2 or ANDA.

Value

- Commercially experienced management to build shareholder value through effective strategy implementation and deep drug development knowledge.
- Near term revenue focus - 18 months
- Exceptional value for investors

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PO Box 546, Salisbury South, ADELAIDE, SA 5106, AUSTRALIA

t: +61 412 911 404

e: gregor.rozenberg@gmail.com

w: www.ceridia.com.au