

LIPOXEN



Lipoxen plc

“Innovation in Biologics and Vaccines”

Proactive Investor Presentation – London: 15 October 2009

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Presentation Structure

1. Introduction
2. Investment proposition
3. The technology platform
4. Peer group and competition
5. Achievements to date
6. Newsflow and milestones : 2009 and 2010
7. Revenue analysis & financial summary
8. Summary

Management Team



Sir Brian Richards, CBE, PhD
Non-executive Chairman

- Founder / Chairman of leading UK biotech PLCs:
- British Biotech, Peptide Therapeutics (now Acambis/Sanofi), Oxford Biomedica, Cozart & CeNeS, Alizyme



M. Scott Maguire, MBA
Chief Executive Officer

- 18 years investment banking & global healthcare experience with Merrill Lynch, W. R. Grace & Andersen
- Appointed CEO of Lipoxen in 2004
- Led the Company's AIM listing in 2006



Peter Laing, PhD
Chief Operating Officer

- Previously, Director of Research at Peptide Therapeutics plc (now Acambis/Sanofi), Director of Research and Development at Actinova Ltd and Director of Development at Syngenix Ltd.
- Joined Lipoxen in 2002 and appointed COO in August 2008



Colin Hill
Chief Financial Officer

- Substantial public company experience in the UK, USA and Australia
- 20 years experience in corporate finance, PE/venture capital in broad range of small-cap enterprises.
- Joined Lipoxen in 2006 as Non Exec; appointed CFO in June 2007

Lipoxen : Introduction

- AIM listed bio-pharmaceuticals group (AIM: LPX)
- Founded 1997 - listing 2006
- Recently closed on £2.9m fund raise with Baxter and management as lead investors
- Our technologies modify and improve existing biologic drugs and vaccines
- Developing new vaccines for major diseases
- Collaborators are world's largest pharma / biotech companies
- **Key Points:**
 1. *We aim to improve drug performance*
 2. *This leads to lower dosage requirements*
 3. *Which is more cost effective and better for the patient*
 4. *Large pharma companies can re-patent their drugs*
- Low cash burn rate
 - clinical trials funded externally
 - manufacturing supported by India's largest biotech company
- 24 employees

Investment Proposition

- Three patent-protected technology platforms:

1. **PolyXen** extending length of action of biologic drugs in the body eg: Insulin and EPO
- c.\$70 billion market
2. **ImuXen** creates new vaccines and improves existing vaccines
- c.\$25 billion market
3. **siRNAblate** addresses the major problem using siRNA technology

- Five drug and vaccine programmes in development

1. **ErepoXen** (improved EPO) partnered with Serum Institute (India's largest biotech)
2. **SuliXen** (improved Insulin) shows improved efficacy vs. Lantus (a \$3bn drug)
3. **HIV vaccine** programme funded by world's leading AIDS vaccine organisation
4. **Influenza vaccine** flu vaccine (H1N1 strain) - funded by UK government
5. **Malaria vaccine** novel malaria vaccine – funded by PATH with research support from NIH

- Publically announced commercial collaborations with major bio-pharmaceutical partners including:



- Multiple revenue streams: feasibility, licensing and grant incomes

- Gross funds raised of £2.9mn (with support of Baxter £0.62mn and Management of £0.36mn) to advance existing programmes to the market and initiate additional proprietary programmes

Three Therapeutic Platforms : Multiple Shots on Goal

bio-polymer technology

PolyXen[®]

EPO, Insulin & others

natural polymer
found in
the human body



Long acting protein drugs

- BIOSUPERIORS
- Improved patient safety & convenience
- Renewed patent life

particle-based nanotechnologies

ImuXen[®]

Vaccines

Delivery of vaccines

siRNAblate

Gene-Silencing

Delivery of siRNA

natural membrane
materials found in the
human body



- Better efficacy
- Reduced side-effects
- No need for refrigerated storage
- Protection of siRNA
- **Enabling** this revolutionary new technology

1. PolyXen® : Better Performance for Protein Drugs

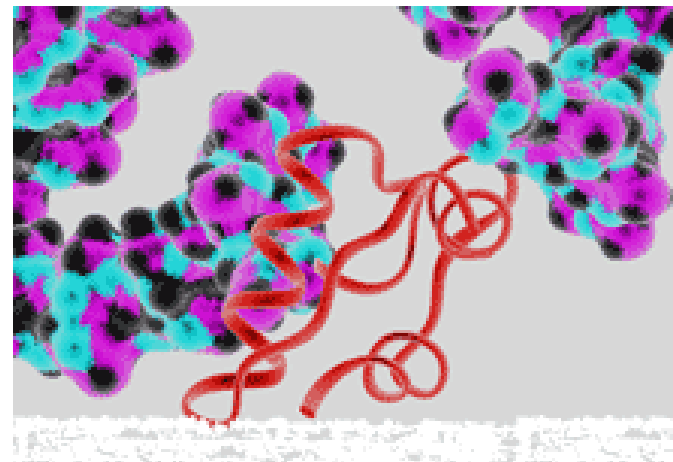
- ✦ Uses a natural polymer to extend the active life of protein drugs in the body
- ✦ Modelled on the multi-billion US\$ success of PEG - a synthetic polymer

- ✦ Key benefits:

- *Better efficacy*
- *Avoidance of side effects*
- *Avoidance of PEG toxicity*
- *Fewer shots*
- *Improved stability*

- ✦ Versatile:

- *Ability to improve the clinical profile of most protein drugs*
- *Applies to over 150 marketed products and 1,350+ products in the clinic and in development*
- *Very attractive acquisition target for Big Pharma / Big Biotech for solving 'pipeline vacuum'*



1. PolyXen® Applications : EPO

ErepoXen® – Long-acting Erythropoietin (EPO)

- Comparison study vs. placebo
 - *Conducted by development partner Serum Institute of India*
 - *64 healthy volunteers*
- Positive Phase I data
 - *No safety issues and well tolerated in the trial*
 - *Higher dose patients showed:*
 - *Clear “red blood cell” response which lasted for between 14 and 20 days*
 - *Sustained rise in haemoglobin levels for 28 days*
- Data supports potential use of the product on a once a month basis
 - *current marketed US\$9bn EPO products need to be given 1 to 3 times a week*
- Next steps
 - *Phase II to commence in Q4 2009, with market launch expected in Russia in 2012*
 - *Canadian Phase II trial in patients to commence in H1 2010 – reporting anticipated in Q4 2010*

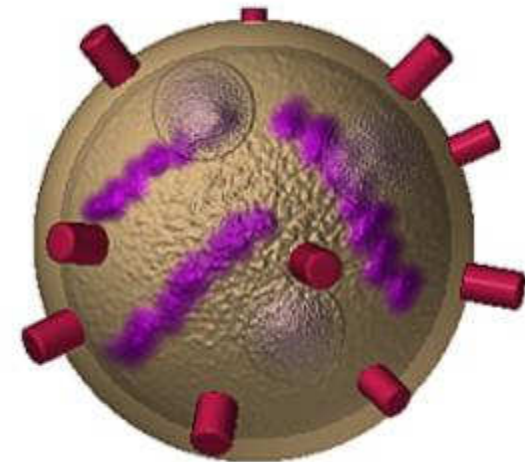
1. PolyXen® Applications : Insulin

SuliXen: Long-acting Insulin

- Comparison study vs. Sanofi Aventis' Lantus
 - *Lipoxen sponsored trial conducted in Russia*
 - *12 healthy volunteers*
 - *Treat Type 1 and 2 diabetes*
- Positive Phase I data
 - *No adverse events reported in the patients treated in trial*
 - *Efficacy and longevity of action confirmed*
- Next steps
 - *Collaboration with Barbara Davis Center for Childhood Diabetes to work on drug for Type I diabetes*
 - *Preliminary results due this quarter*
- Lipoxen could have a superior product to Lantus, the world's most prescribed insulin which generated sales of over US\$3.2 billion in 2008

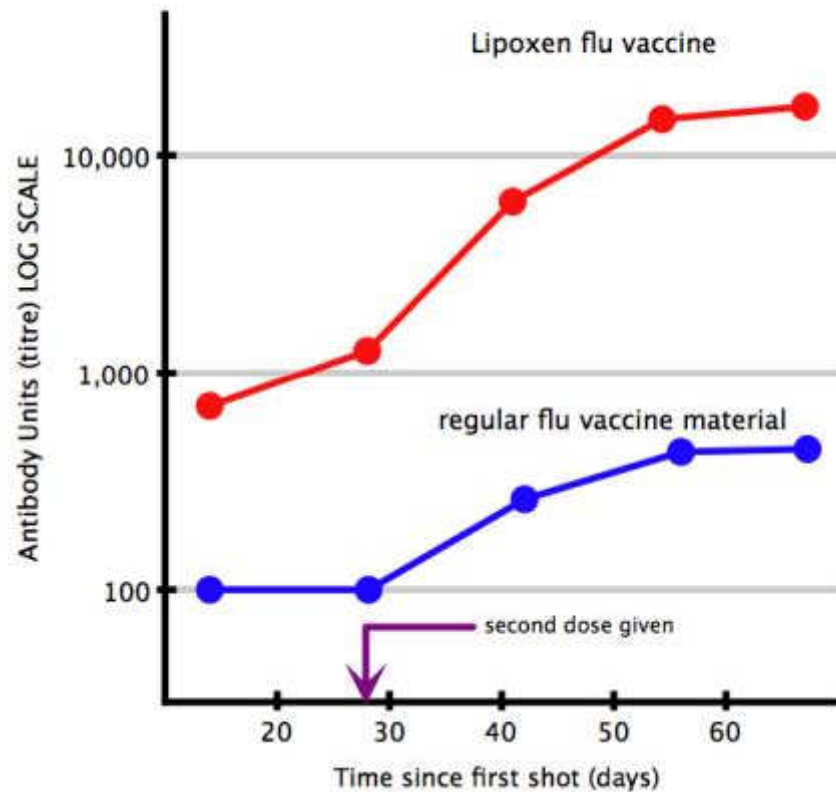
2. ImuXen[®] : Vaccine Technology

- Developing new vaccines for major diseases eg: pandemic Influenza and HIV
- ImuXen[®] generates strong protective immune responses - with a single injected dose
 - *Primate studies have proved efficacy*
 - *Collaborating with two of the world's largest vaccine companies*
- Proof of concept preclinical studies have shown that the benefits of ImuXen[®] for DNA, protein and polysaccharide vaccines include:
 - *Multiple vaccines delivered with a single injection*
 - *Reduction in the number of doses required*
 - *Reduction in side effects*
- ImuXen[®] technology is currently being used in preclinical vaccine candidate research programmes
 - *Influenza*
 - *HIV*
 - *Pneumococcus*
 - *Malaria*
- Next steps
 - *Lead selection of proprietary vaccine candidates*



ImuXen[®]

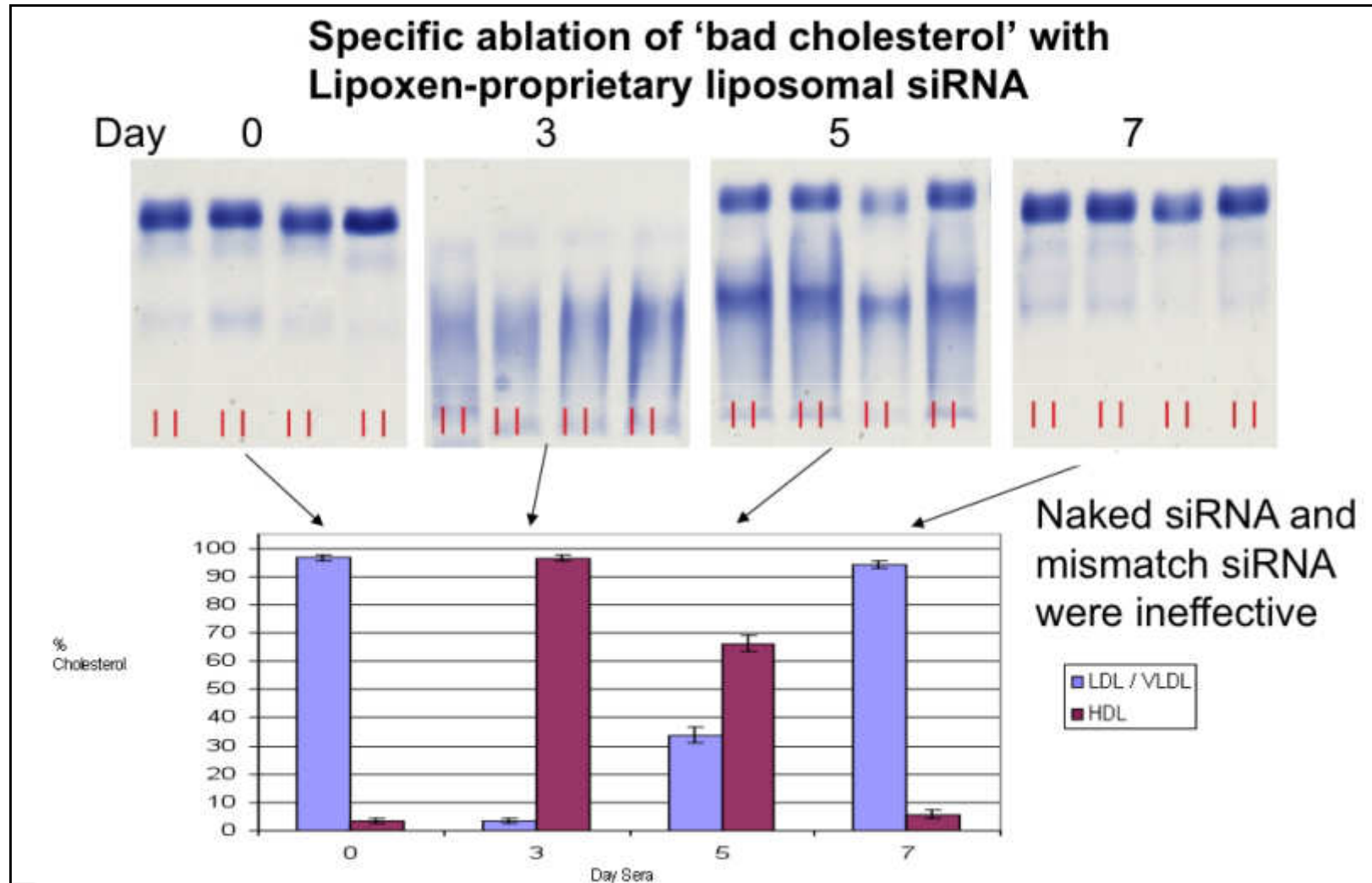
2. Influenza : Unique 'Co-Delivery' Liposomal Formulation



- New positive pre-clinical data announced 1 May 2009
- New vaccine formulation can be distributed in the dry state without refrigeration
- Offers a solution to the vexed supply logistics of seasonal and pandemic flu vaccines
- Potential to 're-shape' the vaccine industry – changing the way many vaccines are made and distributed

Source: Lipoxen

3. siRNAblate : Gene silencing platform



Source: Lipoxen

Peer Group and Competition

Company	Ticker	Technology / Pipeline	Market* / Acquisition Value (US\$ mn)
<u>Vaccine Delivery</u>			
Berna Biotech (acquired by Crucell)	n.a	<i>Liposomal delivery; marketed products for hepatitis A and influenza</i>	447
Vical	VICL	<i>DNA delivery; clinical</i>	191
<u>Protein Delivery</u>			
Cogenesys (acquired by Teva)	n.a	<i>Albumin fusion technology; clinical</i>	400
Enzon Pharmaceuticals	ENZN	<i>Pegylation; licenses & clinical</i>	411
Flamel	FLML	<i>Nanoparticles; preclinical and clinical</i>	219
Halozyne Therapeutics	HALO	<i>Early stage enzyme facilitated drug delivery</i>	673
Maxygen	MAXY	<i>Glycopegylation; clinical</i>	248
Nektar Therapeutics	NKTR	<i>Pegylation; licenses & clinical</i>	890
<u>siRNA</u>			
Mirus Bio (acquired by Roche)	n.a	<i>RNAi delivery</i>	125
Tekmira Pharmaceuticals	TKM	<i>RNAi delivery</i>	56
<u>Platform Technology</u>			
Abmaxis (acquired by Merck)	n.a	<i>Discovery and development of novel human therapeutic antibodies</i>	80
Adnexus (acquired by Bristol-Myers Squibb)	n.a	<i>Biologics in multiple therapeutic areas; preclinical & clinical</i>	430
Avidia (acquired by Amgen)	n.a	<i>Human therapeutic proteins - AvimerTM; clinical</i>	290
Direvo (acquired by Bayer)	n.a	<i>Protein engineering</i>	298
Domantis (acquired by GSK)	n.a	<i>Development of Human Domain Antibodies</i>	454
GlycoFi (acquired by Merck)	n.a	<i>Glycosylation engineering & production of human glycoproteins</i>	400
Sirna Therapeutics (acquired by Merck)	n.a	<i>RNAi-based therapies</i>	1100

* As of 14 October 2009

Source Bloomberg, Companies

Achievements to Date

- * **Human clinical proof of safety and enhanced efficacy on biologic platform technology, polysialic acid (PolyXen®)**

- o Insulin
- o EPO

- * **Baxter** 

- o Lipoxen received US\$1m upfront fee for exclusive licence to PolyXen® for Factor VIII, US\$1.3B sales in 2007
- o US\$75m in potential cash milestones plus royalties linked to sales: additional payments for further development work
- o Lead investor in May 2009 placing - currently third largest shareholder

- * **Serum Institute of India (SIIL)** 

- o Co-Development Partnership for ErepoXen®
- o Contract manufacturing agreement for SIIL to supply proprietary biopolymer (polysialic acid)
- o SIIL currently holds ~28% of Lipoxen and has a representative on Lipoxen's Board of Directors
- o Extensive historic and continuing support to Lipoxen

- * **Schering Plough** 

- o License agreement with upfront payment, milestones executed for veterinary application of long-acting insulin

- * **International AIDS Vaccine Initiative (IAVI)** 

- o World's leading AIDS vaccine organization
- o Recipient of a research grant along with GSK & Crucell to investigate improved HIV vaccine delivery utilising Lipoxen's ImuXen® technology

- * **Influenza vaccine**

- o Positive preclinical data announced

- * **PATH** 

- o PATH, supported by Bill and Melinda Gates, has made a grant to Lipoxen to apply its ground-breaking ImuXen technology to enhance the performance of malaria vaccine candidates with research support from US National Institute of Health (NIH)

- * **Research evaluations**     

- o In place with Amgen, Genzyme, GSK, Genentech, Sanofi iAventis and several more (undisclosed)

News and Significant Events : H2 2009 and 2010

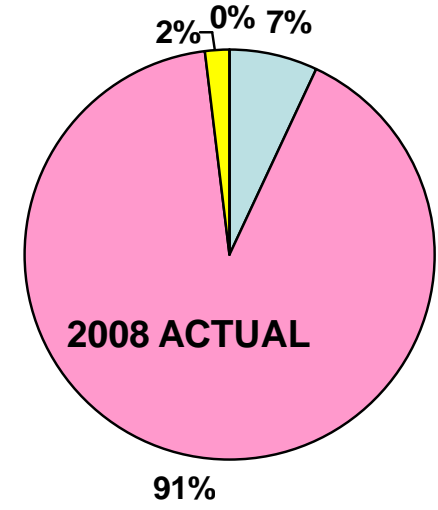
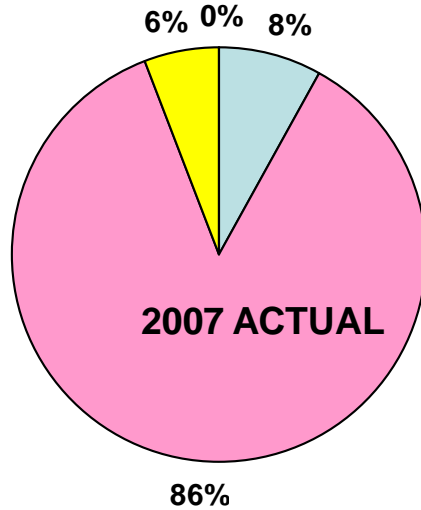
H2 2009

- Commence **Insulin** Phase II trial in Russia
- Commence EPO Phase II trial in India and Russia
- Results from Barbara Davis Institute for **Insulin for Type 1 Diabetes**
- License expected for PolyXen in Biobetter application
- Announce development of additional proprietary candidates
- Additional grant for refrigeration-free **influenza vaccine**
- License expected for **Insulin** and **EPO**

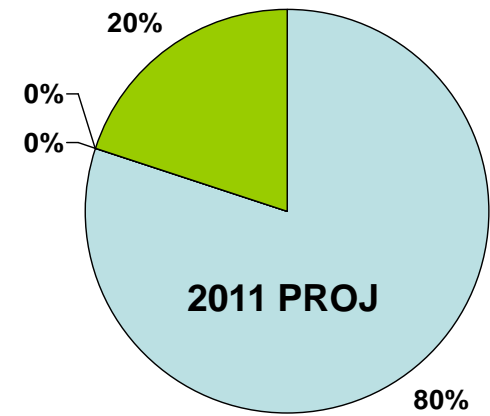
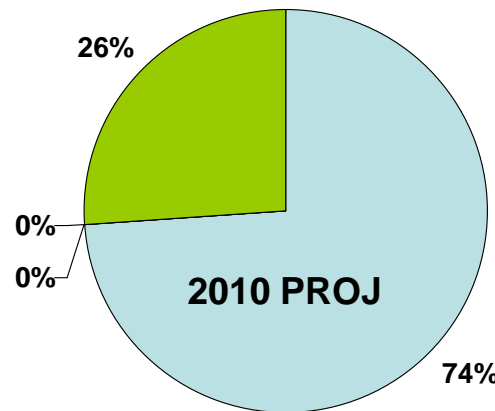
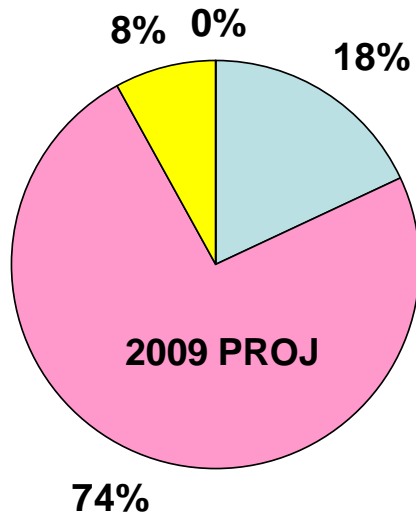
2010

- Baxter milestone: lead selection
- **siRNA** license expected
- Results from IAVI of research for **HIV candidate**
- Commence **Phase II EPO trial** in Canada (in patients)
- Results from **Canadian Phase II EPO trial**
- **HIV vaccine** license expected
- Commence **clinical development of HIV vaccine (IAVI)**
- **Vaccine license** expected
- Commence **EMEA Phase I Insulin**

Multiple Revenue Streams : FY 2007 to FY 2011



- TECHNOLOGY LICENCE FEES
- DEV/FEASIBILITY INCOME
- GRANT INCOME
- PRODUCT OUT-LICENSING

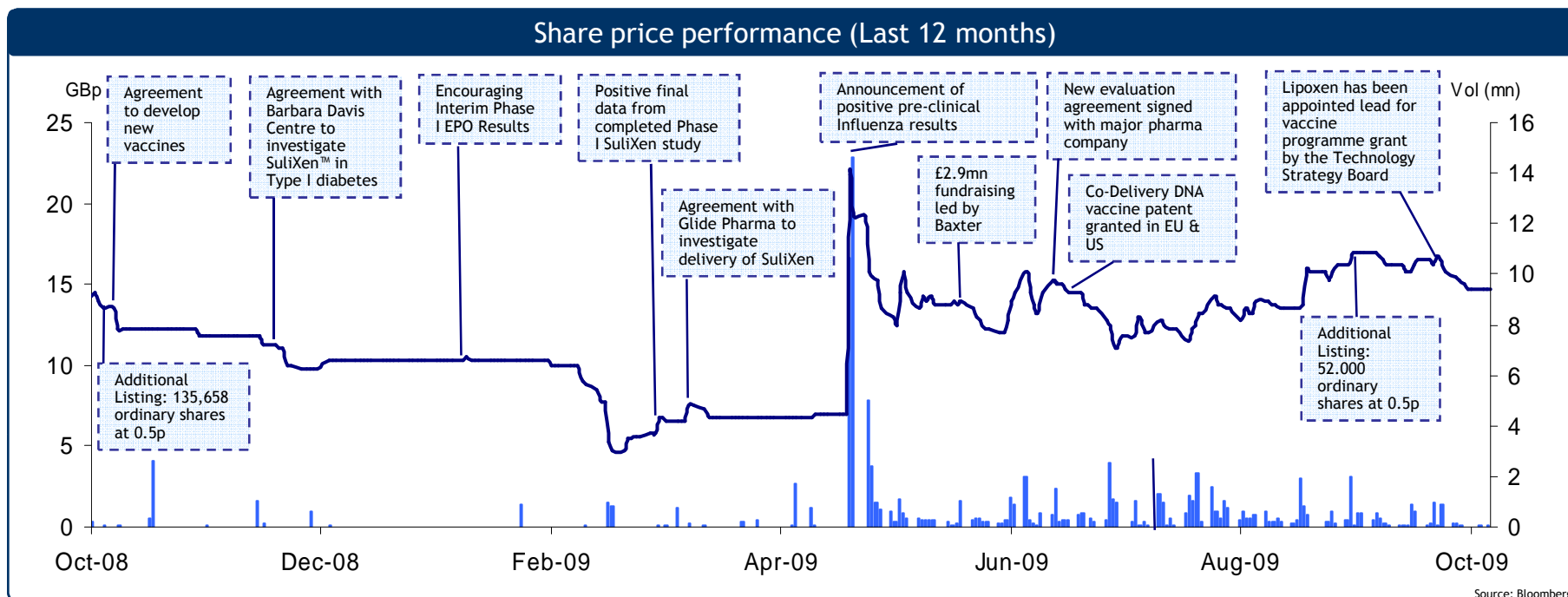


Summary

1. Multiple revenue channels
2. Significant potential through the creation of a broad product pipeline
3. Lower risk of failure due to reformulating current marketed drugs and vaccines
4. Partnerships with some of the world's leading biopharmaceutical companies
5. New funds of £2.9m (gross) raised in May/June 2009 to strengthen balance sheet and provide platform for growth
6. Opportunity to invest ahead of significant clinical and commercial inflection points

Appendices

Market Trading Update



Significant Shareholders

	Current %
FDS Pharma Ass & related parties	27.75%
Serum Institute of India Ltd & related parties	21.79%
Baxter Healthcare SA	4.76%
Pershing Nominees Limited A/C AGCLT	4.56%
Professor Gregory Gregoriadis	3.02%

Source: Company

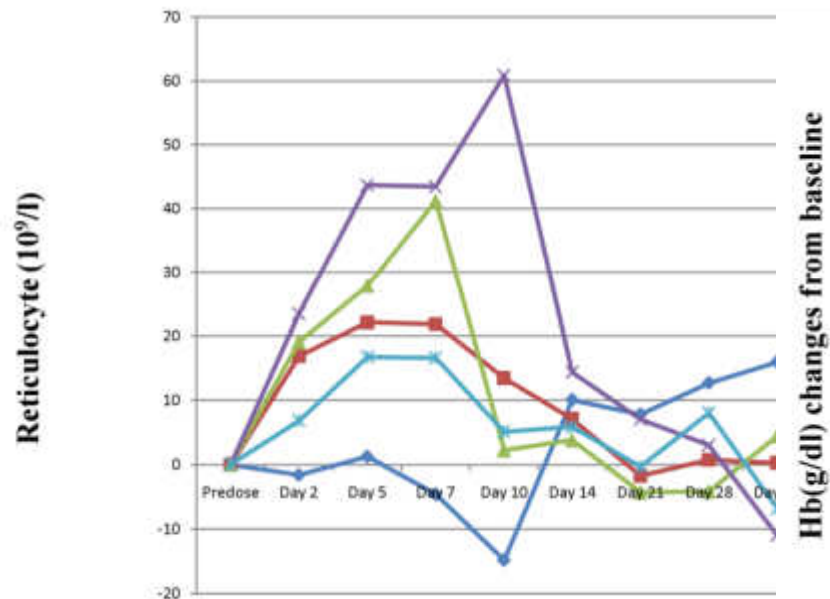
Market Statistics

Last Price (13 Oct 09)	14.75p
52-wk High (30 Apr 09)	21.75p
52-wk Low (27 Feb 09)	4.75p
All Time High (19 June 2007)	52.00p
Average daily volume	0.38mn
Market cap	£22.72mn
Shares Outstanding	154.06mn

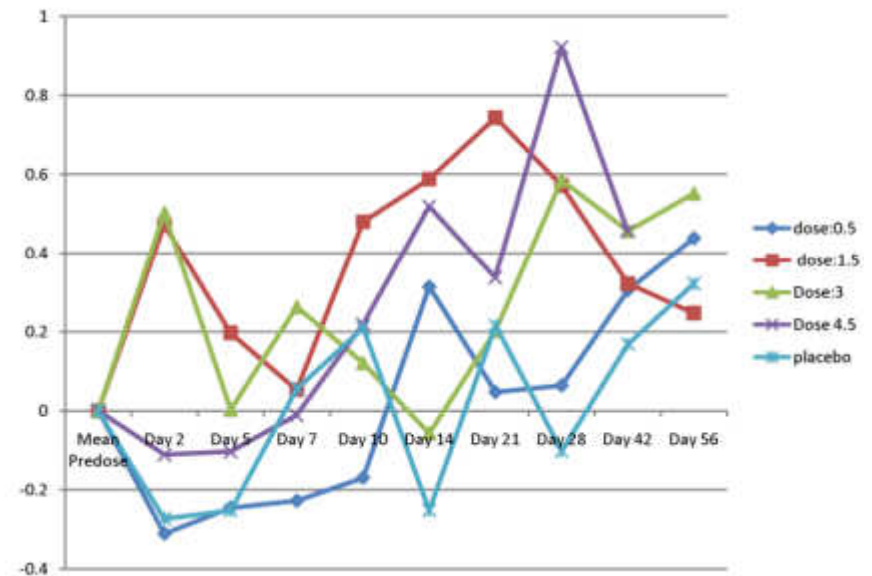
Source: Company / Bloomberg

1. Efficacy of Once a Month EPO Dose

• Reticulocytes



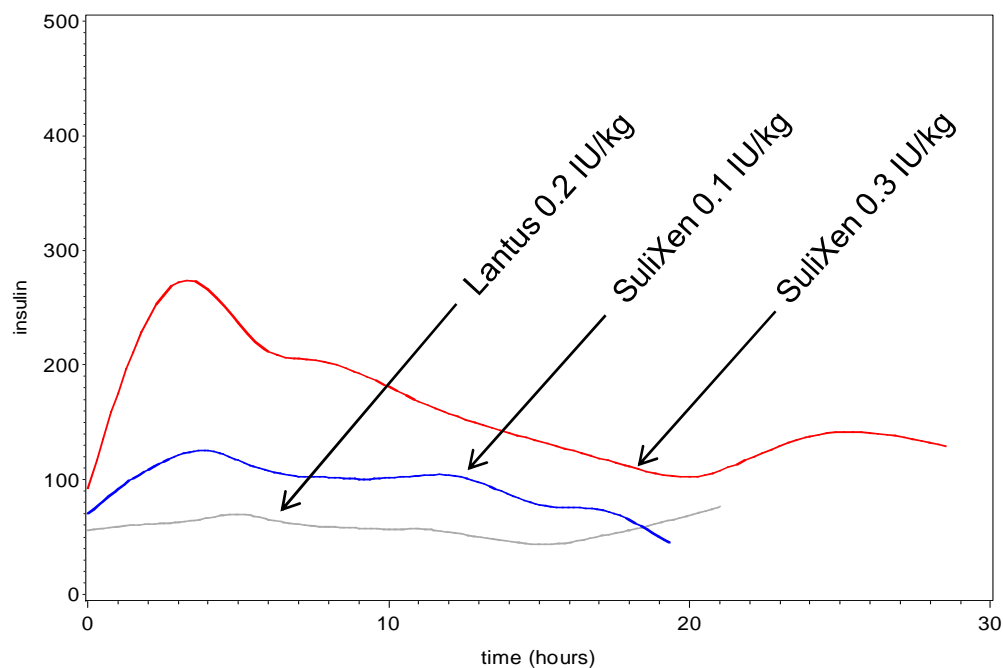
• Haemoglobin



• ***Efficacy and longevity confirmed by higher levels of reticulocytes and haemoglobin***

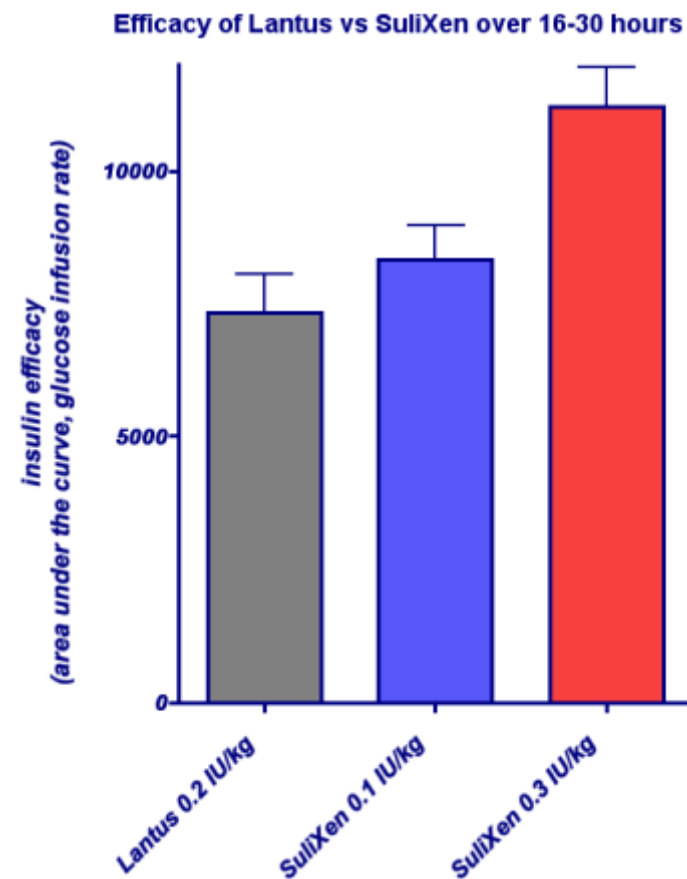
1. Comparison of SuliXen[®] to Lantus[®]

• Longevity of circulation in the blood

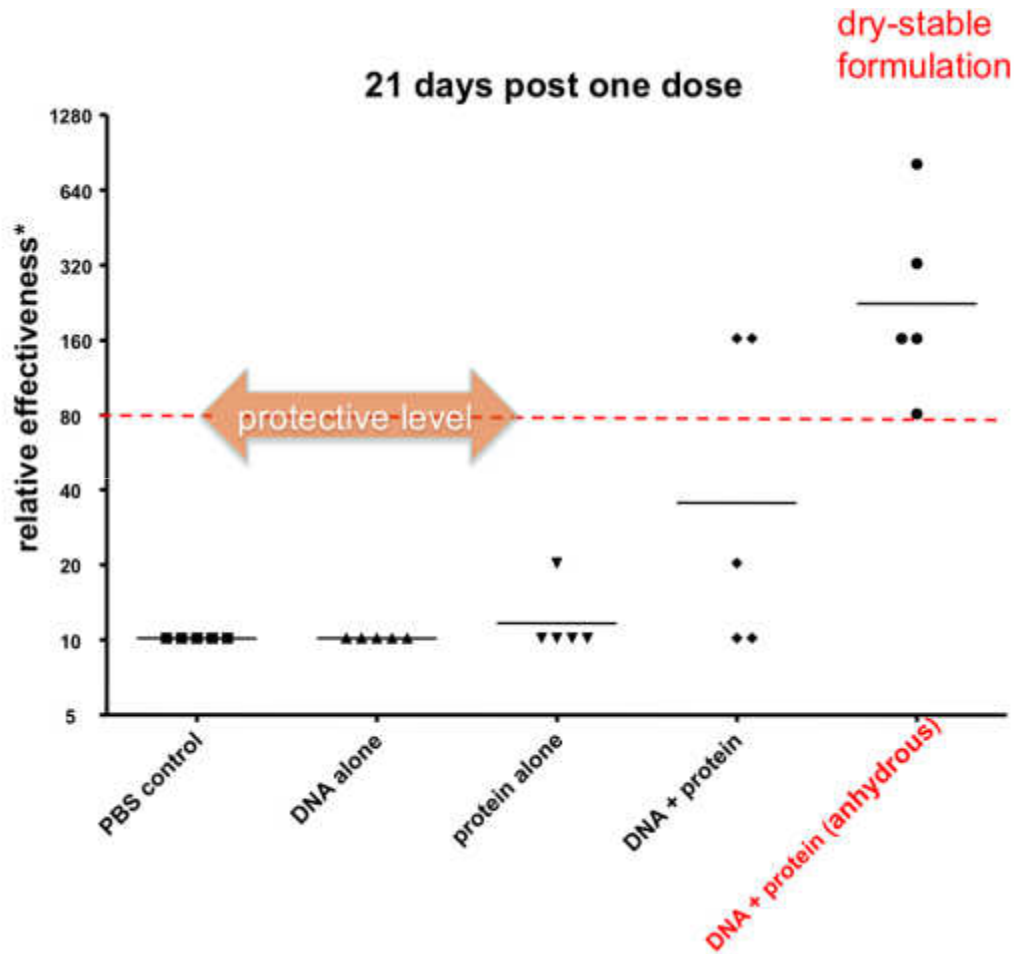


Source: Evidence (CRO)

• Efficacy



Influenza H1N1 preclinical study – dry stable formulation



‘protective’
levels of
antibody
achieved with
a single dose
of anhydrous
liposomal
formulation

* ‘relative effectiveness’ measured by ‘haemagglutination inhibition’ – a measure of virus neutralizing antibodies

The Scale of Our Markets

- Protein and peptide drugs markets are huge
- Estimated to grow at a CAGR of c.10% to reach **\$70bn** by 2010
 - Novel Insulin market estimated at **\$13bn** in 2008
 - EPO market estimated at **\$9bn** in 2008
 - 150 FDA-approved drugs on the market
 - Additional 350 in clinical trials and 1,000 in development all of which are potential for PolyXen
- Vaccines market is estimated to grow at a CAGR of c.26% to reach **\$28bn** by 2011

Recent Next-Generation Deals

- Novartis and HGS for long-acting interferon alpha, deal worth US\$507.5M with US\$45M upfront
- Bayer and Maxygen for long-acting Factor VII with US\$90M upfront
- Biolex and OctoPlus for long-acting interferon alpha deal worth US\$149M with US\$11M upfront
- Roche and Halozyme to a number of Roche molecules deal worth in excess of US\$142M with US\$20M upfront
- Sanofi and Crucell for rabies vaccine deal worth €76.5M with €10M upfront
- Merck acquired GlycoFi for US\$400M for next generation EPO and technology
- Teva acquired Cogenesys for US\$400M for next generation pipeline (including GCSF, IFN beta and insulin)
- MDRNA siRNA delivery deal with Novartis US\$7.3m upfront for non-exclusive rights for liposomal system
- Tekmira Pharmaceuticals RNAi delivery deal with Roche. Funding of up to \$18.4m to support program of two candidates to IND application + \$32m in milestones and royalties on product sales.

Serum Institute of India



- India's largest biotech company
- Manufacturers:
 - Bacterial Vaccines
 - Viral Vaccines
 - Biologic manufacturing facility of c.1.1 billion doses
 - Recombinant and Combination Vaccines
- World's largest producer of Measles and DTP group of vaccines
- Estimates indicate that 2 out of 3 children immunized, with a vaccine, received one manufactured by Serum Institute of India Limited
- Supply to over 140 Nations around the World
- The plant has prequalification from WHO for the Licensed Products
- The plant in Pune is spread over 108,000m²
- Employs 422 Professionals as Scientists
- The development pipeline has products ranging from Oncology to Preventive Diseases such as Meningitis, Pneumococcal etc.

Summary Cash Flow

	12 months to 31 Dec 2006 £'000	6 months to 30 Jun 2007 £'000	12 months to 31 Dec 2007 £'000	6 months to 30 Jun 2008 £'000	12 months to 31 Dec 2008 £'000	6 months to 30 Jun 2009 £'000
Operating loss	(1,922)	(1,588)	(3,444)	(2,013)	(3,864)	(1,436)
ADD BACK: Non-cash items	959	701	1,455	894	2,141	217
Cash outflow from operating activities	(963)	(887)	(1,989)	(1,119)	(1,723)	(1,219)
Decrease/increase) in receivables	(592)	(2)	653	(206)	(636)	575
Increase/(decrease) in payables	(754)	274	26	(81)	181	111
	(2,309)	(615)	(1,310)	(1,406)	(2,178)	(533)
Interest paid	(10)	0	0	0	0	0
Interest received	108	75	153	51	73	3
Taxation received	47	0	0	158	333	0
NET CASH FLOW FROM OPERATIONS	(2,164)	(540)	(1,157)	(1,197)	(1,772)	(530)
Cash flows from investing activities						
Cash from parent company acquired	143	0	0	0	0	0
Purchase of property, plant & equipment	(1,003)	(112)	(159)	(36)	(74)	(19)
Cash flows from financing						
Issue of equity share capital	5,681	1,072	1,072	0	2	2,744
Net (decrease)/increase in cash+equivs	2,657	420	(244)	(1,233)	(1,844)	2,195
Cash and cash equivalents b/f	33	2,690	2,690	2,446	2,446	602
Cash and cash equivalents c/f	2,690	3,110	2,446	1,213	602	2,797

Summary Balance Sheet

	31 Dec 2006	30 Jun 2007	31 Dec 2007	30 Jun 2008	31 Dec 2008	30 Jun 2009
	£'000	£'000	£'000	£'000	£'000	£'000
Non-current assets						
Property Plant and equipment	971	961	867	770	666	549
Goodwill	1,061	1,061	1,061	1,061	1,061	1061
Other receivables	<u>1,370</u>	<u>0</u>	<u>500</u>	<u>0</u>	<u>0</u>	<u>0</u>
	<u>3,402</u>	<u>2,022</u>	<u>2,428</u>	<u>1,831</u>	<u>1,727</u>	<u>1,610</u>
Trade and other receivables	2,059	3,201	1,756	1,764	1,119	468
Cash and cash equivalents	<u>2,690</u>	<u>3,110</u>	<u>2,446</u>	<u>1,213</u>	<u>602</u>	<u>2,797</u>
	4,749	6,311	4,202	2,977	1,721	3,265
Current Liabilities	<u>(268)</u>	<u>(542)</u>	<u>(294)</u>	<u>(212)</u>	<u>(475)</u>	<u>(586)</u>
NET CURRENT ASSETS	<u>4,481</u>	<u>5,769</u>	<u>3,908</u>	<u>2,765</u>	<u>1,246</u>	<u>2,679</u>
NET ASSETS	7,883	7,791	6,336	4,596	2,973	4,289
Net assets per share – basic	6.83	6.51	5.30	3.84	2.48	2.78
Net assets per share – fully diluted	6.40	6.14	5.01	3.65	2.38	2.69

Summary Income Statement

	12 months to 31 Dec 2006	6 months to 30 June 2007	12 months to 31 Dec 2007	6 months to 30 June 2008	12 months to 31 Dec 2008	6 months to 30 June 2009
	£'000	£'000	£'000	£'000	£'000	£'000
Turnover	1,219	517	905	416	1,160	411
<u>CASH SETTLED EXPENDITURE</u>						
R&D expenditure	1,242	866	1,836	1,046	2,004	934
Administrative expenses	940	538	1,058	489	879	696
	<u>2,182</u>	<u>1,404</u>	<u>2,894</u>	<u>1,535</u>	<u>2,883</u>	<u>1,630</u>
<u>Non-cash Expenditure</u>						
Depreciation	57	122	263	133	275	137
R+D equity settled costs	395	230	520	697	1,773	75
Share option expense	507	349	672	64	93	5
	<u>959</u>	<u>701</u>	<u>1,455</u>	<u>894</u>	<u>2,141</u>	<u>217</u>
TOTAL OPERATING COSTS	3,141	2,105	4,349	2,429	5,024	1,847
Operating loss	(1,922)	(1,588)	(3,444)	(2,013)	(3,864)	(1,436)
Net interest	98	75	153	51	73	3
Profit (Loss) before tax	(1,824)	(1,513)	(3,291)	(1,962)	(3,791)	(1,433)
Taxation	(49)	-	-	158	333	0
Loss after tax	(1,873)	(1,513)	(3,291)	(1,804)	(3,458)	(1,433)
Loss per share (pence)	(1.80)	(1.30)	(2.78)	(1.51)	(2.89)	(1.14)

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