

#### Oxford BioMedica

**Annual General Meeting 2008** 

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#### Oxford BioMedica

#### Overview

- Founded in 1996, spin-out from Oxford University, ~85 employees
- Leading company in cancer vaccines and gene-based products
- Four products in clinical development
  - TroVax "best in class" vaccine for solid cancers in Phase III
  - TroVax deal with sanofi-aventis, potential payments >€518m
  - ProSavin novel gene therapy for Parkinson's disease in Phase I/II
- LentiVector core technology for gene delivery and RNAi applications
- Cash balance sufficient to support ongoing operations

















### **Strategy and Board Changes Building the Business**

- Strategy for growth and commercial success
- Maintain leading position in cancer vaccines and gene therapy
- Collaborate with pharma in certain markets for late-stage development
- Objective to expand clinical pipeline by one product per year
- Recently announced Board changes reflect our advanced stage of growth
- Professor Alan Kingsman, co-founder and CEO, to become Chairman
- Dr Mike McDonald, Chief Medical Officer, to become CEO
  - 20 years clinical and regulatory experience with Lilly and SmithKline Beecham



# **Advanced Product Candidates Expanding Clinical Pipeline**

• Four products in clinical development

PRODUCT	PRECLINICAL	PHI	PH II	PH III	TECHNOLOGY	PARTNER/FUNDING
TroVax®	Renal Cancer				MVA poxvirus	sanofi-aventis
TroVax <sup>®</sup>	Colorectal Cancer			2008	MVA poxvirus	sanofi-aventis
TroVax <sup>®</sup>	Prostate Cancer				MVA poxvirus	sanofi-aventis
ProSavin®	Parkinson's Disease	e			LentiVector®	-
Hi-8® MEL	Melanoma				MVA poxvirus	-
MetXia <sup>®</sup>	Pancreatic Cancer				Retrovirus	-
RetinoStat®	Retinopathy				LentiVector®	Foundn Fighting Blindness



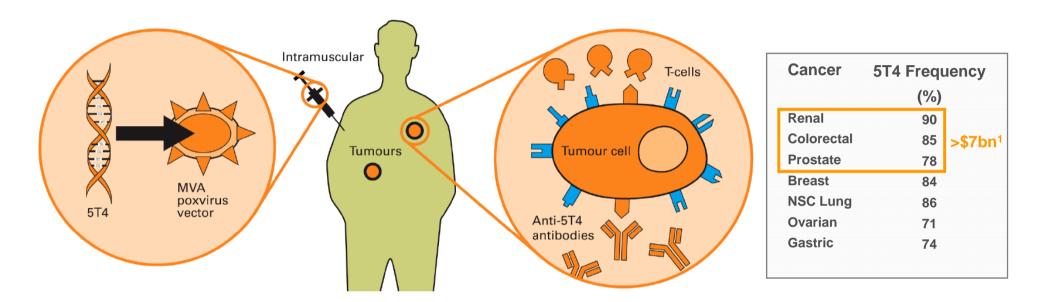
# Other Product Candidates Breadth and Depth

- Eight products in preclinical development or research
- Funding from commercial partners and other organisations

PRODUCT	DISEASE	TECHNOLOGY	PARTNER/FUNDING
StarGen™	Stargardt Disease	LentiVector®	Foundation Fighting Blindness
MoNuDin <sup>®</sup>	<b>Motor Neuron Disease</b>	LentiVector®	ALS and MND Associations
SMN-1G	Spinal Muscular Atrophy	LentiVector®	FightSMA
Innurex <sup>®</sup>	Spinal Cord Injury	LentiVector®	Christopher Reeve Paralysis Foundn
Requinate <sup>®</sup>	Haemophilia	LentiVector®	UK Department of Health
ImmStat®	AIDS	LentiVector®	-
EndoAngio-GT	Cancer	LentiVector®	-
CME-548	Cancer	Monoclonal Ab	Wyeth



## **TroVax**Therapeutic Cancer Vaccine



- 5T4 is a proprietary tumour associated antigen
- Broadly expressed on solid tumours and no expression on essential organs
- TroVax is 5T4 tumour associated antigen delivered by vaccinia (MVA)
- Intramuscular injection stimulates anti-5T4 immune response



#### Clinical Development Extensive Clinical Experience

- Ten Phase I/II & II trials in >190 patients with renal, colorectal or prostate cancer
- Primary endpoints of safety and immunology achieved
- Both antibody and/or cellular responses induced in >90% of patients
- Dose and regimen optimised with various co-medications
- Strong correlation between immune response and clinical benefit<sup>1</sup>
- Three Phase III trials ongoing or starting, recruiting approx 5,000 patients
- Phase III results in renal cancer anticipated in H1 2009



### Phase III TRIST Study First Line Advanced and Metastatic Renal Cancer

#### TRIST: TroVax Renal Immunotherapy Survival Trial

- Placebo-controlled, randomised Phase III trial
- TroVax + first line standard therapy¹ vs. placebo + first line standard therapy¹
- Approx 700 patients in USA, EU & Eastern Europe
- Interim analyses by Data Safety Monitoring Board
- Primary endpoint is improvement in overall survival
- Special Protocol Assessment from FDA for approval on single trial
- Targeting label of "first line treatment in combination with standard therapy"



#### Phase III TRIST Study Current Status

- Patient recruitment completed in March 2008
- Three successful DSMB reviews recommended continuation of TRIST
- Next DSMB review triggered by 200 events, anticipated in Q3 2008
- Trial completes after 309 events, anticipated in H1 2009
- Registration in renal cancer anticipated before end of 2009
- Substantial milestone payments linked to regulatory process



### Phase III Development Colorectal Cancer

- Sanofi-aventis to start Phase III trial in metastatic colorectal cancer
  - 1,300 patients
  - TroVax + first line standard therapy vs. placebo + first line standard therapy
  - First patient anticipated in Q3 2008
- QUASAR with sanofi-aventis to start Phase III trial in early stage colorectal cancer
  - 3,000 patients
  - QUASAR is UK clinical trial network funded by Department of Health and Medical Research Council
  - First patient anticipated in Q3 2008

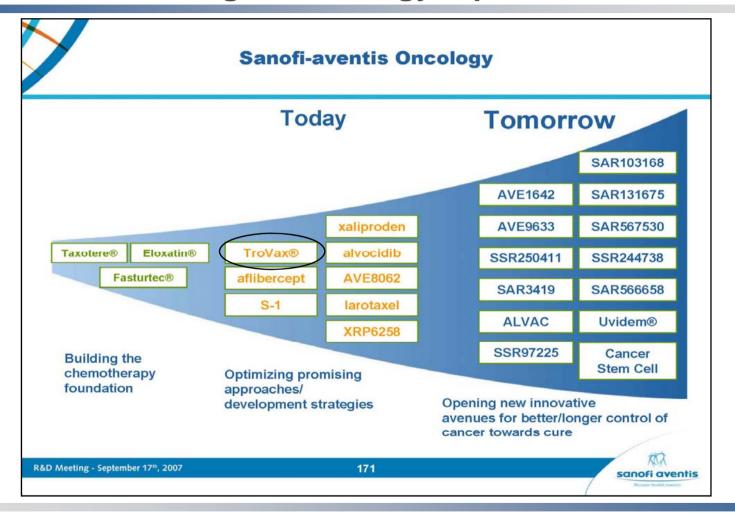


## Sanofi-Aventis Collaboration Partnership with Leader in Oncology and Vaccines

- Global alliance signed in March 2007
- Upfront and first year payments of €48m
- Additional development and regulatory milestones of >€470m
- Additional undisclosed commercial milestones
- Tiered, escalating royalties on all sales
- Sanofi-aventis funds all future activities, starting Phase III in colorectal cancer
- Option to participate in promotion in the USA and EU



# **Sanofi-Aventis Collaboration**High Profile Positioning in Oncology Pipeline





# **TroVax Moving Towards Commercialisation**

- Excellent safety profile lowers hurdles for efficacy
- Endorsement by #2 oncology company with leading cancer vaccine expertise
- Supported by independent clinical trial groups in UK and USA
- Potential approval as additive therapy in multiple cancers
- Market for additive cancer therapy is >\$4bn (eg Avastin)



# Parkinson's Disease The Opportunity

- Disease is well understood caused by loss of ability to make dopamine
- In early stages systemic L-DOPA (dopamine precursor) is efficacious BUT
- Patients progressively lose ability to convert L-DOPA to dopamine
- Long term (1-4 years) L-DOPA treatment causes severe side effects

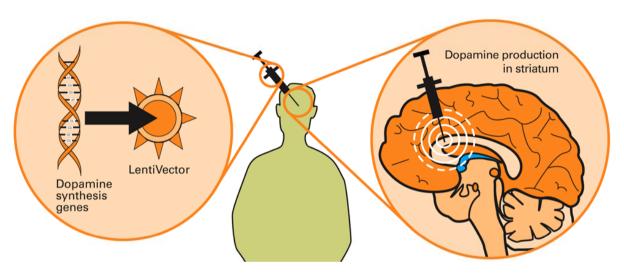


- ProSavin is designed to deliver constant safe and efficacious dose
- 'Cures' symptoms and reverses side effects caused by L-DOPA



#### **ProSavin**

#### **Dopamine Replacement for Parkinson's Disease**

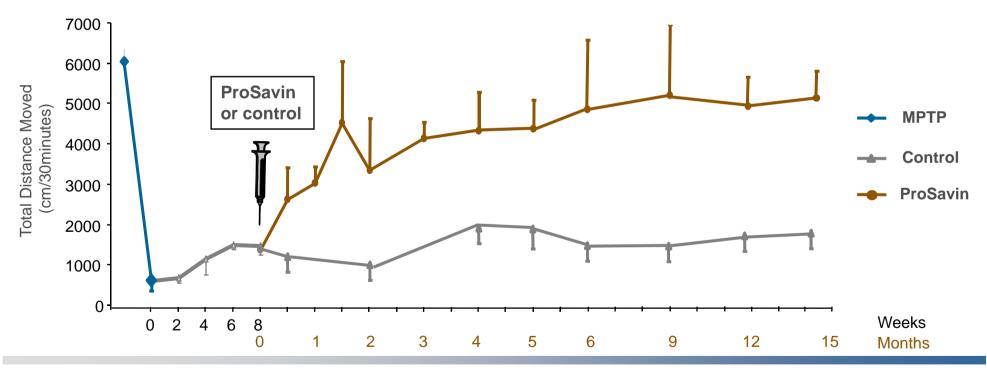


- ProSavin carries genes for dopamine production using LentiVector technology
- Restores dopamine production in the brain
- Single treatment provides long-term benefit
- Current market >\$3bn¹
- Scope to increase market with potent, innovative products (e.g. ProSavin)
- Patient population increasing with demographic change



## **Preclinical Results**Proof of Principle Demonstrated

- Statistically significant recovery of movement in two weeks
- Return to normal by 5-8 weeks; maintained to latest time point (~27 months)
- Similar efficacy in all other behavioural assessments





### ProSavin Clinical Development Accelerated Plan

- Phase I/II trial underway in France
  - Patients failing on L-DOPA but not experiencing disabling side-effects
  - Creative trial design 18 patients, dose escalation<sup>1</sup>, placebo controlled<sup>2</sup>
  - Two patients treated to date with no serious adverse events
  - Anticipate data from first cohort of patients in Q3 2008
- Phase III targeted for late 2009/ early 2010
  - Accelerated development by moving directly from Phase I/II to Phase III<sup>3</sup>
- Potential product launch in 2012-13
  - Independent sales projections ~\$1bn<sup>4</sup> on conservative assumptions



## **2007 Financial Highlights Strengthened Cash Position**

- Cash balance<sup>1</sup> at 31 December 2007 of £38m
- Payments from sanofi-aventis in 2007 of £26m
- Revenue in 2007 of £7m based on IFRS revenue recognition
- Research & development costs in 2007 of £22m
- Cash generated<sup>2</sup> in 2007 of £6m



- . Cash, cash equivalents and current financial assets
- 2. Net cash generated/used in operating activities plus sales and purchases of non-current assets

### **Income Statement**Loss Narrowed in 2007

£m	2003	20041	2005 <sup>1</sup>	2006 <sup>1</sup>	20071
Revenue	0.4	0.5	0.8	0.8	7.2
Cost of sales	-	-	-		(0.4)
R&D costs	(10.8)	(9.0)	(9.3)	(19.5)	(22.1)
Administrative costs	(2.9)	(2.8)	(2.9)	(2.7)	(4.3)
Exceptional costs	-	(1.6)	-	· -	(0.3)
Operating loss before except'l	(12.7)	(10.9)	(11.2)	(21.1)	(19.5)
Loss after tax credit	(10.7)	(10.5)	(9.1)	(17.6)	(15.3)
Loss per share (p)	(3.9p)	(2.8p)	(2.4p)	(3.5p)	(2.9p)
Average number of shares	274m	371m	381m	500m	528m



### **Balance Sheet**Bolstered Cash Reserves in 2007

£m	2003	2004 <sup>1</sup>	2005 <sup>1</sup>	2006 <sup>1</sup>	<b>2007</b> <sup>1</sup>
Cash and short term investments	31.8	22.4	43.8	28.5	38.1
Debtors	2.4	3.3	2.9	4.5	7.3
Non-current assets	2.5	2.9	2.5	2.5	15.7
Total assets	36.7	28.6	49.2	35.5	61.1
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Deferred income	-	0.1	0.1	0.1	18.9
Other current liabilities	1.5	1.7	2.1	4.7	9.6
Other non-current liabilities	-	0.4	0.4	0.6	0.7
Shareholders' equity	35.2	26.4	46.6	30.1	31.9
Total liabilities & s/holders' equity	36.7	28.6	49.2	35.5	61.1



# **Cash Flow**Positive Operational Cash Flow in 2007

£m	2003	20041	2005 <sup>1</sup>	20061	20071
Cash used/generated in operations	(11.5)	(10.8)	(10.1)	(17.7)	2.3
Net interest received	0.6	1.1	1.0	1.4	1.6
Net tax received	1.3	0.4	1.7	0.6	2.4
Capital expenditure	-	(0.4)	(0.3)	(0.2)	(0.4)
Cash burn/generated	(9.6)	(9.7)	(7.7)	(15.9)	5.9
Cash acquired	-	-	-	- -	3.8
Acquisition costs	-	-	-	-	(0.4)
Proceeds of share issues (net)	20.5	0.3	29.0	0.6	0.3
Net cash	31.8	22.4	43.8	28.5	38.1



# Financial Outlook Focus on High Value Opportunities

- Investment focused on products with greatest potential value
- Plan to maintain operational spend at 2007 level
- Net expenditure and cash flow to 8 May 2008 in line with expectations
- Cash position augmented by €10m TroVax milestone payment
- Revenue for current year expected to be £16-19m, an increase of ~140%
- Cash balance remains sufficient to support ongoing operations
- Financial goal to be profitable within 12 months of first product registration



#### **Anticipated Events**

May 2008	TroVax Phase II renal cancer results at ASCO
July 2008	TroVax Phase II colorectal cancer with liver mets results at EACR
Q3 2008	Fourth DSMB analysis of TroVax Phase III TRIST study
Q3 2008	Sanofi-aventis to initiate TroVax Phase III trial in metastatic colorectal cancer
Q3 2008	QUASAR & sanofi to initiate TroVax Phase III trial in early-stage colorectal cancer
Q3 2008	Initial results from Phase I/II trial of ProSavin in Parkinson's
H1 2009	TroVax Phase III TRIST study results
H1 2009	Full development of Hi-8 MEL in melanoma
2009	Commence clinical development of RetinoStat in wet AMD



#### Summary

- Leading company in cancer vaccines and gene-based products
- Developing innovative treatment approaches for unmet medical needs
- Four products in clinical development
- TroVax "best in class" cancer vaccine in Phase III, endorsed by sanofi-aventis
- ProSavin novel treatment for Parkinson's disease in Phase I/II trial
- Focused strategy and strong management team





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