



## **Interim Results for six months ended 30 June 2009**

20 August 2009

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# ProStrakan – an introduction

- International specialty pharma company
- UK based and listed on LSE (PSK.L) – market cap c. £250m
- 2008 full year revenues £56m, growing at 40% in H1 2009
- Growing US oncology supportive care business
- On track for operating profitability late 2009, full year 2010
- Strategy:
  - to in-licence and develop patient-friendly products
  - to sell these products through our own sales force in the EU & US
  - to out-license our products in areas that are non-core

# Key Value Drivers

Product		Indication	Regulatory Status	
EU	US		EU	US
<b>Sancuso</b>		Granisetron patch for preventing chemotherapy induced nausea and vomiting	Filed	Marketed
<b>Abstral</b>		Fast-acting sublingual formulation of fentanyl for breakthrough cancer pain	Marketed	Filed (Aug2009)
<b>Tostran</b>	<b>Fortigel</b>	2% testosterone gel for hypogonadal men	Marketed	Filed (April 2009)
<b>Rectogesic</b>	<b>Cellegesic</b>	Topical nitroglycerin for treating pain associated with chronic anal fissures	Marketed	Filing H2 2009

# 2009 Strategic Highlights

- Total revenues up by 40%
  - Product sales grew by 36%
  - Pan-EU product sales up by 48%
- Further pan-EU launches under way
  - Abstral launched in UK, Germany & France (July 2009)
  - Spanish launch expected H2 2009
- US oncology support franchise established
  - Sancuso sales growth on target
  - Good re-imburement achieved
- Strong pipeline progress
  - NDAs filed for Fortigel (April 2009) and Abstral (August 2009)
  - Cellegesic NDA to be filed in H2
- Revenue-generating out-licensing deals completed

# H1 2009 Operational Highlights

- Total revenues increased 40% to £37.0m (2008: £26.4m)
- Gross profit up 44% to £24.8m (2008: £17.2m)
- Operating loss from continuing operations down 32% to £6.7m (2008: £9.8m loss)
- Pre-tax loss down 20% to £9.4m (2008: £11.8m loss)
- Net cash at 30 June 2009 of £28.1m prior to Aventis settlement (31 Dec 2008: £34.7m)
- Business well financed
- On track for operating profitability late 2009, full year 2010

# Financial Highlights

£millions	H1 2009	H1 2008	Change
Revenue – products	34.6	25.4	+ 36%
Licensing & royalty income	2.4	1.0	+ 140%
<b>Total revenue</b>	<b>37.0</b>	<b>26.4</b>	<b>+ 40%</b>
Gross profit	24.8	17.2	+ 44%
	67%	65%	
Overheads	(29.1)	(23.4)	+ 24%
Other exceptional losses	-	(2.2)	
Depreciation / Amortisation	(2.4)	(1.4)	+ 71%
<b>Operating loss</b>	<b>(6.7)</b>	<b>(9.8)</b>	<b>- 32%</b>
Net interest / tax	(2.8)	(1.3)	
Change in warrant fair value	(0.2)	(0.7)	
<b>Loss for period from continuing operations</b>	<b>(9.7)</b>	<b>(11.8)</b>	<b>- 18%</b>
Discontinued operations	(0.2)	-	
Loss for the period	(9.9)	(11.8)	

# Product Sales

£millions	H1 2009	H1 2008	Growth
Abstral	1.0	-	-
Rectogesic	3.9	3.1	+ 26%
Tostran	1.0	0.6	+ 67%
Xomolix	3.9	2.9	+ 34%
<b>Total Pan-EU</b>	<b>9.8</b>	<b>6.6</b>	<b>+ 48%</b>
Adcal-D3	9.1	7.8	+ 17%
Sancuso	3.7	-	-
Pencial	3.1	2.3	+ 35%
Other products	8.9	8.7	+ 2%
<b>TOTAL PRODUCT SALES</b>	<b>34.6</b>	<b>25.4</b>	<b>+ 36%</b>

## Cash Flow 6 Months to 30 June

£millions	2009	2008
<b>Cash generated from operations</b>	<b>(8.6)</b>	<b>(6.4)</b>
Net interest / tax	(1.9)	(0.8)
Capex – tangible / intangible	(0.8)	(0.2)
Loan drawdown (net)	5.0	10.0
<b>Net cash inflow for period</b>	<b>(6.3)</b>	<b>2.6</b>
Exchange (losses)/gains	(0.3)	(0.1)
Cash at beginning of period	34.7	24.5
<b>Cash at bank 30 June</b>	<b>28.1*</b>	<b>27.0</b>
Cash at bank 31 December 2008	-	34.7

\* Includes a further £5.0m drawdown from £50.0m debt facility - £8.0m still available for drawdown

\* On 2 July ProStrakan settled the outstanding tax issue with Aventis Pharma with a payment of €9.15m, which reduces the cash balance



## **Operating Review**

### 1. Oncology Supportive Care Business

# Sancuso

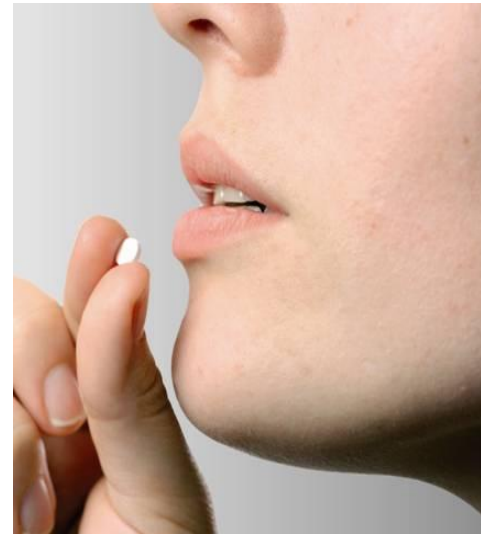
- Transdermal granisetron patch for CINV (Chemotherapy Induced Nausea and Vomiting)
- Detailed by 82 person dedicated US sales force
  - Excellent call frequencies, good recall
  - Strong feedback on efficacy
- Excellent progress in reimbursement
  - Reimbursed so far in 94% of commercially covered lives
  - 68% of Medicare covered lives
  - Priced at \$310 per patch (pre-discount)
    - After 8.8% price increase in June
- £3.7m sales in H1 2009
  - Additional £0.5m invoiced in H1 but not recorded as revenue





# Abstral – US Strategy

- Exclusive rights for US, Canada, Mexico in-licensed 31 July 2008
- Development studies complete
  - Interim Phase III results announced Dec 2007
  - Pain relief at 30 minutes (SPID 0-30 minutes) greater than placebo (p=0.0004)
  - Statistically significant relief seen as early as 10 minutes
  - All primary and secondary endpoints met
  - Studies completed end 2008
- NDA filed by ProStrakan August 2009
  - Awaiting FDA validation
- Deal paid for by increased royalties on sales
  - Increased by 7-9%
  - Minimal cash impact 2008 – 2010
- Major new oncology product launch 2010
  - Fits very well with Sancuso sales force





## **Operating Review**

### 2. Non-Oncology Products

# Tostran / Fortigel

- Testosterone gel for androgen deficient males
- Double strength (2%)/half volume
- Cosmetically pleasant formulation in metered pump
- EU launches successfully completed
  - 48% market share in Sweden
  - 19.5% market share in Spain
- US NDA re-filed April 2009



# Rectogesic / Cellegesic

- Indicated for pain associated with chronic anal fissures
- Only approved prescription product in most of Europe, no approved product in US
- EU launch programme completing
- Approvable status in US
- US pivotal trial completed
  - Results support re-filing NDA
  - Re-filing planned for H2 2009



# Newsflow

- **Sancuso** EU Regulatory review under way
- **Fortigel** US NDA re-filed April 2009
- **Abstral** EU UK, Germany, France launched. Spain H2 2009  
US NDA filed August 2009
- **Cellegesic** US NDA re-filing H2 2009
- **Profitability** Break-even expected by end 2009  
1<sup>st</sup> full year of operating profit expected 2010

# H1 2009 Summary

- **Continuing strong growth**
  - Product sales grew by 36% to £34.6m
  - Total revenues grew by 40% to £37.0m
  - Continued strong cash position of £28.1m at 30 June 2009
- **EU business growing strongly**
  - Pan-European product revenues up 48%
  - Abstral roll-out well-advanced
  - Abstral sales of £1.0m
- **US oncology business well-established**
  - Good levels of reimbursement for Sancuso
  - Sancuso sales on target at £3.7m
  - Two product NDAs filed; one further US filing planned H2 2009



 ProStrakan