

# Press Release

**ProStrakan Group plc**

**Interim Management Statement**

**Galashiels, UK. 18<sup>th</sup> May 2010:** ProStrakan Group plc (LSE: PSK), the international specialty pharmaceutical company, today issues its first Interim Management Statement (“IMS”) for the 2010 financial year.

## **Trading**

The first four months of 2010 (1<sup>st</sup> January – 30<sup>th</sup> April) saw further progress for ProStrakan.

Total product revenues increased by 29% (32% at constant currency rates) with growth in product sales coming from the EU, US and from partners. Income from licensing was lower than for the same period in 2009, as April 2009 saw certain one off receipts being recognised in relation to the out-licensing of Abstral in Central and Eastern Europe. These have not been repeated in 2010 and, accordingly, impact the overall Group revenue when compared with last year.

Total revenues for the first four months of 2010 increased by 21% (23% at constant currency rates) over the corresponding period in 2009 and ProStrakan was profitable on an EBITDA basis for the first four month period in the Group’s history.

## **Product Sales Update**

Sales of the Group’s pan-EU products – Rectogesic, Tostran and Xomolix – increased by 23% during the period, while the Group’s best-selling product, Adcal-D3, which is marketed only in the UK, showed further growth of 20%.

Abstral was launched across Europe during the course of 2009 and we reported sales of £5.8m in its first year on the market. In the first four months of 2010 Abstral has already recorded sales of £5.0m and successfully established itself in each of the countries in which it has been launched. Abstral has achieved the following market shares of doses for the month of March 2010: France 27%; Germany 20%; Spain 10%; Sweden 69%; and UK 21%. There is also evidence of a significance increase in the size of the market for fentanyl-based products for breakthrough cancer pain across the major EU countries in which ProStrakan operates (France, Germany, Spain and the UK). This market has grown by 45% (Q1 2010 v Q1 2009) and of that growth, ProStrakan commanded a 61% share (Source: IMS, March 2010).

Sancuso continues to benefit from the measures implemented in H2 2009 and recorded sales of £2.6m, up 7% (15% at constant currency rates) compared to the same period in 2009. We have initiated a strategy designed to establish the Sancuso brand further in the US market and increase uptake of the product. These initiatives include:

- A specialty pharmacy strategy to assist conventional retail channels, including discounts and a samples programme.
- Enhancement of the Sancuso co-pay assistance programme with a new maximum co-pay card which limits the co-pay that patients are required to make.
- Increased discounts on Sancuso for Medicare and Medicaid patients.
- A strong focus on large oncology hospitals and clinics with a drive to achieve a formulary or clinical pathway status for Sancuso.

The various brand-strengthening investments being implemented each entail a degree of discounting with the consequence that the reported net revenues for Sancuso mask the underlying trend in unit sales, which were materially higher on average for the first four months of 2010 over the same period in 2009.

### **Business Development / Partnering**

Partnering remains a key focus for ProStrakan and is expected to generate a significant ongoing revenue stream in the future. During the first four months of 2010, our various partners launched Abstral in Latvia, Lithuania, Slovenia, Estonia and Hungary; Xomolix in Croatia; and Rectogesic in Israel. Furthermore, our partners filed Abstral for approval in

Canada and have completed the initial stage of the regulatory filing procedure for Sancuso in Saudi Arabia, UAE, Kuwait, Bahrain, Oman and Qatar during the period.

**Fortesta (Tostran)** – Endo Pharmaceuticals Inc, our US partner for Fortesta (branded as Tostran in much of Europe), has now completed the re-analyses requested by the FDA in its complete response to Fortesta’s NDA re-submission. Endo has reported that the results are entirely consistent with the original analysis and, consequently, Endo intends to submit its complete response to the FDA at the end of H1 2010. A further milestone payment will become payable by Endo to ProStrakan upon approval of the NDA.

### **Product Development**

We currently have a number of products at various stages of registration:

**Abstral** – this product is currently in registration in the US. In August 2009, we filed Abstral with the US Food and Drug Administration (“FDA”) who allocated a 10 month review period to this New Drug Application (“NDA”). Our NDA included a Risk Evaluation and Mitigation Strategy (“REMS”) which is being considered as part of ProStrakan’s application.

**Rectogesic** – ProStrakan received a complete response letter from the FDA in March 2010 for our NDA for Rectogesic. We are currently awaiting the opportunity to meet with the FDA to discuss their requirements for a re-submission.

Commenting on today’s Interim Management Statement, Dr Wilson Totten, Chief Executive of ProStrakan, said:

“We continue to make progress on a number of fronts across ProStrakan. Sales growth is encouraging; ongoing partnering activity is strong; and we are working towards the US approval of two of our products. With the first four months of the year under our belts and showing profitability on an EBITDA basis, we continue to focus sharply on growing the business profitably through continued sales growth and tight cost management.”

**Ends**

**Notes to editors:**

There will be a conference call for investment analysts today (18<sup>th</sup> May, 2010) at 8.30am BST. Please contact Val Mugridge at Brunswick on +44 (0) 20 7396 5325 for details.

**About ProStrakan:**

ProStrakan Group plc is a rapidly growing specialty pharmaceutical company engaged in the development and commercialisation of prescription medicines for the treatment of unmet therapeutic needs in major markets.

ProStrakan's head office is located in Galashiels in Scotland. The company's development capabilities are centered in Galashiels and Bedminster, New Jersey, USA. Sales and marketing of ProStrakan's portfolio of products are handled by commercial subsidiaries in the UK, US, France, Germany, Spain, Italy and other EU countries.

You can learn more about the business at: [www.prostrakan.com](http://www.prostrakan.com)

**For further enquiries, please contact:**

<b>ProStrakan</b>	+44 (0) 1896 664000
Dr Wilson Totten, Chief Executive	
Allan Watson, Chief Financial Officer	
Callum Spreng, Corporate Communications	
<b>Brunswick Group</b>	+44 (0) 20 7404 5959
Jon Coles / Justine McIlroy	