

# Press Release

**ProStrakan Group plc**

## **Abstral PDUFA Date Update**

**Galashiels, UK. 2<sup>nd</sup> June 2010** – ProStrakan Group plc (LSE: PSK), the international specialty pharmaceutical company, today announces that the US Food and Drug Administration (“FDA”) has extended the review period under the Prescription Drug User Fee Act (“PDUFA”) for Abstral<sup>®</sup> by three months.

The FDA has issued the extension following its earlier request for additional information on the Abstral Risk Evaluation and Mitigation Strategy (“REMS”). ProStrakan has submitted this information.

Abstral is a rapidly-disintegrating tablet for sub-lingual (under the tongue) administration of fentanyl intended for the management of breakthrough pain in cancer patients who are already receiving opioid analgesics for their underlying persistent cancer pain.

Dr Wilson Totten, ProStrakan’s Chief Executive Officer, said:

“We have provided the clarifications on the Abstral REMS that the FDA requested and we view the extension as a positive sign of the review progress.

“Based on the FDA review progress for other REMS programmes, we had already factored in contingency timing for additional REMS review and we remain on schedule for the launch of Abstral in the US in the second half of 2010.”

Ends

**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 Mclroy	

**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)