

Press Release

ProStrakan Group plc

Galashiels, UK. 10th January 2011

Pre-Close Trading Update and announcement of US FDA approval of Abstral

Trading Update

ProStrakan Group plc (LSE: PSK), the international pharmaceutical company, today issues a pre-close trading update for the 12 months ended 31st December 2010, ahead of the publication of the Group's Preliminary Results, scheduled for Thursday 17th March 2011.

Financials

- Revenues continued to grow strongly in 2010 – total revenues for the year, at some £100m, were up by 27% (29% at constant currency rates) compared with 2009 and in line with management's expectations.
- Product sales recorded strong growth and were up 20% (23% at constant currency rates) versus 2009, with growth in product sales coming from the EU and from the Group's international partners.
- ProStrakan's EU business grew very strongly in 2010, with revenues of around £80m, up 20% (24% at constant currency rates).
- In the US, Sancuso grew strongly until September 2010 at which point revenues were impacted by the previously announced manufacturing supply issue. Total revenues for Sancuso were £6.8m in 2010.
- Partnering revenues were up approximately 150% versus prior year with income from product sales more than treble those of the prior year. Income from licence receipts included a \$12.5m (£8.1m) registration milestone received from Endo Pharmaceuticals Inc in relation to the approval by the US Food and Drug Administration ("FDA") of FORTESTA in the US, as announced on 30th December 2010.
- Product sales highlights were as follows:
 - Abstral achieved excellent sales of some £17m, with a first full year of commercial operations in the UK, Germany, France and Spain.
 - The Group's multi-country products – Tostran, Rectogesic and Xomolix – recorded sales growth of 14% in 2010.
 - Adcal-D3, with sales of around £23m, grew by 13% in 2010.

Products Update

Abstral

ProStrakan today announces that it has received approval from the FDA for Abstral (fentanyl) Sublingual Tablets, for the management of breakthrough pain in cancer patients, 18 years of age and older, who are already receiving, and who are tolerant to, opioid therapy for their underlying persistent cancer pain.

ProStrakan expects to launch Abstral in the US in early Q1 2011 – its second oncology product launch in the US. Launch preparations are at an advanced stage and sales teams have already completed a significant level of training. Abstral will be the only rapidly-disintegrating sublingual tablet for breakthrough cancer pain on the US market, where the overall annual market value for immediate release fentanyl products is \$550m (Source: Wolter Kluwers, August 2010. MAT).

Abstral is the first product to be approved in the US with the FDA mandated class-wide Risk Evaluation and Mitigation Strategy (“REMS”) for transmucosal immediate release fentanyl products. The Abstral REMS allows appropriate prescriptions to be filled at retail pharmacies as well as providing access to Abstral within hospitals.

Abstral has been a significant driver of growth for ProStrakan in Europe. The product is now marketed by ProStrakan across the principal European markets – UK, Germany, France, Spain, Italy and Sweden – and by June 2010 had gained an average share of 24% of the fast-acting fentanyls market across these countries (Source: IMS, June 2010).

FORTESTA

As announced on 30th December 2010, approval has been received from the FDA for FORTESTA (testosterone) Gel. Endo Pharmaceuticals Inc. (NASDAQ: ENDP), with whom ProStrakan has partnered for this product in the US, now plans to launch FORTESTA in early 2011.

FORTESTA is a patented testosterone transdermal gel, for testosterone replacement therapy in male hypogonadism, which utilises a metered dose delivery system designed to permit accurate dose adjustment to individual patient requirements. Each pump actuation provides 10 mg of testosterone in 0.5 mg of gel. This product is approved in the EU and is marketed there by ProStrakan under the brand names Tostran, Tostrex, Fortigel and ltnogen.

As previously announced, Endo Pharmaceuticals has made an upfront payment to ProStrakan of \$10m and FDA approval of FORTESTA has now triggered an approval milestone payment of \$12.5m (£8.1m), with a further potential \$15m of milestone payments payable in 2011 subject to the achievement of early commercialisation events. Further milestone payments of up to \$160m are payable to ProStrakan upon the achievement of certain sales targets. ProStrakan will exclusively supply FORTESTA to Endo Pharmaceuticals for the US and will receive an undisclosed royalty rate on sales generated there.

In 2009 the Testosterone gels market was valued at \$730m, recording growth of 15% over the prior year.

Sancuso

Aveva Drug Delivery Systems, the manufacturer of Sancuso, recommenced production of Sancuso in December 2010 and the release of initial batches for commercial use is anticipated in January 2011.

Development Update

Rectogesic was re-filed with the US FDA on 21st December 2010, following receipt of a complete response from the FDA announced on 1st April 2010. A PDUFA goal date has yet to be received from the FDA but the Group expects a six month review period for the re-filing.

ProStrakan's re-filing of Sancuso in the EU has been validated and approval is expected for this product in Q4 2011.

Refinancing

At a General Meeting on 7th January 2011 shareholders approved a number of resolutions relating to the proposed refinancing, assignment and amendment of the Group's Existing Loan Facility described in more detail in the circular to shareholders dated 21st December 2010. The proposals as defined and referred to in the shareholder circular will become unconditional on, and will complete on, 12th January 2011.

Offer Update

As announced by the Company on 15th November 2010, the Board has received expressions of interest in the Company and its assets which it is evaluating. The process of evaluating these expressions of interest is ongoing and the Company cannot provide any further information at this stage in relation to a potential offeror or offerors or any information in relation to any potential offer.

Peter Allen, Chairman and Acting Chief Executive of ProStrakan, said:

"We are delighted, at the beginning of 2011, to be reporting details of two US product approvals, the recommencement of production of Sancuso and a strong trading update.

"FDA approval of Abstral is another significant step forward for ProStrakan, enabling us to launch our second major oncology support product in the US, the world's largest pharmaceutical market. Abstral is already being prescribed for patients across Europe who suffer the debilitating effects of breakthrough cancer pain and we believe that the benefits of Abstral's rapid pain relief will be recognised by both clinicians and patients in the US.

"FDA approval for FORTESTA will see the launch, by Endo Pharmaceuticals, of ProStrakan's second approved product in the US. Male hypogonadism remains a problem for many men over the age of 40 and our partnership with Endo Pharmaceuticals, who already have a portfolio of urology and endocrinology products in the US, will ensure that FORTESTA is available to clinicians across the US.

"2010 has demonstrated once more that ProStrakan's business model of distributing our proprietary products through our own sales forces and those of our partners is robust. Our EU business has once again performed strongly and we look forward to reporting growth in

the US in 2011 with the re-establishment of Sancuso and the launch of Abstral into the US oncology support market.”

Ends

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Additional Product Notes

Abstral

Breakthrough pain is an acute and often severe flare of pain, experienced by patients suffering from cancer, which occurs even though a person may be taking opioid pain relief medicine regularly for their persistent pain. It is known as breakthrough pain because it is pain that "breaks through" a regular pain medicine schedule. It may be caused by the cancer itself or it may be related to cancer treatment.

Formulated in strengths of 100µg, 200µg, 300µg, 400µg, 600µg and 800µg, Abstral is a rapidly disintegrating sublingual tablet formulation of fentanyl citrate designed for oral transmucosal delivery. The product offers an alternative therapeutic choice to patients and clinicians with a simple, patient friendly and predictable way of delivering fentanyl transmucosally while retaining the individualised dose titration aspects required for optimal treatment of breakthrough pain.

Abstral is in-licensed by ProStrakan for Europe, the US, Canada and Mexico from Sweden-based Orexo AB. In line with ProStrakan’s overall distribution strategy of generating further meaningful revenue streams in territories that are non-core, Abstral has been out-licensed by ProStrakan in Canada – where it is currently under review – to Paladin Laboratories Inc. and in Central & Eastern Europe (“CEE”) to Gedeon Richter Plc, which has launched Abstral (under the brand name Lunaldin) in six CEE countries.

Pharmacokinetic studies have confirmed rapid absorption of fentanyl from Abstral with dose proportional pharmacokinetics across the available dose range and a plasma concentration profile that is appropriate to the desired time course for episodic breakthrough pain.

Abstral has been shown to be effective in a double-blind, placebo controlled, randomised Phase III study in cancer patients. The efficacy results showed statistically significant improvements for pain intensity and pain relief measures for breakthrough pain episodes treated with Abstral compared with episodes treated with placebo. Abstral showed a

statistically significant difference in Pain Intensity reduction compared to placebo over the first 30 minutes of breakthrough pain. Statistically significant improvements in pain intensity difference (PID) were observed for Abstral (compared to placebo) as early as 10 minutes after administration, which continued throughout the measurement period of 60 minutes ($P \leq 0.0055$).

In addition, the percentage of breakthrough pain episodes that required the use of rescue medication during the Double-blind Treatment Phase was higher for episodes treated with placebo (27.4%) than for episodes treated with Abstral (11.2%). The mean patient satisfaction with Abstral during the Double-blind Treatment Phase was statistically significantly better for breakthrough pain episodes treated with Abstral compared with episodes treated with placebo ($p = 0.0006$).

Abstral was well-tolerated in opioid-tolerant cancer patients treating breakthrough pain episodes as needed for up to 12 months with no reported local effects due to Abstral in the oral cavity.

The Abstral REMS program will allow the dispensing of Abstral in retail pharmacies across the US, once they are enrolled in the program. ProStrakan has partnered with RelayHealth to develop and deliver an innovative REMS program for Abstral that is designed to integrate with the pharmacy management system to automatically verify that all REMS requirements have been met prior to the pharmacist dispensing Abstral. The Abstral REMS program has been designed to minimize burden on prescribers and pharmacies and allow appropriate patient's access to Abstral.

The goals of the Abstral REMS are to mitigate the risk of misuse, abuse, addiction, overdose and serious complications due to medication errors by:

- Prescribing and dispensing Abstral only to appropriate patients, which includes use only in opioid-tolerant patients.
- Preventing inappropriate conversion between fentanyl products.
- Preventing accidental exposure to children and others for whom it was not prescribed.
- Educating prescribers, pharmacists, and patients on the potential for misuse, abuse, addiction, and overdose.

The FDA has requested that all immediate-release fentanyl products are brought within a single REMS model and then within a single REMS system within 2011. It is anticipated that the Abstral REMS will be very similar to the class-wide REMS for all immediate-release fentanyl products.

As part of the approval, the Company has agreed to conduct a post-approval clinical study of Abstral in children.

Common adverse reactions to Abstral include nausea, constipation, drowsiness and headache. Serious adverse reactions, including deaths, have occurred with other immediate-release fentanyl products. Deaths have occurred because of improper selection of patients and/or incorrect dosing.

A full copy of the FDA press release related to the approval of Abstral can be found at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm239490.htm>

FORTESTA

Male hypogonadism, is frequently characterised by reduced libido, loss of muscle mass, bone density and diminished energy levels. These symptoms, if confirmed by low blood testosterone levels, can be alleviated through testosterone replacement therapy.

An estimated 13.8 million American men have testosterone levels characterised as below normal (testosterone <300ng/dl). However, only approximately 9% of men with low testosterone are treated with testosterone replacement therapy. In a multicentre, open-label, non-comparative, pivotal Phase III trial, 90-day study involving men with hypogonadism, 77.5% of patients using FORTESTA had an average serum total testosterone concentration within the normal range at day 90. The most common side effect in this trial was application site reactions.

FORTESTA is clear and odourless and is gently applied directly to the front and inner thighs with one finger, and not to the upper body.

Sancuso

Sancuso is a transdermal patch that delivers granisetron, an established 5-HT₃ receptor antagonist, steadily into the bloodstream for up to seven days. It helps to prevent the side-effects of nausea and vomiting in patients undergoing chemotherapy (CINV) for up to five consecutive days, without the need for daily injections or having to swallow pills.

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 centred in Galashiels and Bedminster, New Jersey, US. 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.

www.prostrakan.com