

# Press Release

**ProStrakan Group plc**

## **ProStrakan Partners with Endo for Fortigel (FORTESTA) in the US**

**Galashiels, UK. 26<sup>th</sup> August 2009** – ProStrakan Group plc (LSE: PSK), the international specialty pharmaceutical company today announces that it has signed an exclusive licensing and distribution agreement for Fortigel<sup>®</sup> (testosterone) 2% Gel in the United States of America with Endo Pharmaceuticals Inc. (Nasdaq: ENDP). Endo plans to market this product in the US under the brand name: FORTESTA<sup>™</sup>.

FORTESTA is a patented 2% 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. This product is in registration in the US, where the Food and Drug Administration (FDA) is currently reviewing ProStrakan's New Drug Application submission.

Under the terms of the agreement, Endo Pharmaceuticals has agreed to make an upfront payment to ProStrakan of US\$10m with potential for a further US\$40m in milestone payments by the end of 2010, comprising a milestone payment for the achievement of FDA approval and, separately, milestones for the achievement of early commercialisation events. Further milestone payments of up to US\$160m are payable to ProStrakan upon the achievement of certain sales targets. ProStrakan will exclusively supply FORTESTA to Endo Pharmaceuticals in the US and will receive an undisclosed royalty rate on sales generated there.

Endo Pharmaceuticals already has a portfolio of urology and endocrinology products in the US and plans to offer FORTESTA alongside the new, long-acting injectable testosterone product, Nebido, which is currently in registration in the US.

FORTESTA (branded variously in Europe as Tostran, Tostrex and Itnogen) is marketed across Europe by ProStrakan's own in-house sales forces and is outlicensed by ProStrakan to Bayer Schering Pharma in 147 countries, in many of which this product is planned to be promoted alongside Nebido.

In 2008, the total US testosterone market was valued at US\$873m, with transdermal gels representing 85% of this market (source: IMS Health).

ProStrakan will use 50% of the proceeds from the upfront and FDA approval milestone payments to reduce debt under its existing £50m credit facility, of which the Company has currently drawn down £42m. Following this early repayment, the Company has agreed with its lenders that it will make no further draw-downs from this facility. ProStrakan will commence repayment of the remainder of this facility on schedule from December 2010. Early repayment of a proportion of the debt facility will result in a commensurate interest saving while still providing the Company with sufficient cash to service the ongoing needs of the business.

Commenting on the announcement of this strategic partnership with Endo Pharmaceuticals for FORTESTA, Dr Wilson Totten, Chief Executive of ProStrakan, said:

“The US testosterone gel market is the largest in the world and partnering with Endo ensures that FORTESTA will achieve its full potential, becoming accessible to urologists and their patients across the United States.

“This arrangement allows ProStrakan to continue our strategy of focusing on our growing US oncology supportive care franchise while capitalising on the full value of FORTESTA in both the short and longer term.”

Ends

## **Further enquiries:**

### **ProStrakan**

Dr Wilson Totten, Chief Executive  
Callum Spreng, Corporate Comms

Tel: +44 (0) 1896 664000

### **Brunswick Group**

Jon Coles / Justine McIlroy

Tel: +44 (0) 20 7404 5959

### **Trout Group (for US investor enquiries)**

Gitanjali Jain Ogawa

Tel: +1 (646) 378-2949

## **About Hypogonadism**

Estimates show that around 6%-12% of men over the age of 40 have clinically low testosterone (source: Araujo et al 2004<sup>1</sup>).

This condition, known as male hypogonadism, is frequently characterised by reduced libido, loss of muscle mass, bone density and diminished energy levels. These symptoms 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.

## **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, 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.

[www.prostrakan.com](http://www.prostrakan.com)

## **About Endo**

Endo Pharmaceuticals is a specialty pharmaceutical company engaged in the research, development, sale and marketing of branded and generic prescription pharmaceuticals used to treat and manage pain, overactive bladder, prostate cancer and the early onset of

puberty in children, or central precocious puberty (CPP). Its products include LIDODERM<sup>®</sup>, a topical patch to relieve the pain of postherpetic neuralgia; Percocet<sup>®</sup> and Percodan<sup>®</sup> tablets for the relief of moderate-to-moderately severe pain; FROVA<sup>®</sup> tablets for the acute treatment of migraine attacks with or without aura in adults; OPANA<sup>®</sup> tablets for the relief of moderate-to-severe acute pain where the use of an opioid is appropriate; OPANA<sup>®</sup> ER tablets for the relief of moderate-to-severe pain in patients requiring continuous, around-the-clock opioid treatment for an extended period of time; Voltaren<sup>®</sup> Gel, which is owned and licensed by Novartis AG, a nonsteroidal anti-inflammatory drug indicated for the relief of the pain of osteoarthritis of joints amenable to topical treatment, such as those of the hands and the knees; SANCTURA<sup>®</sup> and its XR version for treatment of overactive bladder; VANTAS<sup>®</sup> for the palliative treatment of advanced prostate cancer; and SUPPRELIN<sup>®</sup> LA for the treatment of early onset puberty in children. The company markets its branded pharmaceutical products to physicians in pain management, neurology, surgery, oncology, endocrinology and primary care. More information, including this and past press releases of Endo Pharmaceuticals, is available at [www.endo.com](http://www.endo.com).

1. Araujo AB, O'Donnell AB, Brambilla DJ et al. Prevalence and incidence of androgen deficiency in middle-aged and older men: estimates from the Massachusetts Male Aging Study. *J Clin Endocrinol Metab* 2004; 89(12): 5920–5926.