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## **Diamyd puts focus on pain projects and reduces costs**

*Diamyd Medical AB is concentrating its resources on the Company's drug candidates for the treatment of pain and diseases of the nervous system. The termination of the Phase III program with the diabetes therapy Diamyd® means significantly lower costs for the Company which creates strategic leeway.*

The primary development focus of Diamyd Medical is shifted from the diabetes therapy Diamyd® to the Company's portfolio of drug candidates for the treatment of chronic pain. The pain portfolio is based on the patented technology Nerve Targeting Drug Delivery System (NTDDS). NTDDS represents a new type of treatment that delivers gene-based drugs directly to nerve cells, providing a local effect in the cells targeted by the treatment. Besides pain relief the technology has potential to be used for the treatment and prevention of diseases in the nervous system, such as neuropathy, erectile dysfunction (impotence), neurodegenerative diseases and cancer. Research and development of NTDDS is mainly being carried out by the subsidiary Diamyd, Inc. in Pittsburgh, USA.

Results from a Phase II study with the furthest developed drug candidate, NP2 Enkephalin for the treatment of severe cancer pain, is expected around year end. At the same time the next drug candidate in the portfolio, NG2 GAD for the treatment of diabetes pain for instance, is planned to be ready to enter clinical phase, the phase of drug development which comprises studies in humans. The portfolio also includes several projects in earlier stages of development.

"The shift of the Company's primary development focus to the unique NTDDS technology gives us a fresh start before fall," says Peter Zerhouni, President and CEO of Diamyd Medical. "The next milestone will be the results from the Phase II trial with NP2 Enkephalin, which we hope will establish proof of principle for this new method of treating pain as well as the entire NTDDS platform."

The two parallel Phase III studies with the diabetes therapy Diamyd® in Europe and the US are being closed since Diamyd®, as previously reported, did not demonstrate sufficient efficacy neither in the European Phase III study nor in a similar, smaller study conducted by the research consortium TrialNet. Diamyd Medical is also terminating most of the employees in Sweden since they have mainly worked on the Phase III studies with Diamyd® and in related areas. The Phase III program with Diamyd® has accounted for approximately two thirds of the Company's costs which will, consequently, decrease substantially going forward. The Company expects to have approximately SEK 400 million in liquid assets at the end of the calendar year.

"Through strict cost control we safeguard our favourable financial position, which represents a strength in the current turmoil of the capital markets," says Peter Zerhouni. "Having plenty of cash on hand gives us valuable strategic leeway, not least when we get the results from the Phase II study with NP2 Enkephalin."

The interest in Diamyd® and the active substance GAD65 is still high among diabetes researchers. GAD65 plays an important role in type 1 diabetes and continues to have potential to be used against the disease. Important discussions are ongoing within the research field about why the studies with Diamyd® did not meet the endpoints and how lessons learned from these and other studies in type 1 diabetes can guide the future development of GAD65 towards a diabetes drug. One approach being tested is to treat earlier in the disease process, before the onset of the disease. An externally funded and researcher-initiated Phase II study with Diamyd® is ongoing since 2008 in order to prevent type 1 diabetes in children at high risk of developing the disease, and that study continues. Other potential ways forward are giving more or higher doses of Diamyd®, or combining Diamyd® treatment with other drugs.

Work still remains in analyzing the large amounts of data collected in the Phase III studies with Diamyd® and new data is still being collected. To complete the safety database of the US Phase III study and in consultation with the US Food and Drug Administration (FDA), the Company has decided to follow the patients who received injections of Diamyd®, but not the ones who received placebo, for six months after the last injection.

The last follow-up visit is planned to take place in December. In the European Phase III-study, all of the patient visits have been completed.

**For more information, please contact:**

Peter Zerhouni, President and CEO Diamyd Medical AB (publ.)  
Phone: +46 8 661 0026

**For press material, please contact:**

Andreas Ericsson, Diamyd Medical AB (publ.)  
press@diamyd.com  
Phone: +46 8 661 0026

**About NTDDS**

Diamyd Medical's portfolio of drug candidates for the treatment of pain comprises the drug candidates NP2 Enkephalin, NG2 GAD and NE2 Endomorphin. They are based on the Company's patented NTDDS platform (Nerve Targeting Drug Delivery System) and developed for the treatment of chronic pain, such as cancer pain and diabetes pain. NTDDS delivers gene-based drugs directly to nerve cells, providing a local effect in the cells targeted by the treatment. NTDDS also has potential to be used for treating diseases of the peripheral and central nervous system such as peripheral neuropathy, erectile dysfunction (impotence), neurodegenerative diseases and cancer.

NP2 Enkephalin produces the opioid enkephalin locally for the treatment of pain and is the furthest developed drug candidate in the portfolio. NP2 Enkephalin has been evaluated in a clinical Phase I study for treatment of chronic cancer pain and is now being tested further in a Phase II study.

The Phase I study with NP2 Enkephalin was designed as an open label, dose-escalation study in patients with intractable pain due to malignant cancer. Although the study was not primarily conducted to study efficacy, substantial and sustained pain relief was observed. No treatment related serious adverse events have been reported by any participant in the study. The Phase I study has laid the groundwork for future studies with other drug candidates that use NTDDS to treat other diseases and conditions.

In the ongoing Phase II trial with NP2 Enkephalin, the study subjects' pain scores and their concomitant pain medication usage are being followed. The study is a multicenter, placebo-controlled clinical trial designed to enable a statistical evaluation of pain relief and will recruit approximately 32 subjects with severe cancer pain. The study includes a four-week double-blind study period, after which all patients will be offered up to two additional doses of active NP2 Enkephalin in an open label study extension.

The next NTDDS-based drug candidate in Diamyd Medical's pain portfolio is NG2 GAD for the treatment of diabetes pain for instance. NG2 GAD has potential to be used for the treatment of several diseases.

**About Diamyd Medical**

Diamyd Medical is a Swedish pharmaceutical company focusing on the development of pharmaceuticals for the treatment of pain and autoimmune diabetes. The portfolio of development projects for the treatment of chronic pain uses the Company's patented NTDDS (Nerve Targeting Drug Delivery System) platform to administer drugs directly to the nervous system. The development project within the area of diabetes consists of the protein GAD65 for the treatment and prevention of autoimmune diabetes.

Diamyd Medical has offices in Sweden and in the US. Shares are listed on Nasdaq OMX in Stockholm (ticker: DIAM B) and on OTCQX in the US (ticker: DMYDY) administered by the Pink OTC Markets and the Bank of New York Mellon (PAL). Further information is available on the Company's website: [www.diamyd.com](http://www.diamyd.com).

*This information is disclosed in accordance with the Swedish Securities Markets Act, the Swedish Financial Instruments Trading Act, or the requirements stated in the listing agreements.*

**Diamyd Medical AB (publ.)**

Karlavägen 108, SE-115 26 Stockholm, Sweden. Tel: +46 (0)8 6610026, Fax: +46 (0)8 661 63 68  
E-mail: info@diamyd.com. VAT no: SE556530-142001

