

# DIAMYD MEDICAL

”In the treatment of Diabetes and Diabetes related complications”

Extra General Shareholders meeting  
March 10, 2008



# Agenda

- ▶ 1. Opening of the meeting
- ▶ 2. Election of the Chairman Extra General Shareholder's Meeting
- ▶ 3. Drawing up and approval of the voting list
- ▶ 4. Approval of the Agenda
- ▶ 5. Election of secretary and two persons to attest the minutes
- ▶ 6. Decision on proper notice of Extra General Meeting
- ▶ 7. The Board of Directors proposal of authorization and voting
- ▶ 8. Closing

# About Diamyd Medical

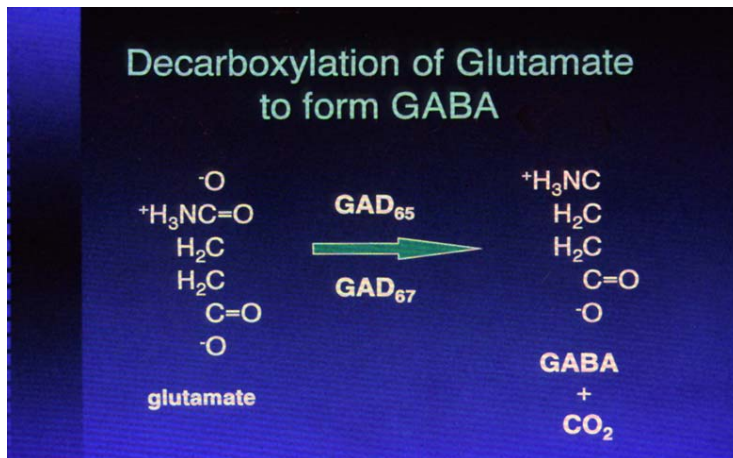
- ▶ BioPharmaceutical company listed on NGM 1997
- ▶ Listed on OMX since 2002 (NOMX ticker: DIAM B)
- ▶ US ADR Level 1 since 2006 (ticker: DMYDY)
- ▶ Offices in Stockholm, Sweden & Pittsburgh, PA, USA

Autoimmune diabetes & Diabetes related complications

**Diamyd<sup>®</sup> & NTDDS**

# Diamyd®

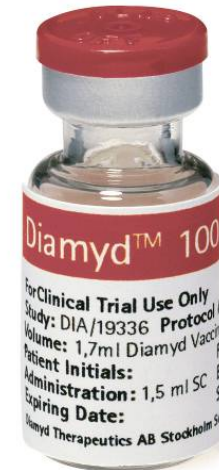
- ▶ GAD is a major antigen in the autoimmune attack against pancreatic beta cells that results in insulin dependent diabetes, also called autoimmune diabetes



- ▶ Diamyd Medical has an exclusively licensed patent portfolio which protects the therapeutic use of recombinant GAD

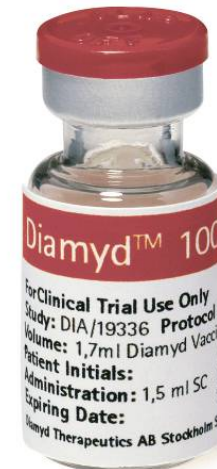
# Treatment with Diamyd®

- ▶ Small dose – 20 µg in 0.5 mL subcutaneous injection
- ▶ Two simple injections (day 1 and day 30)
- ▶ Significant effect for more than 30 months
- ▶ Clean safety profile
- ▶ Easy to administer, no hospitalization
- ▶ High acceptance among parents and patients



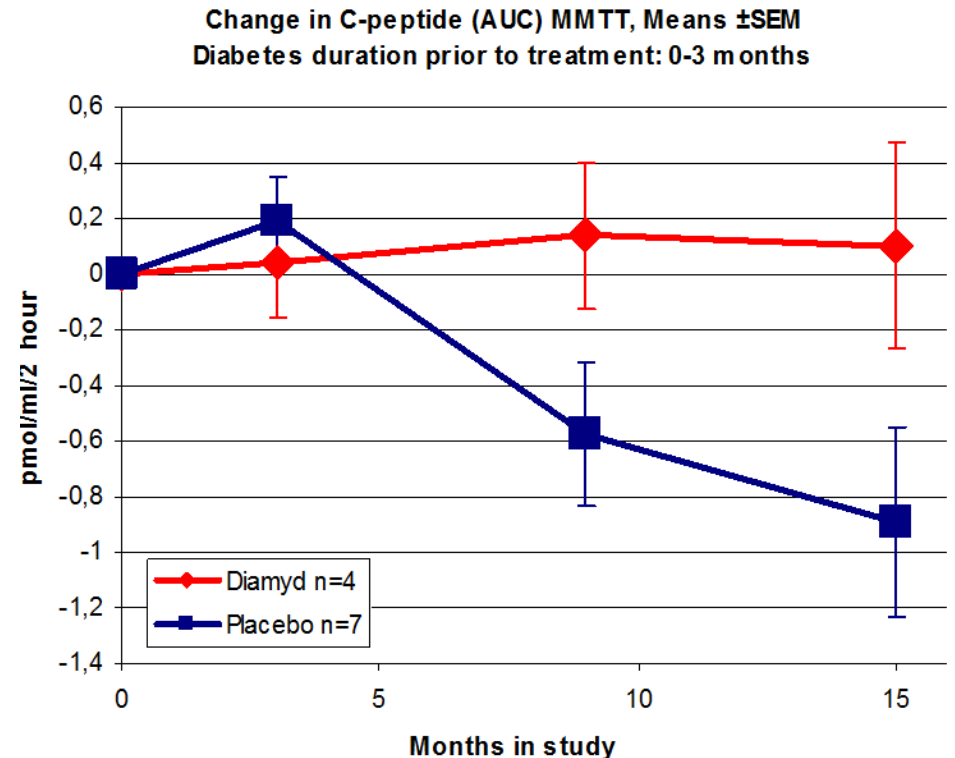
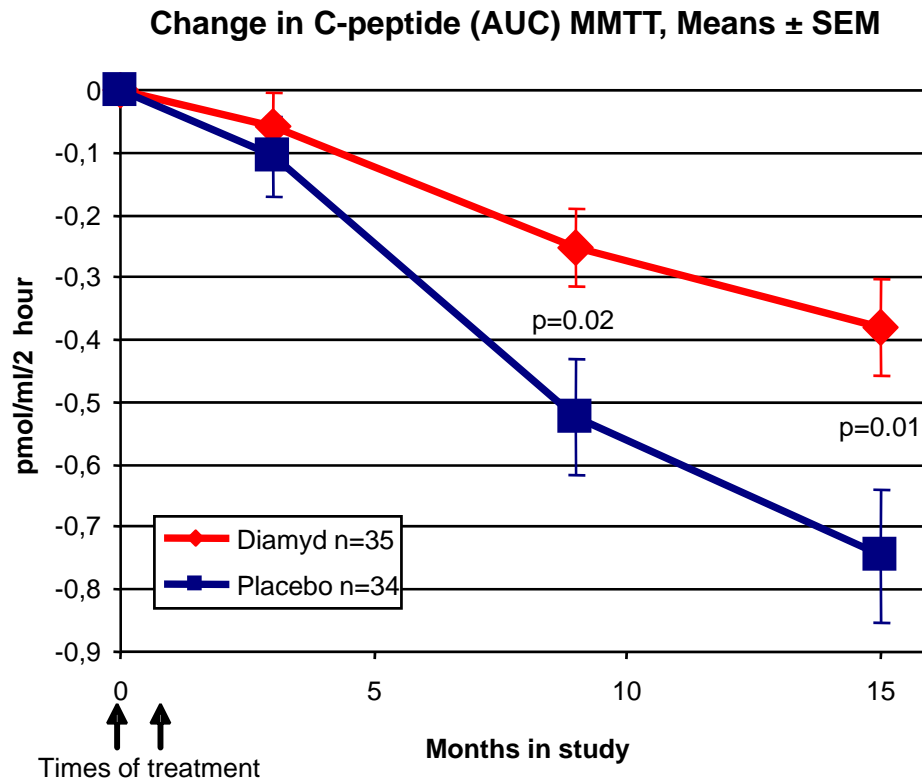
# Diamyd<sup>®</sup> Clinical Trials to Date

- ▶ No treatment related Serious Adverse Events in any Diamyd<sup>®</sup> study!
- ▶ 149 patients treated with Diamyd<sup>®</sup> in total, of which 35 children
- ▶ Up to 5 yrs of follow-up



# Diamyd<sup>®</sup> Efficacy in Type 1 Diabetes

- ▶ Left: Patients with diabetes type 1 for less than 18 months
- ▶ Right: Patients with diabetes type 1 for less than 3 months



# Received email (Swedish)

- ▶ Idag:
- ▶ Skiter jag i svenska "Jante"
- ▶ Ger jag tusan i att man inte ska "ropa hej förrän man är över bäcken"
- ▶ Bryr jag mig inte om att "man ska inte vara för glad för då..."
- ▶
- ▶ Idag:
- ▶ Har jag facit på hand
- ▶ Vet jag att det ÄR alldeles på riktigt och sant
- ▶ att vår älskade Maria är en av 30 ungdomar i Sverige som har fått verksamt vaccin för diabetes
- ▶ att hon är en av fyra som kom in till sjukhuset i exakt rätt tid och gick in i diabetesstudien i exakt rätt stund och därmed är en av de som visar så gott resultat att det ser ut som om man har lyckats stoppa sjukdomsförloppet.
- ▶ Att hon idag efter tre långa ovissa år i en blindtest har ett medelvärde på sitt långtidsblodsocker på 4.
- ▶
- ▶ Med innerlig värme och glädje böjer jag mig ödmjukt inför DIAMYD, svensk sjukvård, svensk forskning och den som varsamt vakade över Maria den dagen hon blev sjuk och en av deltagarna.
- ▶
- ▶ Om framtiden vet man inget, hur långt vaccinet "bär henne" har vi ingen aning
- ▶ Men idag känns livet som en solig sommardag, på cykel i nedförsbacke och härlig medvind.
- ▶
- ▶ *Med vänliga hälsningar*
- ▶ *Eva*

*(Maria och Eva är fingerade namn)*



# Worldwide recognition of Diamyd®

- ▶ ***Press Release, Stockholm, Sweden, November 22, 2007***  
*“Diamyd Medical announced today that it has executed a Clinical Trial Agreement with the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) for a planned clinical study with the Diamyd® GAD-alum diabetes vaccine in 126 new onset type 1 diabetes patients...”*

The study is conducted and sponsored by the NIH/NIDDK global network TrialNet, a group of the world's foremost experts and key opinion leaders in type 1 diabetes. The study is separate from the company's phase III program.

# Current Status and Near-term Plans



- Start phase III trials during spring 2008
- 2 x 300 early onset T1D patients
- 0-3 months since diagnosis
- 15 month study period and 15 month follow-up

- ☑ US IND for phase III trials with Diamyd<sup>®</sup> filed in December 2007  
– Principal Investigator: Professor Jerry Palmer, Seattle

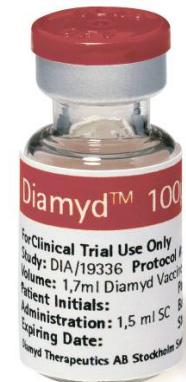
Approval expected March 11<sup><</sup>, 2008

- ☑ EU phase III trials with Diamyd<sup>®</sup> filed in Sweden in January 2008  
– Principal Investigator: Professor Johnny Ludvigsson, Linköping

Approval expected March 18<sup><</sup>, 2008

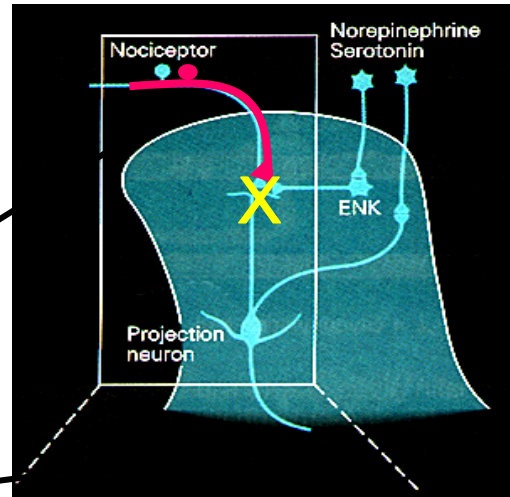
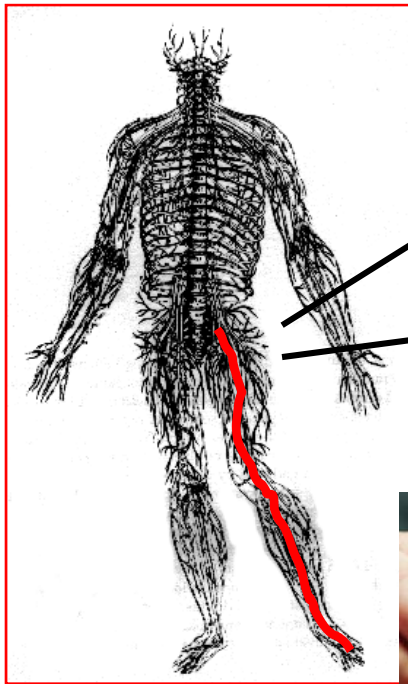
# Diamyd<sup>®</sup> Applications

- ▶ Recent onset type 1 diabetes
- ▶ Preventive treatment of subjects with risk for developing type 1 diabetes
- ▶ Type 2-LADA
- ▶ Combination therapies with beta cell regeneration agents, e.g. GLP-1
- ▶ Use in beta cell transplantation
- ▶ Stem cell therapy



# Nerve Targeting Drug Delivery System (NTDDS) New Class of Nerve Therapies

*HSV Gene Delivery new class of nervous system disease therapies*



- Intradermal delivery  
Vector taken up by neuron
- Therapeutic agent released into the synapse of the 1<sup>st</sup> order neuron and spinal cord

# NP2 – NTDDS+Enkephalin for Treatment of Chronic Pain

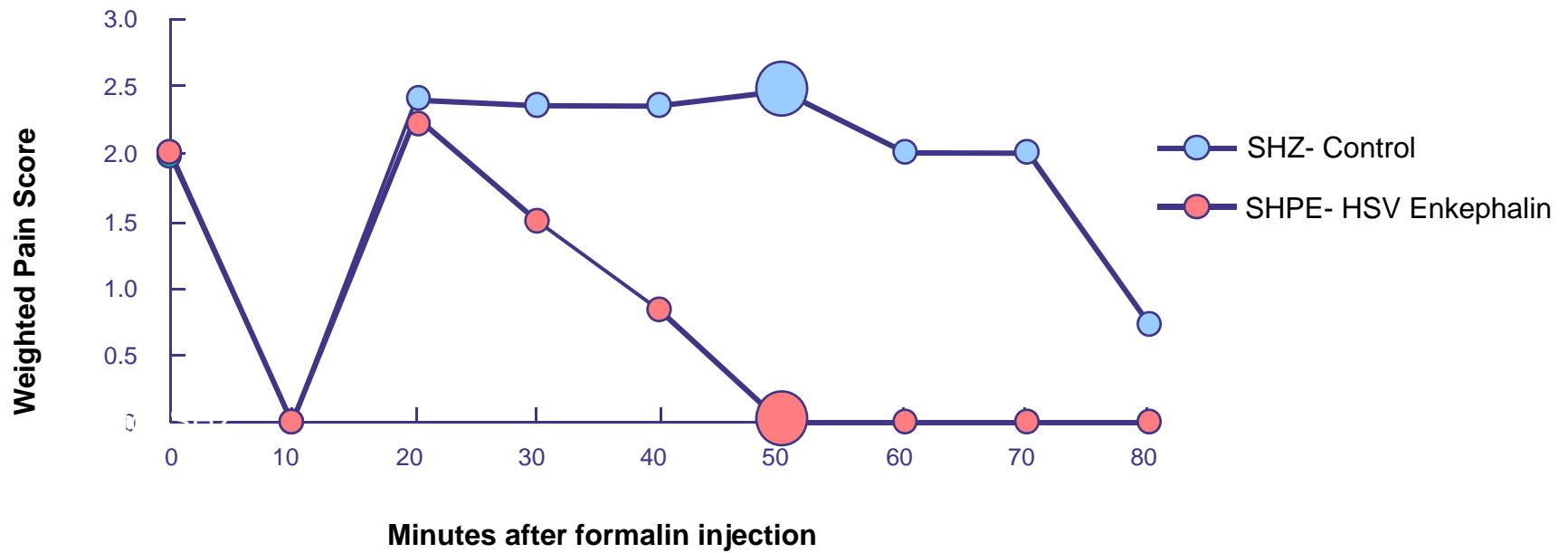
Preproenkephalin (PPE) is processed to form leu- and met-enkephalin opioid peptides. Binding to neuronal opioid receptors blunts pain signal generation.

Enkephalin peptides also have anti-inflammatory effects by acting on opioid receptors expressed on immune cells (eg. macrophages).



# Acute / Inflammatory Pain - Formalin Footpad Test

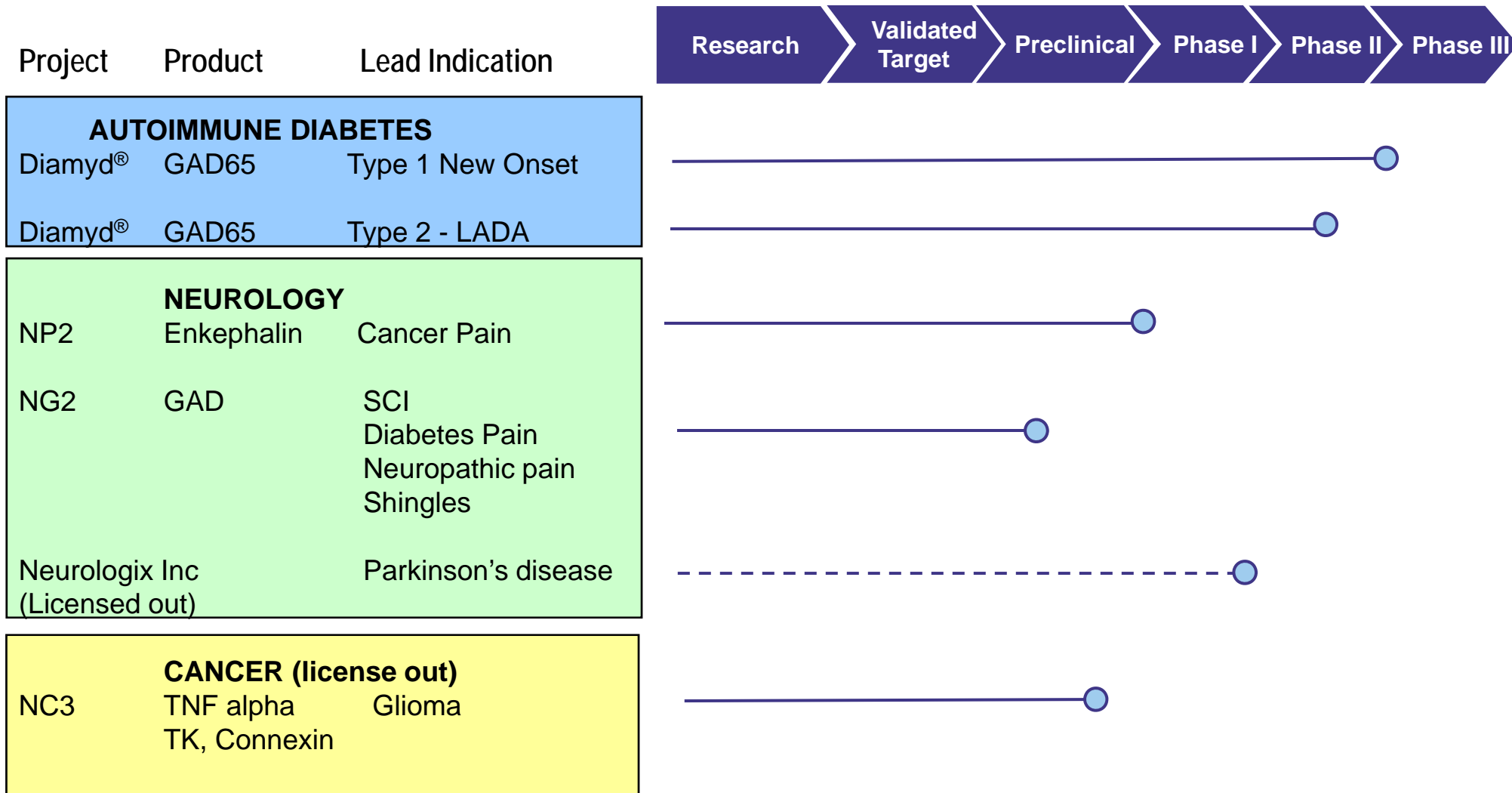
## *HSV Enkephalin Reduces Acute Pain*



# NP2 – Phase 1 Safety Trial – Cancer Pain

- Phase 1 Clinical study Q2 2008
  - Dose escalation trial with 12 patients in three dose cohorts
- IND approved February 2008
- University of Michigan – Principal Investigator David Fink, MD
- Localized pain from cancer. Pain rated very bad for 2 weeks prior to trial. Pain score and opioid use monitored
- Clinical GMP Manufacturing completed - COA issued

# Product Pipeline





# Proposal

- ▶ The Board of Directors proposal for authorization on one or several occasions before the next Annual Shareholders' Meeting, with or without consideration of the preferential shareholder rights to issue 91,000 shares of series B and warrants which will give the right to subscribe for 991,000 B-shares.

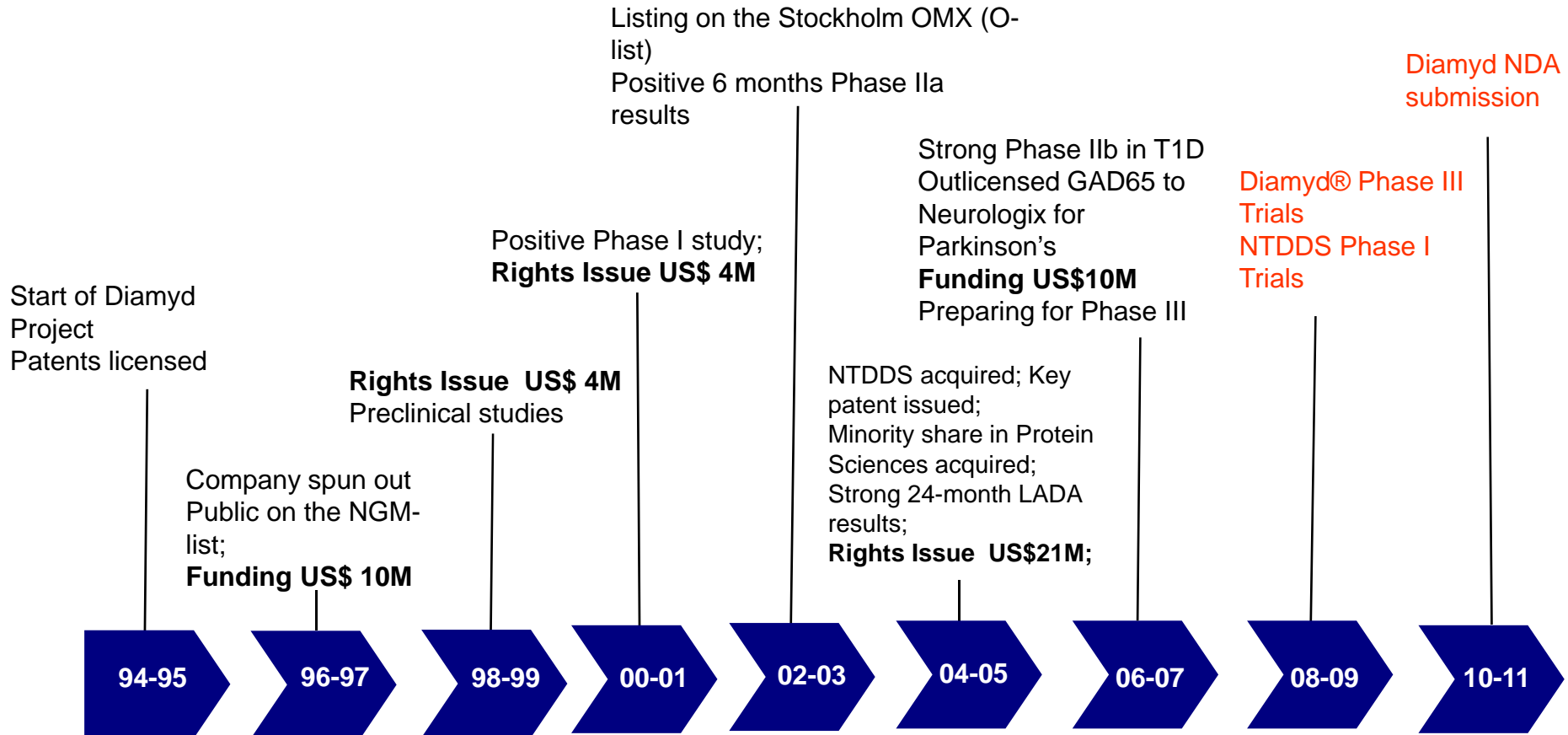
## Proposal cont.

- ▶ The authorization is proposed to be valid for acquiring whole or parts of companies, assets, and cash or for settlements or other conditions as stated in chapter 2 §5 second paragraph 1-3 and 5 in the Companies Act.

## Proposal cont.

- ▶ After full execution of the authorization of issuing shares in combination with the authorization given at the Annual Shareholders' Meeting, the dilution is calculated to 10 percent of the share capital, based on the total number of shares.
- ▶ After full execution of the authorization of the warrants and if they are fully subscribed, the dilution is calculated to additionally 10 percent.

# Diamyd Investment History & Future



Over the years, the Company has had a modest cash burn, and shareholders have invested a total of approximately US\$55M (SEK350M)

# Potential Roadmap – Current View

## Diamyd®

- Phase III studies in US and EU
- TrialNet intervention trial
- 5 year data from Phase IIa LADA trial
- Publication of 30 month results from Phase IIb type 1 diabetes trial
- Partnership deal

## NTTDS

- Phase I trial in cancer pain NP2
- Co-operation with other companies
- File IND for first GAD indication NP3
- Outlicense glioma project

## Other

- Neurologix - Phase II with GAD in Parkinson's

## Diamyd®

- Phase III - last patient in
- TrialNet intervention trial - last patient in
- LADA confirmation study
- Apply for Licence sales
- Set market strategy

## NTTDS

- Phase I trial NP2 final
- Start Phase II NP2
- Phase I trial with NP3 start
- License agreement with other companies

## Diamyd®

- Results Phase III trials
- Filing for market approval
- Add more indications

## NTTDS

- Phase II/III NP2
- Phase II NP3
- Partnership deal

2008

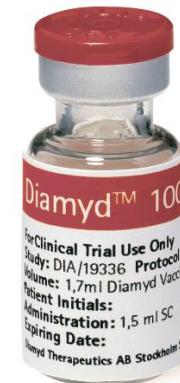
2009

2010

# Investment Strategy

Selling 10% of shares plus additionally 10% in options will give Diamyd a possibility to

- ▶ *Run full speed with Phase III studies*
- ▶ *Continue partnership discussions as a Phase III company*



# Disclaimer

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