

# Panion Animal Health AB

Investor meeting at Mangold, Stockholm, 14 Dec 2018

Share issue; 7-21 December 2018  
Spotlight Stock Market

Anja Holm, CEO



## The board of Panion

Dede Willis – expert in start-ups, USA

Lars Thunberg – chairman, economy expert

Merry Kamstrup – veterinarian, expert in eye diseases

Lars Friis Mikkelsen – veterinarian, expert in experimental animals

## Panion's mission

To develop and commercialize a gene therapy treatment for dogs with drug refractory epilepsy based on CombiGene AB's technology and platform. In addition, Panion aims at inlicensing or acquiring other, similar assets, i.e. animal health applications of human health development projects or products.



## Management

Anja Holm – CEO, veterinarian

Carlos N. Velez – Business development  
and inlicensing, pharmacist

Katarina Holm – CFO

## Panion, USA

Carlos N. Velez

Dave Petrick, FDA-expert

Beth Oman, clinical trial monitor

Steven Radecki, biostatistician



## Advisory Board

David Woldbye, Ass. Prof., KU Neuroscience, DK

Karen Munana, Prof., veterinary neurology, USA

Curtis Dewey, Ass. Professor, neurologist, USA

Dominic Marino, Head of staff, neurologist, USA



## Licence agreement: Gene therapy for animals with epilepsy

Panion started as an affiliate to CombiGene AB:

- \* Patent & preclinical studies
- \* gene therapy; human epilepsy

Licence agreement Panion-CombiGene:

USA + Europe, veterinary use

Panion has access to scientific studies and data from trials performed since 2004





## What is gene therapy?

Genes = DNA

In all cells of the body

Codes for proteins that enable all cellular functions

Gene therapy provides "healthy" genes to "disabled" cells, or adds a specific function



## Epilepsy in dogs

Epilepsy is caused by defects in the cells of the brain

Over-activity causes seizures, cramps, etc.

Approx. 1% of all dogs

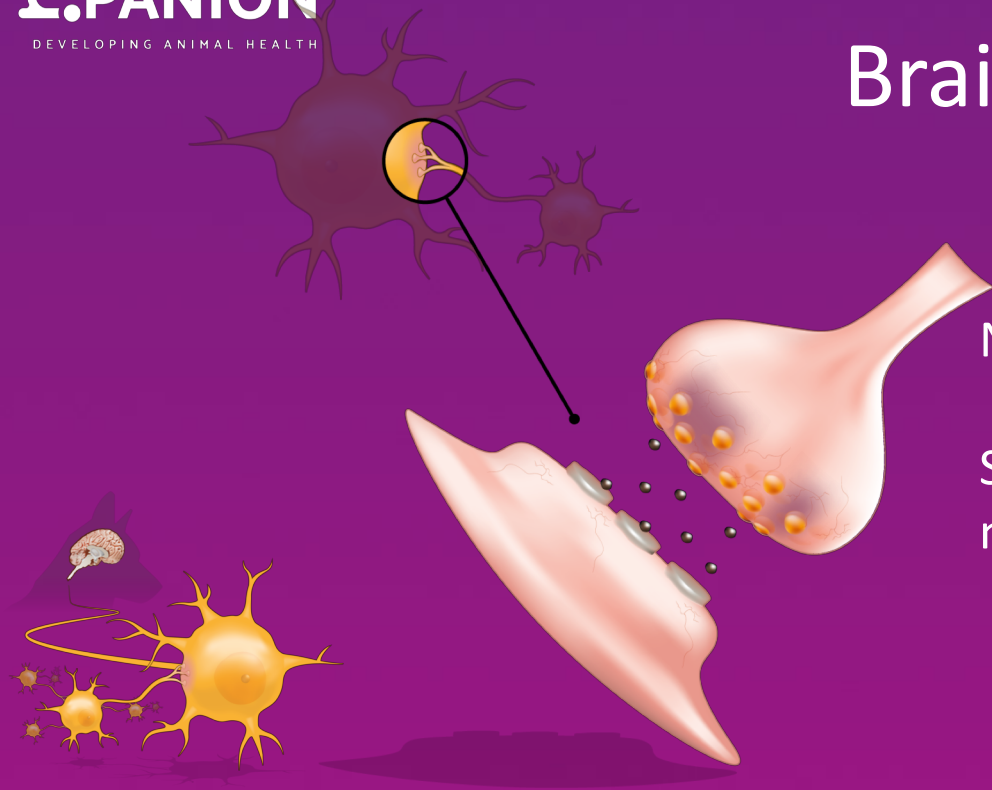
30% of these are drug refractory

Different types of attacks

# Epileptic seizure - dog



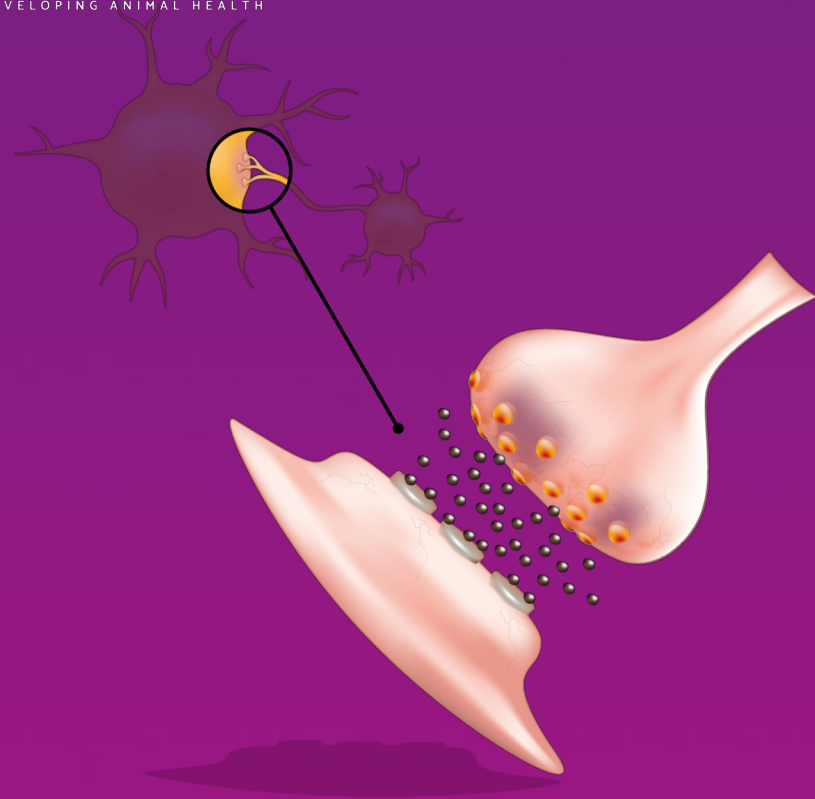
# Brain cell signals



Neurotransmitter glutamate

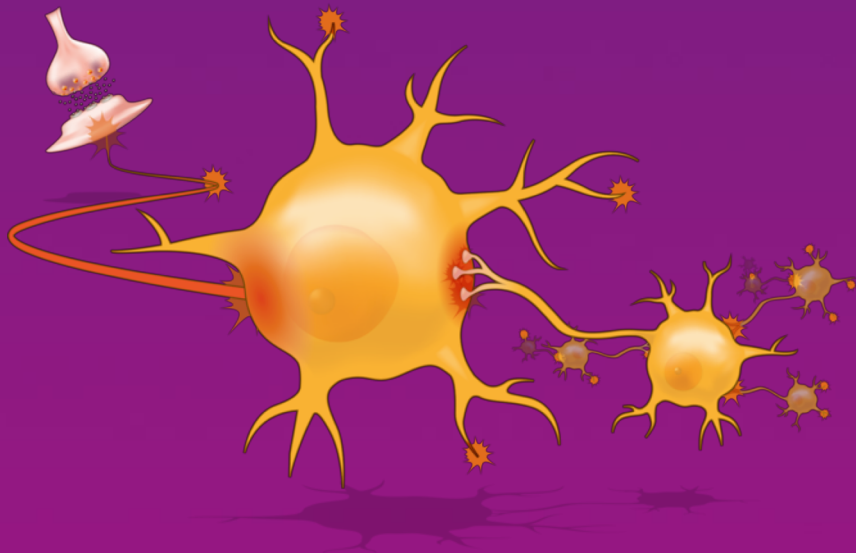
Signals from one brain cell to the next

# Epilepsy



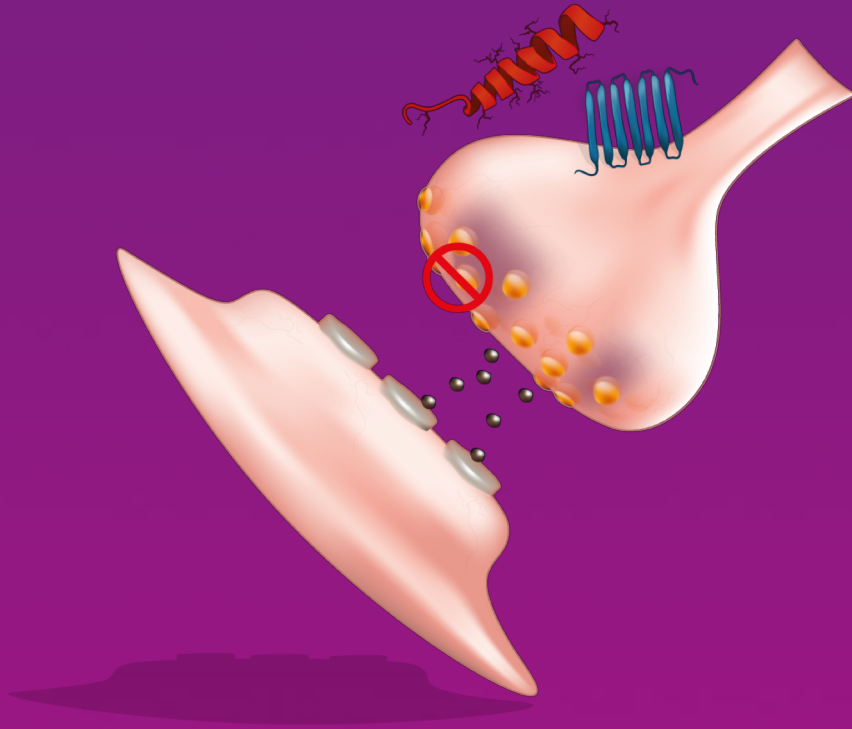
Increased glutamate release  
Increased synaptic communication  
spreading

# Epilepsy



Synchronous hyperactivity in the signals of the brain cells

→ seizures and attacks

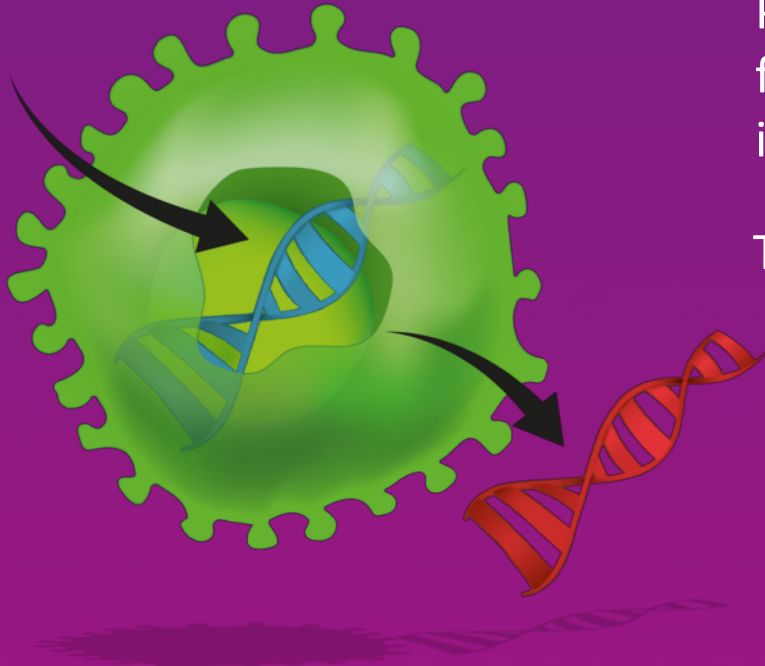


The brain cells release protein NPY  
presumably to stop the seizure again

NPY binds to the specific receptor Y2

Normalisation of the synaptic  
signalling -> seizure stops

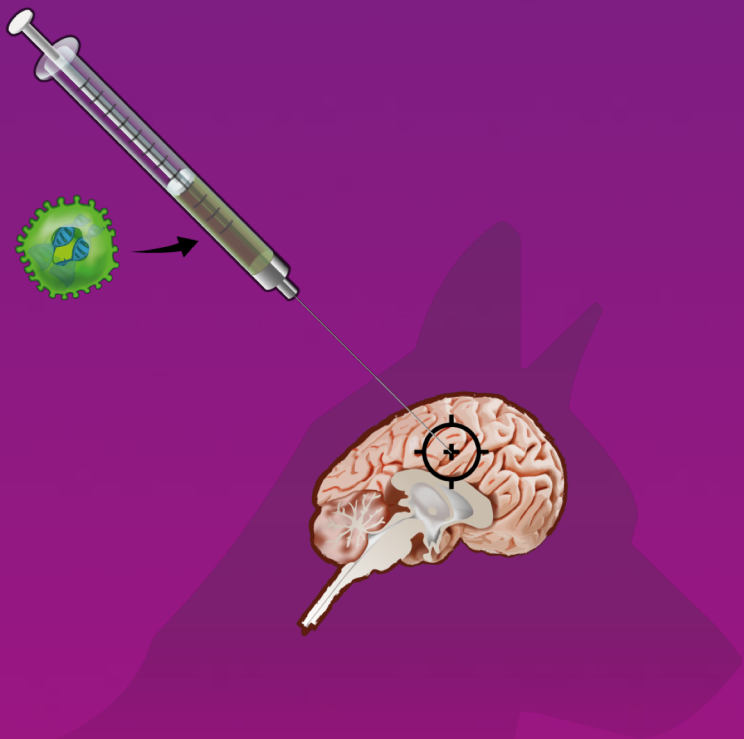




Production of a gene vector  
for transporting new NPY and Y2 genes  
into the cell

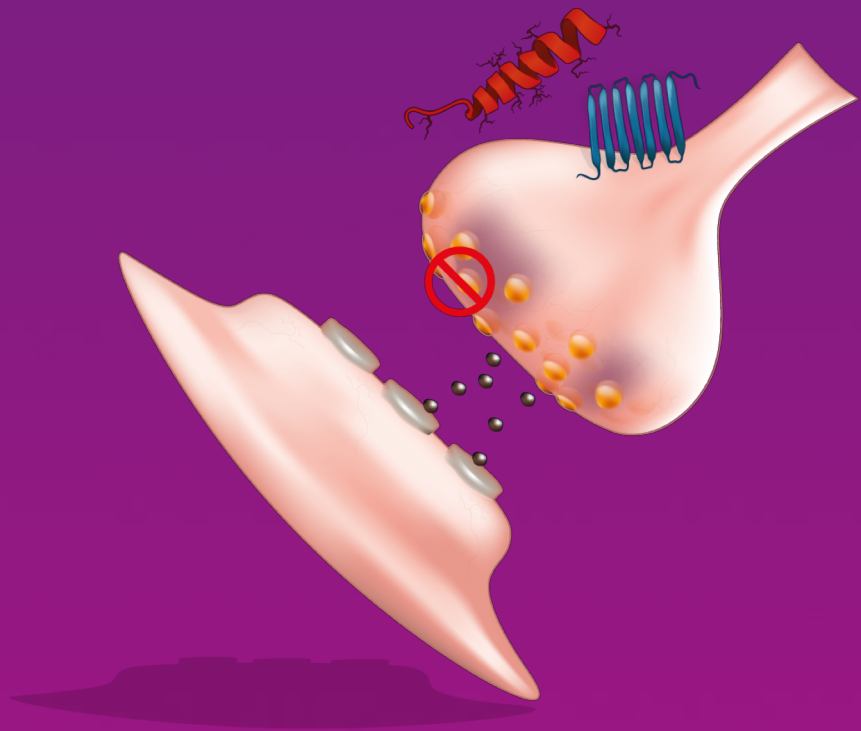
The DNA of the vector is exchanged

- NPY and Y2 transgenes in
- Viral DNA out



Determination of the epileptic focus

Precise injection of vector carrying genes for NPY and Y2

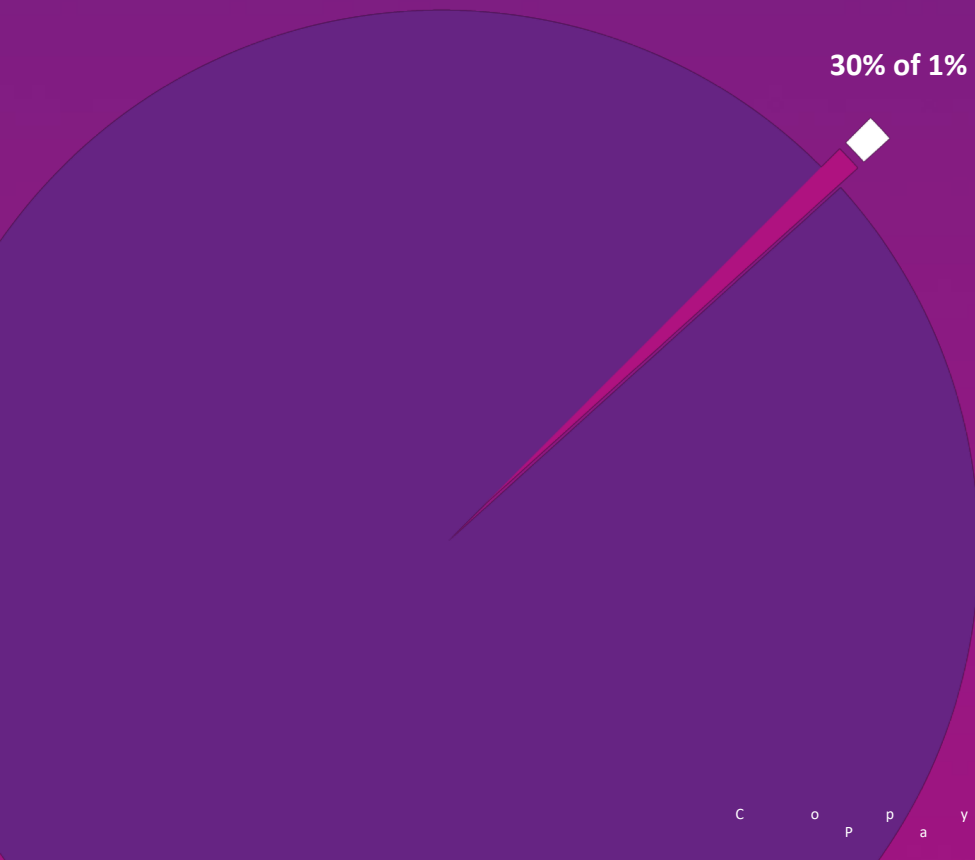


Vector-induced protein NPY and Y2  
are over-expressed in the epileptic  
focus area

Reduce the excess glutamate release

Normalisation of the synaptic  
communication  
→ reduced epilepsy

## Target group of dog patients?



### Number of dogs in USA and EU

- > 1% has epilepsy
- > for 30% medicine has inadequate effect
- = number of potential patients

USA: appr. 78 million dogs -> ~234 000

EU: appr. 75 million dogs -> ~225 000

Patients must be correctly selected for successful treatment

Expected only one single treatment with life-long effect -> opportunity for a high price

# Studies and data available rats

**CombiGenes preclinical data**

**Many rat studies; note:**

**Dose-response study, rats:**

**Success**

**Long-term efficacy, rats:**

**Success**



# Studies and data available dogs

**Panion's dog-data from  
Copenhagen university**

**First safety study, dogs:  
Experimental vector, low dose  
No adverse events**

**Second safety study, dogs:  
CG01-vector, new dose + method  
No adverse events**



## Clinical study in dogs, USA

**Client-owned family dogs with true epilepsy**

**Pilot-study on large hospital in New York;  
Long Island Veterinary Specialists, LIVS  
Contract + study-protocol in place**

**Time plan:**

**First patient Q1-19**

**Each patient total duration 7 måneder**

**Preliminary data expected end of Q4-19**





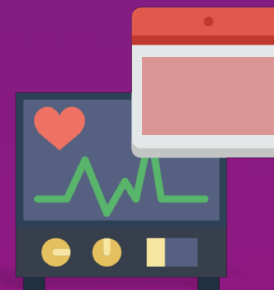


**Pilot Clinical trial, dogs  
USA (started)**

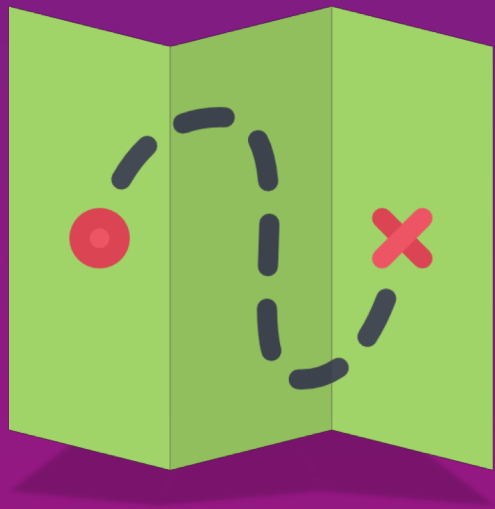
## Next steps



**Regulatory target animal  
safety study, dogs (GMP-vector)**



**Pivotal Clinical trial, dogs  
(GMP-vector)**



## Marketing approval requires

Studies documenting safety and efficacy for dogs

Controlled production of the medicine

(Good Manufacturing Practice = GMP)

Application at authority (FDA/EMA) -> approval

# GMP production

## License agreement with CombiGene

- CombiGene
  - Product development
  - Services agreement
  - Supply agreement
- Panion
  - License fee + royalties
  - Specific veterinary product costs



## Cooperation with authorities

USA:

Application file opened with US-FDA

MUMS (Minor Use Minor Species) status in USA,  
dogs:

- Annual fee-waiver

- Market exclusivity 7 years after approval

- Option for fast "Conditional approval"

Presubmission meeting with FDA's Center for  
Veterinary Medicines, October 2018.



## Cooperation with authorities

Europa:

MUMS status in EU for dog and cat:

Reduced data-requirements for approval

SME status in EU:

Reduced fee for application and advice

Access to help from EMA, fx translations

Meeting with EMA's Innovation Task Force, Juni 2018



## Panion's plans

Develop gene therapy against epilepsy in cats (after dogs)

In-licensing of other products; gene therapy or other innovative therapies

Careful due-diligence for robust decision-making

Market survey started for two potential projects  
- ensure positive forecast

Re-use animal studies performed for testing of human medicine, for new animal medicines





## Share issue

Shares registered at Spotlight StockMarket  
Mangold handles the emission

Signing period: 7-21 december 2018

Secure financing of USA study  
Central persons will become share owners in Panion

Signing of shares by board and management  
expected



# Thank you for your interest in Panion

Anja Holm

CEO for Panion Animal Health AB

More information:

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