

# **Corporate Information**

#### **Background**

Newron Pharmaceuticals S.p.A is a biopharmaceutical company focused on developing novel therapies for diseases of the Central Nervous System, inflammation and pain. The company is based in Bresso, Italy, with additional clinical development operations in Basle, Switzerland, and Bristol, UK. Newron is publicly-traded on the SWX Swiss Exchange under the symbol NWRN.

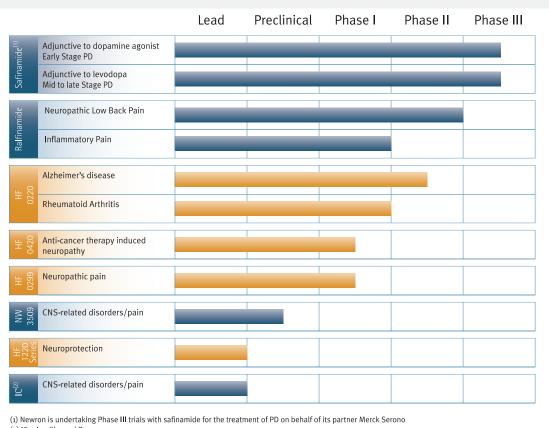


Newron has established a late-stage product pipeline including its lead compound, safinamide, which is currently in phase III development for the treatment of early and mid to late stage Parkinson's disease (PD) with Merck Serono, and ralfinamide, an innovative ion channel inhibitor which is ready to start phase IIb/III trials for Neuropathic Low Back Pain (NLBP). Newron's pipeline was expanded in February 2008 when it acquired the private UK company Hunter-Fleming, which has added three

development-stage compounds and one pre-clinical program. An additional compound is in late pre-clinical development for the treatment of asthma, through a separate company in which Newron holds partownership. The acquisition has broadened Newron's CNS expertise into the pioneering area of neuroinflammation.

#### Safinamide:

- A unique molecule with a novel dual mechanism of action based on the enhancement of the dopaminergic function (through potent reversible inhibition of MAO-B and of dopamine uptake) and reduction of glutamatergic activity by inhibiting glutamate release
- Results of a six month phase III trial (2006) as adjunctive treatment to dopamine agonists in early PD demonstrated a positive effect in motor symptoms and activities of daily living, as well as an improvement in cognitive function while associated with good tolerability
- Results of the 12-month extension of the trial in 2007 showed that the addition of safinamide does not cause any tolerability/safety risk when compared with dopamine agonist monotherapy. It also showed that, at a dose of 50 to 100 mg once daily, safinamide continues to provide sustained improvement of Parkinson's disease motor symptoms and may delay the time to intervention for therapeutic adjustments.



- (3) HF 1020 in preclinical development for asthma is part of Newron's equity holding in Trident



#### Ralfinamide:

- An innovative therapeutic oral agent for neuropathic pain with potential in inflammatory pain
- Small molecule, part of a new chemical class with linear kinetics and excellent "drugability"
- Blocks ion channel subtypes implicated in pain transmission
- Long-lasting anti-allodynic and anti-hyperalgesic effects in models of neuropathic pain
- No development of tolerance on chronic dosing
- Clear evidence of efficacy in a phase II placebo controlled trial in patients with neuropathic pain demonstrated that ralfinamide may provide a unique therapeutic benefit for patients with NLBP. Phase IIb/III trials in NLBP are expected to commence next

#### HF0220:

- A first-in-class therapeutic with powerful cytoprotective and regenerative effects
- An ongoing phase II safety and tolerability study exploring biological markers in patients with Alzheimer's disease
- A phase II study in rheumatoid arthritis to be initiated next

# HF0420:

 A low molecular weight oligosaccharide in phase I for prevention of anti-cancer therapy induced neuropathy

#### HF0299:

 A naturally occurring human steroid in phase I with potential in the treatment of neuropathic pain

#### NW 3509:

 Novel treatment for mania and other CNS diseases, in pre-clinical stage

## **Drug Discovery**

Newron's pre-clinical and clinical pipeline is supported by a portfolio of early-stage proprietary compounds.

#### Strategy

Newron's goal is to become a fully integrated biopharmaceutical company focused on the discovery, development and commercialisation of drugs for the treatment of CNS-related diseases, inflammation and pain, originated from its internal discovery effort and from licensing and acquisitions.

## **Collaborations**

In 2006, Newron signed an agreement with Serono (now Merck Serono) giving them exclusive worldwide rights to develop, manufacture and commercialise safinamide in PD, Alzheimer's disease (AD) and other therapeutic applications. The deal is worth up to \$200 million in upfront and milestone payments, plus royalties to Newron, and gives the company the option to co-promote safinamide in Italy and Spain.

# Management

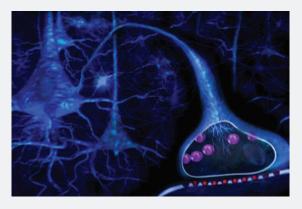
Newron's senior management has an average of 25 years of experience in developing and bringing to the market drugs for CNS diseases such as AD, PD, epilepsy, sleep disorders etc. In addition, senior executives from the pharmaceutical and life science venture capital industry serve on the Board, chaired by Rolf Stahel.

- Luca Benatti, Chief Executive Officer, Director, Founder
- Stefan Weber, Chief Financial Officer
- Ravi Anand, Chief Medical Officer
- Carlos De Sousa, Chief Business Officer
   Stefano Possetti VP Clinical Developmen
- Stefano Rossetti, VP Clinical Development & Regulatory Affairs
- Marco Caremi, VP Strategic Marketing and Head of Legal Affairs
- Patricia Salvati, VP Preclinical R&D, Founder

#### **Funding**

From inception in 1999, Newron raised a total of €62.2m of equity from a group of international life science venture capital investors including 3i, Atlas Venture, Apax, HBM BioVentures, HBM BioCapital and TVM Capital.

In December 2006, Newron was floated on the SWX Swiss Exchange, raising €74.3m.



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