

NeuroVive – a presentation with estimated stock potential

A link to a complete stock analysis, in Swedish by löparn
<http://hem.passagen.se/fingerpr/loparn/PDF/NeuroVive.pdf>

NeuroVive Pharmaceutical, [NVP.ST](#), is a Swedish drug developing company which in April 2011 entered an external French Phase III clinical study with their promising cyclosporin-A-based formulation and drug candidate CicloMulsion, just over a year after NeuroVive had completed its own Phase I trial. The Phase III trial is almost free for NeuroVive since the company is only sponsoring the study with CicloMulsion and placebo.

http://www.neurovive.com/press/2011/110419_First_Heart_Attack_Patient_Treated_with_NeuroVives_CicloMulsion.php

The Phase III study will enroll 1,000 patients with the aim to investigate the efficacy of CicloMulsion in cardiac cell protection after myocardial infarction before PCI treatment to prevent reperfusion injury which otherwise occurs when the blood flow is restored to the heart. A promising French external combined Phase I / II pilot study was completed in 2008.

<http://www.nejm.org/doi/full/10.1056/NEJMoa071142#t=article>

A potential market entry in Europe may occur around 2015-2016 if the study and registration process are successful. As of March 2012 over 250 patients had been included in the study and all was going well. According to the 2011 year end report as of Feb 21 2012 the study is conducted with “ great enthusiasm”, which might be interpreted as a sort of hint of slightly increased probability for success (even if the study is double blinded) since NeuroVive did not use that kind of rather strong expression before. The investigators and NeuroVive are planning to expand the study to Belgium and Spain which would be beneficial for a later drug registration purpose. The world market for drugs against reperfusion injury is very big since millions of people suffer from acute myocardial infarction annually, and many of these patients are undergoing PCI treatment. There are currently no effective drugs available. CicloMulsion is now the first promising drug candidate against reperfusion injury that is known to have commenced Phase III trials. Thus a potential CicloMulsion licensee could get an important so-called first-mover advantage in the market, even if the current cyclosporin-A-formulation only will have a new patent pending. CicloMulsion still according to NeuroVive will be protected to some degree through classified information regarding the clinical trials data base. Generic competitors therefore may have to perform their own complete reperfusion phase I-III clinical trials or wait ten years after the information is no longer protected by the law.

Research also indicates a very big Orphan Drug Designation-protected market potential for NeuroVive in traumatic brain injury (TBI). An external promising combined Phase I / II trial in the USA has previously been completed successfully.

<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2770729/>

NeuroVive will begin its own Phase II/III clinical trials in 2012 starting with Phase IIa with their TBI drug candidate NeuroSTAT. Phase IIb/III is scheduled to follow around 2013-2014.

http://www.neurovive.com/press/2011/110303_NeuroVive_and_the_European_Brain_Injury_Consortium_Sign_TBI_Clinical_Trial_Collaboration.php

There is an estimate that around 3 million people in USA and EU suffer from severe TBI annually. The world market is estimated by NeuroVive to be worth around USD 4 billion. There are no effective neuroprotective drugs on the market today. NeuroVive will probably look for a partner to co-finance this study or a licensee to pay expenses until a possible market introduction.

The statistically estimated probability for success in the Phase III clinical trials is relatively high or could roughly be estimated to 65 % as a common assumption for such advanced trials after the two promising Phase II external clinical trials in each case and much positive preclinical work.

An ischemic stroke project is in preclinical phase in a collaboration with the Dutch company to-BBB. Here they combine NeuroSTAT with to-BBB's [G-technology](#) to a drug candidate called NVP014, with the aim to be able to transport the drug through the blood brain barrier. The project has received a grant from EU after having been highly ranked. Neither in this case are there any effective neuroprotective drugs on the world market today, although the free radical scavenger edaravone is approved in Japan. NeuroVive has a scientific strength in all the three major projects regarding the mechanism of the cyclophilin-D-inhibiting cyclosporin-A (CsA) which now is well researched and understood including the mitochondria based nerve cell and cardiac cell protection mechanism after several preclinical and clinical trials. In addition, the side effects has since long ago been well known due to the fact that CsA has been a drug for decades as an immune system suppressant in organ transplantation. Furthermore in neuroprotection and cardioprotection CsA is administered for a much shorter time and therefore the risk for a backlash due to unknown adverse effects should be relatively low. The mechanism of CsA is thoroughly explained in a well written article published in USA titled [Cyclosporine TBI's Miracle Drug](#).

NeuroVive is also looking for other cyclophilin-D-inhibiting molecules for mitochondria protection in neurological and other diseases. In this case they work together with the British company Selcia. NVP 016 - NVP019 are examples of such drug candidates. They are also performing advanced research concerning molecules for controlling mitochondria energy production. An example is NVP015 which is expected to reach Phase I around 2014.

The clinical research portfolio may look something like this during 2013 to 2015 if the company can fulfill its plans :

Reperfusion injury Europe in the late stage of Phase III or registering with CicloMulsion

Reperfusion injury China Phase III with CicloMulsion

TBI Europe Phase IIa followed by Phase IIb/III with NeuroSTAT

TBI USA Phase II followed by Phase III with NeuroSTAT

TBI China Phase III with NeuroSTAT

Ischemic stroke Europe Phase I followed by Phase II with NVP014

Ischemic stroke China Phase III with NVP014

Energy regulation Phase I with NVP015

NeuroVive if successful in both their reperfusion injury and TBI projects has a potential to achieve a royalty based profit before tax of very roughly SEK 800 million around 2017-2018, which could be compared to the company market value of less than SEK 300 million as of May 3 2012 when the share price was below SEK 14. The earnings potential from the ischemic stroke project is much bigger than the current ongoing clinical projects, over SEK 1000 million. The stock price has a potential to reach over SEK 100 within a few years if NeuroVive is successful in the Phase III reperfusion injury clinical study and the stroke project reaches Phase I which probably are the highest risk/potential until 2014. In an even longer term within five years or so, the stock potential is far higher assuming the TBI project would be successful. Naturally on the other hand the level of risk generally in this type of small drug developing companies is very high since there is a probability that the projects fail in the end. The management and board members directly and indirectly through Maas Biolab, LLC control over 30 % of the outstanding shares.

NeuroVive's shares are now listed on the Swedish trading platform AktieTorget (www.aktietorget.se). The AktieTorget market is focused on emerging, entrepreneurial businesses through an electronic trading system supplied by the OMX Nordic stock exchange in Stockholm, Sweden. NeuroVive has the intention to be listed on NASDAQ OMX Small Cap.

[NeuroVive 2011 annual year-end report](#)

A March 2012 [presentation](#) produced by the company.

Web site: <http://www.neurovive.com>

/This short presentation was made by löparn.