NeuroVive PHARMACEUTICAL

# Newsletter

December 2016


## Broadening portfolio and earlier inflection points

*The year is coming to an end, and it is time to summarize the year that has passed. All in all, it has been an eventful year, especially the second half.*

During the autumn, we communicated positive data regarding our compound NV556 in an experimental model of NASH (non-alcoholic inflammatory fatty liver disease), as well as presented our new business model. We now have two complementary NASH opportunities in our pipeline, each having a large potential commercial value. If the continued preclinical development confirms the results so far, we will initiate out-licensing discussions already during the second half of 2017.

The NASH projects are in line with the company's new two-part business model based on our core mitochondrial medicine expertise. One part involves accelerated development of projects in large specialist and open care indications with high commercial potential, from discovery to the preclinical phase. Successful such projects will be out-licensed at the preclinical phase and further development to the market place will be done by the partner.

In the second part of the business model opportunities such as the current orphan drug projects - traumatic brain injury (TBI) and genetic mitochondrial diseases – will be developed all the way to the market. This model allows us to have an increased number of projects in our portfolio that can create value near and long term, and provide future revenue streams. It furthermore diversifies the risks in our portfolio.

Overall, 2016 was challenging to NeuroVive, but also brought with it many new opportunities. We are now looking forward to continue building and developing our portfolio of exciting research and development programs, creating value for all our stakeholders. I wish to thank all shareholders for the confidence given to us during the year, and, not to say the least, thank our employees and external partners for a job very well done.

Merry Christmas and a Happy New Year!
Erik Kinnman
CEO

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**We have asked Erik what news we should be looking for in the project portfolio during 2017.**

### Which milestones can we expect regarding your clinical project in TBI?

"For the Traumatic Brain Injury (TBI) project with NeuroSTAT, we expect very important results during the coming year. By mid-2017, we expect results from both the ongoing preclinical study at University of Pennsylvania (PENN), as well as data from the ongoing clinical Phase II safety study, CHIC. In the PENN study, we have up until now completed two out of three parts. The first part was a confirmatory bioequivalence study aimed at expanding knowledge from previous ciclosporin studies. The second part was a detailed pharmacokinetics (measuring parameters like half-life and organ distribution of the drug) and brain exposure study, vital for choosing the optimal dosing in the third and final part of the study examining NeuroSTAT's efficacy in the TBI experimental model. The first two parts of the study have been successfully performed and we look forward to the aggregated results including also the third and final part. These results will, together with clinical NeuroSTAT results in CHIC, form the basis for decisions regarding the continuation of the clinical development", Erik explains.

### How is the NVP015 project progressing?

"In the discovery project NVP015, where an acute treatment of energy crisis in patients with genetic mitochondrial disease is developed, we are currently in the process of screening a new series of succinate prodrugs with improved stability in the bloodstream. The most promising compounds from these series are currently being tested in various experimental models. This optimization process has been expanded during the year to include a higher number of interesting compounds than originally planned, and a drug candidate is planned to be selected in the second half of 2017".

### Can we expect any news in the out-licensing portfolio?

"Currently we have two assets targeting the NASH indication, NV556 and NVP022. The present data shows that NV556 prevents fibrosis development in an experimental model of NASH. Further experimental activities with NV556 in NASH are ongoing. We are also developing a new class of compounds, NVP022, with a completely different mechanism of action, that may be supplemental to the treatment of NASH. This project is based on our core expertise in mitochondrial energy regulation and strongly supported by our partner company Isomerase's expertise in innovative chemistry. Both NV556 and NVP022 can play important roles in the combinations of therapies likely required to combat NASH. If the results observed so far are confirmed, we plan to initiate out-licensing discussions with potential partners already during the second half of 2017.

Finally, we are currently evaluating additional exciting programs to further expand our mitochondrial medicine pipeline in the orphan drug area as well as in the large specialist and open care space. We hope to be able to tell you more about these opportunities in the beginning of the year to come", Erik concludes.

**ABOUT NEUROVIVE**

NeuroVive Pharmaceutical AB is a leader in mitochondrial medicine. The company is committed to the discovery and development of medicines that preserve mitochondrial integrity and function in areas of unmet medical need. The company's strategy is to take drugs for rare diseases through clinical development and into the market. The strategy for projects within larger indications outside the core focus area is out-licensing in the preclinical phase.

NeuroVive is listed on Nasdaq Stockholm, Sweden (ticker: NVP). The share is also traded on the OTCQX Best Market in the US (OTC: NEVPF).

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