



Theranexus

SHIFTING THE LINES AGAINST
CENTRAL NERVOUS SYSTEM
DISORDERS



THERANEXUS PROVIDES 2018 FULL-YEAR RESULTS AND UPDATE ON ACTIVITIES

-  NEW CLINICAL DEVELOPMENTS WITH CONTROLLED CASH CONSUMPTION
-  THERANEXUS PROGRAMS PROGRESS REPORT
-  CASH AVAILABLE AS OF 31 MARCH 2019: €12.4M

Lyon, 17 April 2019 – Theranexus, a biopharmaceutical company innovating in the treatment of neurological diseases and pioneer in the development of drug candidates modulating the interaction between neurons and glial cells, today announces its results for the year ending 31 December 2018 and reviews the company's recent clinical milestones and outlook.

Franck Mouthon, Chairman, CEO and co-founder of Theranexus commented, "2018 brought the launch of new clinical trials on all three of our drug candidates as well as the addition of new faces to the teams driving our various programs. This ramping up of the various developments was achieved against a backdrop of controlled cash consumption. Clinical programs deployed in 2018 have forged ahead in 2019, accompanied by the development of our next-generation Neurolead platform, which was awarded over €6 million in funding earlier this year. Neurolead will strengthen our ability to select and qualify drug candidates with a view to broadening and enhancing our portfolio."

Full-year financial results 2018

In k€ (French GAAP)	2018	2017
Sales turnover	0	0
Operating income	175	164
Other purchases and external expenses	4 969	1 477
Salaries and benefits	2 117	1 370
Depreciation of fixed assets	55	26
Other operating expenses	24	11
Operating expenses	7 166	2 883
Operating result	(6 990)	(2 719)
Financial result	(31)	(126)
Corporate tax on profits	1 721	730
Net income	(5 301)	(2 115)

The 2018 full-year results were approved by the Company's Board of Directors on 16 April 2019 and were the subject of a report by the Company's Statutory Auditors.

Other purchases and external expenses amounted to €4,969k in 2018 compared with €1,477k in 2017. This increase is mainly due to the new clinical programs to treat Parkinson's disease (Phase II), Alzheimer's disease (Phase Ib) and the clinical program targeting neuropathic pain.

The increase in salaries and benefits, from €1,370k in 2017 to €2,117k in 2018, resulted from the recruitment of new employees in the scientific, clinical and financial divisions (15-employee workforce as of 31 December 2018).

As a result, the operating loss widened from -€2,719k in 2017 to -€6,990k in 2018.

The financial result, mainly reflecting interest on loans and repayable advances, amounted to -€31k in 2018, compared to -€126k in 2017.

The Research Tax Credit for the 2018 financial year totaled €1,706k, compared with €719k in 2017.

After taking into account €1,721k in tax income, mainly from the Research Tax Credit, net income was negative (-€5,301k in 2018 compared with €-2,115k in 2017).

Cash and cash equivalents totaled €15,170k as of 31 December 2018 and €12,446k as of 31 March 2019. Cash outflows for the financial year (excluding cash flow from financing activities) remained under control: €6,000k in 2018 compared with €2,242k in 2017, generally in line with the change in the net result.

Theranexus Programs Progress Report

Drug Candidate THN102 - Narcolepsy and Parkinson's Disease

THN102 (modafinil/flecainide combination) is currently undergoing a Phase II clinical trial to treat a triad of non-motor symptoms (sleepiness, attention and cognitive disorders) in Parkinson's disease patients, for which no approved treatment is currently available. This triad, a major unmet medical need in the disease, has a very high market value potential (estimated at over \$2 billion). The trial's efficacy criteria compared to placebo include evaluations of sleepiness, alertness and cognition. The trial, which will include 60 patients naive of any treatment for these symptoms at the time of the trial, has already enrolled more than half of its participants in Europe and the United States to date. Results from the trial are expected in the second half of 2019.

Concerning narcoleptic patients, as reported on 27 February 2019, the results of THN102 Phase II failed to demonstrate any difference in efficacy between THN102 and modafinil alone with respect to the trial's primary endpoint (Epworth Sleepiness Scale). Extensive data analysis corroborated an over-representation of severe narcoleptic patients with very low response to modafinil, thus precluding any superiority on the part of THN102. Further work on the narcolepsy program is pending results from the Phase II trial on Parkinson's disease.

Drug Candidate THN201 - Alzheimer's Disease

THN201 is a drug candidate for the treatment of Alzheimer's disease-related neurocognitive disorders currently in a Phase Ib trial to evaluate its superior pharmacological efficacy over the standard of care treatment in healthy volunteers. THN201 contains a combination of donepezil, which acts on neuronal activity, and mefloquine, affecting glial cell activity. The trial, comprising 150 healthy volunteers, has recruited more than 40% of total volunteers to date. Volunteers are spread over 8 sites in France. The results will be published by the close of 2019.

Drug Candidate THN101 - Neuropathic pain

The Phase I program for safety, tolerability and pharmacokinetics in patients with neuropathic pain is ongoing. Phase I program results necessary to commence the Phase II program are due by the end of the first half of 2019.

The Phase II program has already been defined. It will include 370 patients suffering from neuropathic pain of diabetic or post-zosterian origin (following shingles) in 40-45 investigation sites across Europe. The trial's primary endpoint will be based on regular self-assessment of pain by patients using a numerical scale.

Neurolead, a new platform enabling screening based on neuron-glia interactions

In early 2019, Theranexus announced that it had secured funding for a new platform called Neurolead developed in collaboration with the Collège de France and the French Alternative Energies and Atomic Energy Commission (CEA). This next-generation drug candidate discovery platform combines the latest innovations in neuroscience and the use of artificial intelligence tools tailored on a project-by-project basis. It aims to extend and systematize the therapeutic concept promoted by Theranexus by increasing its scope of therapeutic applications on neuron-glia interactions. Neurolead will also optimize the medical value potential of drug candidates by integrating the identification and precise qualification of medical needs from design through to development. Theranexus is currently pursuing preclinical selection and characterization activities for upcoming drug candidates expected to further expand the Company's clinical project portfolio. Bpifrance's €6 million funding package in support of Neurolead will be split among Theranexus and its academic partners. Two thirds of this amount will go towards financing Theranexus' activities directly (50% in the form of pure grants and 50% as advances, repayment of which is conditional on the success of the project), the last third financing the activities of the academic partners (French Alternative Energies and Atomic Energy Commission and the Collège de France) taking part in the platform. Theranexus is currently continuing its preclinical selection and characterization of the next drug candidates to be added to its clinical projects' portfolio.

Recently, Theranexus announced a research collaboration with IRISA (French Institute for Research in Computer Science and Random Systems) aimed at strengthening the therapeutic targeting of neuroglial interactions through the use of artificial intelligence technologies.

Next financial publication:

9 July 2019 (before market opening): Cash position as of 30 June 2019

ABOUT THERANEXUS

Theranexus is a clinical-stage biopharmaceutical company that emerged from the French Alternative Energies and Atomic Energy Commission (CEA) in 2013. It develops drug candidates for the treatment of nervous system diseases. Theranexus identified the key role played by non-neuronal cells (also known as “glial cells”) in the body’s response to psychotropic drugs (which target the neurons). The company is a pioneer in the design and development of drug candidates affecting the interaction between neurons and glial cells. The unique, patented technology used by Theranexus is designed to improve the efficacy of psychotropic drugs already approved and on the market, by combining them with a glial cell modulator. This strategy of combining its innovations with registered drugs means Theranexus can significantly reduce development time and costs and considerably increase the chance of its drugs reaching the market.

The proprietary, adaptable Theranexus platform can generate different proprietary drug candidates offering high added-value for multiple indications.

Theranexus is listed on the Euronext Growth market in Paris (FR0013286259- ALTHX).

More information at: www.theranexus.com



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