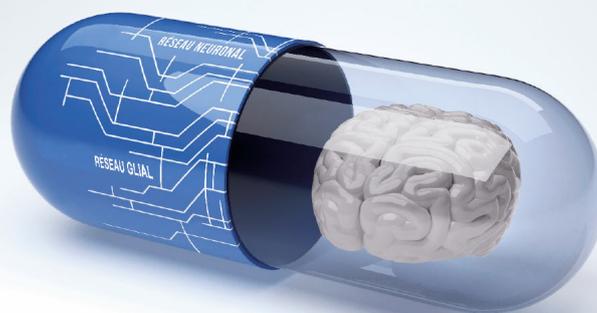




Theranexus

SHIFTING THE LINES AGAINST
CENTRAL NERVOUS SYSTEM
DISORDERS



Theranexus Announces its First Half 2019 Results

Lyon, 26 September 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 first half 2019 results and presents an update on the current status of its programs.

Franck Mouthon, Chairman, CEO and co-founder of Theranexus, made the following comments: *"During the first half of 2019, Theranexus pursued the development and expansion of its drug candidate portfolio. We are eager to share the Phase I clinical results of our drug candidate THN201 for Alzheimer's disease at the end of 2019 and the Phase 2 results of our drug candidate THN102 for Parkinson's disease in Q1 2020. The first year half was also marked by the signing of a term sheet with the Beyond Batten Disease Foundation (BBDF) for the development and marketing of the drug candidate BBDF 101 in Batten disease. These many developments were accompanied by rigorous expenditure management, in line with our ambitious company development program."*

First half 2019 financial results

In k€ (French GAAP)	H1-2019	H1-2018
Turnover	0	0
Operating income	574	101
Other purchases and external charges	2,905	2,034
Wages and social security charges	1,215	992
Amortization and depreciation of fixed assets	30	21
Other operating expenses	10	1
Operating expenses	4,161	3,048
Net operating income/(expenses)	-3,587	-2,947
Net financial income/(expense)	-132	0
Non-recurring income/(expenses)	0	0
Income tax	941	893
Net income/(expense)	-2,778	-2,054

The Company's half-year report for the first half of 2019 will be available on its website on 30 September 2019.

Other purchases and external charges increased during the period to €2,905 K up from €2,034 K in the first half of 2018. This increase was driven by the ramp-up of the Phase II program for Parkinson's disease and the launch of the Phase Ib program for dementia during the second half of 2018.

The increase in wages and social security charges, which rose from €992 K in the first half of 2018 to €1,215 K in the first half of 2019, mainly reflects the full-year effect of recruitments made during 2018, notably the strengthening of the R&D team.

As a result, the operating loss widened from -€2,947 K in the first half of 2018 to -€3,587 K in the first half of 2019.

The net financial expense amounted to €132 K for the first half of 2019 due in particular to interest incurred on financing granted by banking institutions, that was put in place at the start of the second half of 2018, and by Bpifrance.

After taking into account €941 K in tax income, mainly from the Research Tax Credit, net losses were -€2,778 K in the first half of 2019 compared with -€2,054 K in the first half of 2018.

Cash at 30 June 2019 amounted to €10,231 K. This amount does not include income from the €2,245 K in funds raised at the start of July 2019, or repayment of tax credits due for fiscal 2018 which amounted to €1,721 K.

Situation of the clinical trial drug candidate portfolio, partnerships and ongoing key scientific projects

Drug Candidate THN102 – Parkinson's Disease and Narcolepsy

On 24 September, Theranexus announced the recruitment of its last patient with Parkinson's disease naive of any treatment for this pathology to its Phase II clinical trial which aims to evaluate the tolerance and efficacy of its drug candidate THN102 (modafinil/flecainide combination) on non-motor symptoms of the disease (drowsiness, attention and cognitive disorders). This triad, a major unmet medical need in the disease, has a very high market value potential (estimated at over \$2 billion). The results for THN102 are expected in Q1 2020.

On narcolepsy patients, an in-depth analysis of the results of the Phase II trial confirmed the over-representation of poorly responding narcoleptic patients, which resulted in a lack of difference in efficacy between THN102 and the standard-of-care drug¹. Further work on the narcolepsy program is pending results from the Phase II trial on Parkinson's disease.

In addition, the Company announced the issuance of a patent in China, thereby strengthening international coverage of its drug candidate THN102 up to 2034.

Drug Candidate THN201 – Completion of recruitment for the Phase Ib trial to treat Alzheimer's disease-related neurocognitive disorders

On 17 September, Theranexus announced inclusion of the last healthy subject in its Phase Ib trial comparing the pharmacological efficacy of its drug candidate THN201 with the standard-of-care treatment in Alzheimer's disease-related neurocognitive disorders. The results are expected in Q4 2019.

THN201 contains a combination of donepezil, which acts on neuronal activity, and mefloquine, affecting glial cell activity. A total of 152 healthy subjects were recruited at 10 sites in Europe. The trial is being conducted as a double-blind, randomized, three parallel-group study to evaluate the procognitive activity, tolerance and pharmacokinetics of THN201 compared with the standard-of-care treatment alone and a placebo. THN201 has already demonstrated a preclinical pharmacological efficacy profile superior to the standard-of-care treatment in Alzheimer's disease and an excellent tolerance profile.

¹ See 2018 Reference Document p 68 to 70 - https://www.theranexus.com/images/pdf/THERANEXUS_DDR_2018_VFINAL.pdf

Drug Candidate THN101 – Neuropathic pain

The results of the Phase I safety, tolerance and pharmacokinetics trial in patients with neuropathic pain are positive and enable Theranexus to actively prepare for Phase II. The clinical trial should include 370 patients suffering from neuropathic pain of diabetic or post-Zosterian origin (following shingles) in 40 to 45 investigation sites in Europe. The trial's primary endpoint will be based on regular self-assessment of pain by patients themselves using a numerical scale.

Signing of a term sheet with the Beyond Batten Disease Foundation (BBDF) for the development and marketing of the drug candidate BBDF 101 in Batten disease

On 27 June 2019, Theranexus signed a term sheet with the Beyond Batten Disease Foundation (BBDF) to lead the clinical development program aimed at securing approval and commercialization for drug candidate BBDF 101 for Batten disease. BBDF financed the research to identify and validate BBDF101 for treating the juvenile form of Batten disease. Theranexus and BBDF will jointly lead the clinical development program in the United States to secure regulatory approval for the product. Theranexus will have an exclusive worldwide license for commercial use of the product. The agreement gives the Company a six-month exclusivity period and should be signed by the end of 2019.

To finance the clinical development program aimed at securing approval and commercialization for drug candidate BBDF 101 for Batten disease, Theranexus raised approximately €2.2 million in a private placement on 11 July.

Neurolead, a new platform enabling active agent screening of neuron-glia interactions

Theranexus was awarded a €6.2 million funding package under Bpifrance's Investments for the Future scheme, for the Neurolead program. This program, coordinated by Theranexus in collaboration with the Collège de France and the French Alternative Energies and Atomic Energy Commission, aims to design and industrialize a unique platform for the identification and characterization of drug candidates targeting neurological disorders. Neurolead, using the latest innovations in neuroscience and AI tools, plans to extend and systematize the therapeutic concept pursued by Theranexus by enhancing its therapeutic application capabilities. The consortium agreement should be signed by the end of 2019. Theranexus and its partners have not as yet received funds from Bpifrance.

Scientific update

The Company recently announced the publication of two scientific papers, one focusing on expanding the proprietary library of glial effector cells in the journal **ASSAY and Drug Development Technologies**, and the other on the clinical pharmacological profile of THN102 in the **British Journal of Clinical Pharmacology**.

In June 2019, Theranexus established its Scientific Board composed of 4 leading experts, which will assist and guide the Company in its choices, especially the development of strategies for identifying, selecting and qualifying drug candidates targeting interactions between the brain's two cell populations, neurons and glial cells, for the treatment of central nervous system (CNS) disorders.

Overall, during 2019 Theranexus attended a number of conferences and meetings. The Company notably presented its latest findings on the role of astroglial connexins in the efficacy of THN201 in neurocognitive disorders linked to Alzheimer's disease² at the AD/PD conference³, and its new scientific data on neuron-glia interactions at NeuroFrance and Advances in Cell Based Screening in Drug Discovery, and more recently, on the mechanism of action and impact of THN101 on neuropathic pain during the European Pain Congress (EFIC).

² Involvement of astroglial connexins in the efficacy of THN201 in neurocognitive disorders linked to Alzheimer's disease

³ Conference on Alzheimer's and Parkinson's Diseases and related neurological disorders

Next financial publication:**15 October** (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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