



Theranexus

SHIFTING THE LINES AGAINST
CENTRAL NERVOUS SYSTEM
DISORDERS



Theranexus Announces its First Half 2020 Results

Lyon, 29 September 2020 – 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 2020 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: *"The continuation of our activities over this period, especially the BBDF-101 program for Batten disease, was underpinned by rigorous expenditure management. We are also ensuring to maintain a cash position that gives us visibility for at least the next 18 months. And we are still actively seeking industrial partnerships and working to secure additional non-dilutive funding for the development of our clinical programs."*

First half 2020 financial results

In K€ (French GAAP)	H1-2020	H1-2019
Turnover	0	0
Operating income	271	574
Other purchases and external charges	2,271	2,905
Wages and social security charges	1,174	1,215
Amortization and depreciation of fixed assets	188	30
Other operating expenses	0	10
Operating expenses	3,634	4,161
Net operating income/(expenses)	-3,363	-3,587
Net financial income/(expense)	163	-132
Non-recurring income/(expenses)	0	0
Income tax	330	941
Net income/(expense)	-2,870	-2,778

The Company's half-year report for the first half of 2020 will be available on its website on 30 September 2020.

Other purchases and external charges decreased during the period to €2,271 K, down from €2,905 K in the first half of 2019. This is primarily because we reached the end of the clinical trials launched in 2018 for Parkinson's disease (Phase IIa) and Alzheimer's disease (Phase Ib), and to a lesser extent because of the impact on laboratory work of the lockdown measures imposed in response to the COVID-19 health crisis.

Wages and social security charges fell to €1,174 K in the first half of 2020. With staff numbers remaining the same over the period, this slight drop can be attributed to use of the French government's partial furlough scheme during the lockdown.

The increase in amortization and depreciation of fixed assets (€188 K in the first half of 2020 as opposed to €30 K over the same period in 2019) is due to the first recognition of amortization over this period of laboratory equipment acquired through the Neurolead program and deployed in 2019.

As a result, the operating loss narrowed from -€3,587 K in the first half of 2019 to -€3,363 K in the first half of 2020.

Net financial income amounted to €163 K in the first half of 2020, in particular because of gains made by Theranexus on its own shares held by virtue of its liquidity agreement.

After recording €330 K in tax income, mainly from the Research Tax Credit, net losses were -€2,870 K in the first half of 2020, compared with -€2,778 K in the first half of 2019. The total Research Tax Credit granted to Theranexus was lower over the period than in the first half of 2019 (the grants received over the first semester of 2020 through Neurolead reduced the basis for Research Tax Credit).

On 30 June 2020, total available funds stood at €11.3 M and pro forma cash¹ at €13.3 M.

Progress report on Theranexus clinical programs

Drug candidate THN102 – Excessive daytime sleepiness (EDS) in Parkinson's disease

THN102 is the first potential treatment for excessive daytime sleepiness (EDS) in patients with Parkinson's disease, following the positive results of the clinical trial unveiled in March 2020. To continue developing THN102, Theranexus is looking to conclude a partnership agreement with a manufacturer. The Group will keep the market informed of any significant progress in the discussions underway.

Drug candidate THN201 – Cognitive disorders in patients with Alzheimer's disease

In January 2020, the drug candidate THN201, a combination of donepezil and mefloquine, underwent a Phase Ib clinical trial on 150 healthy volunteers. The trial revealed an extension of the pharmacological profile of THN201 compared to donepezil, the standard-of-care treatment for this indication. The good pharmacological profile of THN201 has led Theranexus to seek an industrial partner to continue its development.

Drug candidate THN101 – Neuropathic pain

After finalizing a Phase I trial in late 2019 which established good tolerability for the drug candidate THN101 – a combination of amitriptyline, which acts on neuronal activity, and mefloquine, affecting glial cell activity –, the Company intends to continue with Phase II if permitted by its funding sources.

Drug candidate BBDF-101 for Batten disease, a rare orphan pediatric disorder of the nervous system

In late 2019, Theranexus and the Beyond Batten Disease Foundation (BBDF) signed an agreement granting Theranexus an exclusive, global license for the development and commercial use of drug candidate BBDF-101 in juvenile Batten disease, a rare, fatal disorder of the nervous system for which there is no treatment. BBDF-101 is a drug candidate combining trehalose and miglustat, two active ingredients each with its own specific activity of interest for the disease as well as a synergistic effect.

In August 2020, the Food and Drug Administration (FDA) awarded BBDF-101 Orphan Drug Designation (ODD) and Rare Pediatric Disease Designation (RPDD). With these new designations, Theranexus and BBDF will enjoy an accelerated approval process, at least seven years of post-approval protection and exemption from filing fees, as well as a salable, transferable priority review voucher issued upon approval of BBDF-101 that can be used to speed

¹ Bank balances plus residual payments for the loan under the French state guarantee scheme (PGE) which the Company is expecting to receive in the next few weeks.

up the approval process for any other drug. The European Committee for Orphan Medicinal Products (COMP) has recently issued a positive recommendation for BBDF-101's designation as an orphan medicinal product. Orphan medicinal product designation from the European Medicines Agency (EMA) is expected in the near future.

After discussions with the FDA, Theranexus has begun a series of preclinical studies to confirm the safety of BBDF-101 over a long exposure time, with the aim of supplementing the data already available so that the clinical program can be launched in 2021.

Latest scientific news

Theranexus has been particularly active in terms of scientific news recently, with the publication of five scientific articles reflecting its scientific excellence.

Two articles published in **Frontiers in Neuroscience** and **Neuropharmacology** report on the use of functional ultrasound imaging technology as a tool to determine the profile of drugs targeting the central nervous system (CNS) and improve understanding of the mechanism of action of drugs active in the brain.

The three other articles, published in **Frontiers in Neuroscience**, **SLAS Discovery** and **Therapies**, highlight the role of connexins as therapeutic targets in Alzheimer's disease, demonstrate connexin hemichannel activity and endorse Theranexus' innovative approach to drug discovery for CNS disorders.

Mathieu Charvériat, Theranexus Chief Scientific Officer and co-founder, also chaired and moderated a session on the identification of new connexin modulators for CNS disorders at the 33rd Virtual European Congress of Neuropsychopharmacology (ECNP), which took place in September.

Next financial publication:

Thursday 15 October 2020: Cash position as of 30 September 2020

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).



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