



# Theranexus

SHIFTING THE LINES AGAINST  
CENTRAL NERVOUS SYSTEM  
DISORDERS



## THERANEXUS ANNOUNCES ITS 2017 ANNUAL RESULTS AND PRESENTS AN UPDATE ON THE PROGRESS OF ITS CLINICAL TRIALS

- 🌀 AVAILABLE CASH AS OF 31 DECEMBER 2017: €18.2 MILLIONS
- 🌀 UPDATE ON CLINICAL STUDIES

**Lyon, April 26<sup>th</sup>, 2018** – Theranexus, an innovative biopharmaceutical company specialising in the treatment of neurological diseases and a pioneer in the development of drug candidates that exploit the interaction between neurons and glial cells, today announced its 2017 annual results and presented an update on its clinical activity.

Commenting on the results, Franck Mouthon, CEO and co-founder of Theranexus, noted: "2017 was a key year for restructuring, one which was marked by our IPO in October and by the strengthening of our teams. With these new resources, we are accelerating our clinical developments in 2018, with important first milestones such as obtaining approvals for Phase 2 clinical trials for THN102 in Parkinson's disease in a first European country and in the United States."

### 2017 Annual Financial Results

In K€ (French generally accepted accounting principles – GAAP)	2017	2016
Sales turnover	0	0
<b>Operating revenues</b>	<b>164</b>	<b>98</b>
Other purchases and external charges	1,477	1,439
Salaries and benefits	1,370	688
Depreciation on fixed assets	26	22
Other operating expenses	11	7
<b>Operating expenses</b>	<b>2,883</b>	<b>2,157</b>
<b>Operating result</b>	<b>(2,719)</b>	<b>(2,059)</b>
Net financial income	(126)	(110)
Extraordinary profit	0	(2)
Corporate tax	730	584
<b>Net income</b>	<b>(2,115)</b>	<b>(1,587)</b>

The annual results for 2017 were approved by the Company's Board of Directors on 26 April 2017 and were the subject of a report by the Company's Statutory Auditors.

The Reference Document will be available on the Company's website from 27 April 2017.

Other purchases and external expenses were stable overall in 2017 at €1,477,000 compared with €1,439,000 in 2016. The launch of new clinical programmes in Parkinson's disease, Alzheimer's disease and neuropathic pain had a limited impact since they took place at the end of the fourth quarter of 2017.

The increase in salaries and benefits, from €688,000 in 2016 to €1,370,000 in 2017, reflects the Company's structure and is in line with its development plan. In a period of 18 months up until 31 December 2017, Theranexus thus recruited: a Medical Director, a Financial and Administrative Director, as well as 3 employees in R&D, one clinical employee and one person in Business Development.

As a result, operating losses fell from -€2,059,000 in 2016 to -€2,719,000 in 2017.

The financial result, relating mainly to interest on loans and repayable advances, amounted to -€126,000 in 2017, compared to -€110,000 in 2016.

After taking into account €730,000 of tax income, mainly from the Research Tax Credit, net income was negative at -€2,115,000 in 2017 compared with -€1,587,000 in 2016.

Cash and cash equivalents at 31 December 2017 amounted to €18,226,000 thanks to the Company's successful IPO in October 2017. Cash outflows for the year (excluding cash flows related to financing) remained under control: €2,242,000 in 2017 compared with €1,640,000 in 2016, generally in line with the change in the net result.

### **Update on clinical studies on the drug candidate THN102**

As recently announced (see press releases dated 19 and 23 April 2018), the Company obtained:

#### **THN102 in Parkinson's disease**

- The first approval of clinical trials of THN102 in Parkinson's disease in Europe (Hungary) and
- Approval in the United States ("IND") for the clinical trial of its drug candidate THN102 in Parkinson's disease.

This marks an important step in the development strategy of the THN102 drug candidate.

In particular, Theranexus was able to confirm that, on completion of its regulatory development, THN102 would be eligible for the 505(b)(2) approval pathway. This pathway offers the opportunity to benefit from the large volume of data available for currently registered molecules included in the exclusive composition of the combination, which reduces the remaining necessary work for the Company ahead of its registration.

### **THN102 in narcolepsy**

In addition, the Company has made progress in the clinical study of the drug candidate THN102 in narcolepsy. At the date of publication of the basic document (September 2017), the study included 20 patients registered in 3 investigation centres, with results expected in the third quarter of 2018. To date, the study has 37 patients and 5 active centres in France, with a goal of recruiting 48 patients and of at least 42 patients completing the study. The recruitment rate to date suggests that this schedule is still possible, although the possibility of a one-quarter lag cannot be excluded (in which case, results would arrive in the fourth quarter of 2018). Because narcolepsy is an orphan disease, the rate of recruitment depends on the flow of patients into the study centres and the recruitment of patients by rival studies.

*“Recent regulatory approvals and feedback in the US and Europe constitute an important milestone in the clinical development of THN102,”* said Franck Mouthon, CEO of Theranexus. *“Our work to advance the Narcolepsy study also reaffirms our determination to produce the results of this phase 2 for THN102 in narcolepsy as early as possible in the second half of 2018.”*

### **Update on clinical studies on THN101 and THN201 drug candidates**

As recently announced (see press release dated 21 March 2018), the Company obtained clinical pharmacokinetic results for the THN01 glial modulator used in its THN201 and THN101 drug candidates. The objective of the study was to determine the dose to be administered to achieve target plasma exposure and to be able to make progress in the manufacture of pharmaceutical batches for clinical research programmes on the two drug candidates.

The drug candidate THN201 is designed to treat neurocognitive disorders relating to Alzheimer’s disease. It is a combination of donepezil, the first line of treatment for this disease, and mefloquine. This drug candidate continues its specific clinical development in 2018. The drug candidate THN101 aims to improve treatment of neuropathic pain. In the same way, it consists of a combination of the gold standard treatment for this type of pain, amitriptyline, and mefloquine, again at a low dose. This drug candidate also continues its specific clinical development in 2018.

### **ABOUT THE STUDY IN PARKINSON’S DISEASE**

This study is a randomised, double-blind, placebo-controlled, complete 3-way cross-over phase 2a trial to investigate safety and efficacy of two THN102 doses in subjects with excessive daytime sleepiness associated with Parkinson’s disease, meaning that each patient will receive all of the following treatments successively and in a random order: THN102 200 mg modafinil/2 mg flecainide, THN102 200 mg modafinil/18 mg flecainide, and a placebo. This study will be coordinated by Professor Jean-Christophe Corvol of Pitié Salpêtrière Hospital in Paris and will be conducted in more than 20 centres in Europe (France, Germany, Hungary, Czech Republic) and in the United States. The study will include 60 patients with Parkinson’s disease who suffer from Excessive Daytime Sleepiness, characterised by an Epworth Sleepiness Scale score of 14 (out of 24) or higher. The primary endpoint of the study is treatment tolerance in these patients, with secondary endpoints including an evaluation of drowsiness, alertness, and cognition.

## ABOUT THE STUDY IN NARCOLEPSY

This study entitled “Tolerance and efficacy of THN102 on drowsiness in narcoleptic patients” (NCT02821715) aims to demonstrate the superiority of THN102 over the reference treatment (modafinil) in narcoleptic patients with excessive residual daytime drowsiness despite treatment. It involves a minimum of 42 patients, is double-blind (neither the patient nor the doctor know which treatment is being assessed) and compares three treatments (modafinil 300 mg/day alone or in combination with two doses of flecainide, 3 and 27 mg/day) in cross-over over three periods: each patient receives each of the three treatments at random during three two-week periods. This study is coordinated by Professor Yves Dauvilliers, Principal Investigator of the study, at the Montpellier University Hospital and is being conducted in parallel in five centres in France (Lille, Paris, Bordeaux, Garches and Montpellier). The main outcome of the phase II study is measured by the Epworth Sleepiness Scale (ESS), and the study will be successful if the THN102 drug candidate, with one or two doses, scores significantly lower than modafinil alone on this scale. Narcolepsy is a rare disorder with an estimated global prevalence of 56 cases per 100,000 in the United States and 47 cases per 100,000 in the European Union.

## 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-bourse.com](http://www.theranexus-bourse.com)



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