



THERANEXUS PUBLISHES ITS 2023 FULL-YEAR RESULTS AND PRESENTS ITS PROGRESS REPORT

Lyon, France – 29 April 2024 – 6pm CET – Theranexus, a biopharmaceutical company innovating in the treatment of rare neurological diseases, today publishes its results for the year ending 31 December 2023 and its cash position as of 31 March 2024, and presents its progress report.

“During 2023, we concentrated our efforts on conducting the Phase I/II clinical trial of our Batten-1 drug candidate, receiving positive opinions from the Food and Drug Administration (FDA) and the European Medicines Agency (EMA) on the design of our Phase III trial for Batten disease. The positive 18-month efficacy and safety results announced recently illustrate the strong therapeutic potential of Batten 1. We are currently exploring various funding options to begin the trial that should enable us to gain approval for Batten-1. At the same time, we are continuing our research with the AlstroSight project team and Inserm Transfert to identify and characterize novel, innovative therapeutic targets for rare neurological diseases. In the same vein, in collaboration with Diverchim and Inserm’s ARNA laboratory, we are sponsoring the PickASO project which aims to develop an innovative drug candidate, the first antisense oligonucleotide targeting the TFE3 protein regulating autophagy. Our ambition is to broaden and enhance our portfolio of products in the field of rare neurological diseases with significant unmet medical needs”, explained Theranexus Chairman and CEO, Mathieu Charvériat.

2023 annual financial results (French GAAP)

€K	2023	2022
Turnover	-	-
Operating income	319	1,246
Other purchases and external charges	5,076	3,967
Wages and social security charges	2,600	3,165
Amortization and depreciation of fixed assets	256	332
Other operating expenses	31	39
Operating expenses	7,963	7,503
Net operating income/(expenses)	(7,644)	(6,257)
Net financial income/(expense)	14	(158)
Non-recurring expenses	-	(771)
Income tax	802	619
Net income/(expense)	(6,828)	(6,567)

The 2023 full-year results were approved by the company's Board of Directors on 29 April 2024 and were the subject of a report by the company's Statutory Auditors.



As in 2022, operating income for 2023 (€319 K) mainly consisted of operating grants: in particular €239 K awarded by BPI France for the balance of the PSPC Neurolead project, and €52 K funded by ANR for the NI2D project co-developed with CERMEP.

Other external charges (€5,076 K in 2023 compared with €3,967 K in 2022) mainly included R&D costs incurred by the company. The increase recorded is due to the study purchases and research services item relating to the continuation of the Phase I/II clinical trial for Batten-1. The trial began in the first half of 2022, with progressive recruitment of patients during 2022, which explains the lower 2022 expenses compared to 2023.

Wages and salaries registered a significant decline between 2022 and 2023, falling from €3,165 K to 2,600 K. This substantial decline is due to the departure of two staff members who are yet to be replaced, the end of apprenticeship and internship contracts, and the absence of variable salary components for the 2023 financial year (unlike in 2022 during which bonuses were paid).

Amortization and depreciation costs for 2023 were €256 K compared to €332 K in 2022.

The net financial result for 2023 benefited from interest rates that were higher than during the previous year, and therefore rose as a result of interest on cash investments.

The major part of the €802 K tax income is due to Research Tax Credit (CIR). For 2023, Research Tax Credit stood at €785 K. The calculation includes grants and repayable advances received for the NeuroLead project, which are deducted from the expenses eligible under the program. Research Tax Credit was €583 K for 2022.

Cash position as of 31 March 2024

On 31 March 2024, total available funds stood at €3.1 M, which added to the expected payments due (final PSPC Neurolead payment, reimbursement of the 2023 Research Tax Credit), will cover cash requirements until early Q2 2025.

The company is considering different solutions to fund its activity beyond that date:

- A partnership agreement for its most advanced drug candidate Batten-1; and/or
- A capital raise.

Arrival of Christine Placet as Chief Financial Officer

“Moreover, we are delighted to welcome Christine Placet as our new Chief Financial Officer who takes over from Thierry Lambert. We sincerely thank Thierry, who supported the company since its IPO, for his strong commitment and we wish him all the very best for his future endeavors. Christine joined Theranexus in early April. Her solid experience in the financing and running of biotech companies such as Trophos and Coave Therapeutics for some twenty years are undeniable assets for the financial running of Theranexus and the company’s development strategy” **concluded Theranexus Chairman and CEO, Mathieu Charvériat.**

Christine Placet graduated from Kedge Business School. After 8 years’ experience with Ernst and Young, and 9 years of financial management in SMEs, in 2004 she joined the biotech Trophos as Chief Financial Officer and subsequently Chair of the Board of Directors until the company was sold to the Roche group



for €470 M in 2015. In 2016, Christine Placet was appointed CEO of the biotech company Horama (now Coave Therapeutics). After two funding rounds of €4 M and €22 M, and initial product entry into the development phase, she recruited her successor to devote time to consulting from 2021 onwards. She joined Theranexus as Chief Financial Officer in April 2024.

Highlights of 2023 and Q1 2024

In January 2023 the company and its partner BBDF presented initial safety and pharmacokinetic results achieved in the Phase I/II trial to evaluate Batten-1 in Batten disease. After a 9-week course with the maximum dose of 600 mg/day in six patients with juvenile Batten disease (CLN3) aged 17 and over, Batten-1 showed good user safety and tolerability, and a pharmacokinetic profile in line with expectations.

In February 2023 the company formed a project team for rare neurological diseases, jointly with INRIA, Claude Bernard University Lyon 1 and Hospices Civils de Lyon.

In May 2023 Theranexus and its partner BBDF won approval from the FDA (American health authorities) on efficacy endpoints for the future Phase III trial to evaluate Batten-1 in Batten disease (CLN3), then in June won the same approval from the European Medicines Agency (EMA).

In July 2023 the company raised funds of roughly €3.1 million through the issuance of 2,412,511 new shares. The American Beyond Batten Disease Foundation took a 11.6% stake in the company (on a non-diluted post-fundraising basis).

In June and September 2023, the company and BBDF announced highly promising interim results after 6 and 12 months of treatment in the Phase I/II trial for Batten disease (CLN3) with a reduction in neurofilaments (a neuronal death biomarker) and stabilization of motor symptoms for treated patients in comparison to the decline expected with the natural disease course.

The positive final 18-month safety and efficacy data announced on 18 April 2024 also showed stabilization of motor symptom progression in young adult patients. These results are highly encouraging for patients and their families, and in collaboration with BBDF and the clinical trial investigators the company has implemented an Expanded Access Program (EAP) to enable the 6 trial patients to continue receiving the treatment in view of its highly favorable risk-benefit profile.

The company does not currently have the funds to begin the pivotal Phase III trial in Europe and the United States for patients with juvenile Batten disease before the end of 2024. It should secure funding, for example via one or a combination of the following routes: an industrial partnership, the issuance of shares or other securities giving access to capital, debt or non-dilutive funding (grants, repayable advances, etc.). Theranexus is considering all these options to have the resources required for its development.

Lastly, the PickASO project sponsored by Theranexus, and its partners Diverchim and Inserm's ARNA laboratory received government support via the "Innovations in biotherapies and biomanufacturing" call for proposals under the France 2030 investment plan. The project will receive a €4.7 M, 3-year funding package broken down into grants and repayable advances. PickASO aims to produce a revolutionary autophagy activation therapy with the development of a novel antisense



oligonucleotide, an innovative drug candidate targeting TFEB, the protein identified as an autophagy regulator.

About Theranexus

Theranexus is an innovative biopharmaceutical company that emerged from the French Alternative Energies and Atomic Energy Commission (CEA). It specializes in the treatment of rare neurological diseases. The company has a unique platform for the identification and characterization of advanced therapy drug candidates targeting rare neurological disorders and an initial drug candidate in clinical development for Batten disease.

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

For more information:

<http://www.theranexus.com>

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