Press Release

Annual results 2020

- **Cash and cash equivalents of €9.2m at 31 December 2020**
- **Focus on the valuation of CER-001 in severe kidney diseases**

Toulouse, FRANCE, Lakeland MI, UNITED-STATES, February 25, 2021, 6:30 pm CET **ABIONYX Pharma (FR0012616852 - ABNX - PEA PME eligible)**, a new generation biotech company dedicated to the discovery and development of innovative therapies for patients, today announces its annual results for the financial year ending 31 December 2020 and provides an update on activity to date. Audit procedures on the consolidated financial statements have been carried out. The certification report will be issued after completion of the procedures required for the filing of the universal registration document.

Selected financial information

(*as of 31 December 2020/Consolidated financial statements under IFRS*)

Millions €	2020	2019
Revenue	0	0
R&D expenditures	-1.7	-0.7
Administrative, sales and marketing expenses	-1.3	-1.8
Operating income	**-3.0**	**-2.5**
Financial income	1.2	4.8
Financial expense	-0.1	-0.4
Net financial items	**1.1**	**4.4**
Net income	**-1.9**	**1.8**
Net cash flows related to operating activities	-0.6	-3.9
Net cash flow from investing activities	-0.1	0.0
Net cash flows related to financing activities	1.5	0.8
Cash position variation	**0.8**	**-3.1**
Cash and cash equivalents at the end of the period	**9.2**	**8.3**

Details of the main changes in the consolidated financial statements

As ABIONYX Pharma's activities are dedicated to the discovery and development of innovative therapies to improve the lives of patients, the company did not generate any revenues in the financial year 2020.

Research and development expenses amounted to €1,698 K over the period, compared to €744 K for the financial year 2019. This level of expenditure includes the initial costs relating to the new CER-001 production campaign and costs related to exploratory studies for the valuation of its existing assets.

General and administrative expenses amounted to €1,270 K in 2020 compared to €1,781 K the previous year. The decrease is mainly due to lower fees and continued efforts to control current expenses.

After taking all these factors into account, **operating profit** fell from a loss of €2,525 K at 31 December 2019 to a loss of €2,968 K at 31 December 2020.

Following Bpifrance's debt waiver following the total technical failure of the CER-209 project for which a repayable advance had been granted, financial income of €900 K was recognised in December 2020. **Financial income** thus amounted to €1,082 K at December 31, 2020, compared with €4,412 K at December 31, 2019.

The **net result** was a loss of €1,886 K at 31 December 2020 compared with a profit of €1,849 K at 31 December 2019.

Cash and cash equivalents amounted to €9,154 K at 31 December 2020, compared with €8,331 K at 31 December 2019. The Company obtained the repayment of the 2018 and 2019 CIRs for a cumulative amount of €1,725 K, to which was added the amount of €1,860 K following the capital increase of October 2020.

Key highlights in 2020

In 2020, the company decided to focus on the **valuation of CER-001**, which is proving to be of interest for short-term treatments and severe indications, mainly renal at the moment.

In early 2020, the French National Agency for Drug Safety (ANSM) granted a Temporary Authorisation for Named Use (ATUn) for CER-001 in an ultra-rare kidney disease for which existing treatments are proving insufficient. In February 2020, a new Temporary Authorisation for Named Use (ATUn) for CER-001 was granted in Italy for an ultra-rare kidney disease for which existing treatments are proving to be insufficient.

Given the availability of stocks of CER-001, ABIONYX Pharma has committed to supply the product free of charge over a period of three months under these two ATUns. In order to respond to possible new ATUn requests, the company carried out a capital increase of around €1,860 K (including the premium) intended to strengthen the company's cash position with a view to launching a new production campaign for CER-001, a mimetic HDL which is a biological product. This new campaign is accompanied by a relocation of production to France.

In the last quarter of 2020, the company received authorisation from the Italian regulatory authorities to initiate the start of a new phase 2a clinical study for CER-001, called RACERS, in patients with septicaemia at high risk of developing acute kidney damage, in partnership with the University of Bari.

This study follows the positive therapeutic signals found in nATUs in France and Italy in ultra-rare kidney disease and the positive preclinical results announced in the journal Metabolism on 15 December, which demonstrate that CER-001 improves renal function. The study is fully funded with current assets was designed with key support from Italian Key Opinion Leaders from the University of Bari and will be managed with the CBVF consortium.

The overall preclinical results and clinical signals point to the efficacy of CER-001 in kidney disease and a potentially modifying effect on the progression of the inflammatory cascade in septicaemia. They mark the repositioning of CER-001 in severe renal diseases that have not seen a breakthrough innovation for a long time. The company is awaiting further preclinical and clinical results.

Next press release: **Cash position and activity update for Q1 2021, May 6, 2021**

About ABIONYX Pharma

ABIONYX Pharma is a new generation biotech company dedicated to the discovery and development of innovative therapies for patients. The biotech assets inherited from CERENIS Therapeutics constitute a rich portfolio of valuable programs for the treatment of metabolic diseases as well as with a HDL targeted drug delivery platform.

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