Press release

ABIONYX Pharma announces its 2022 full-year financial results

- **2022 revenues: €5.3 million**
- **Reduction of the annual operating loss**
- **Cash position of €4 million as of December 31, 2022**
- **Continued clinical development following the succession of positive clinical results**

Toulouse, FRANCE, Lakeland MI, USA, March 29, 2023, 6:30 p.m. CEST - **ABIONYX Pharma, (FR0012616852 - ABNX - PEA PME eligible)**, a new generation biotech company dedicated to the discovery and development of innovative therapies for patients, today announced its 2022 financial annual results as approved by the full Board of Directors and an update on the activity to date. The audit procedures on the consolidated accounts have been completed. 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 December 31, 2022/Consolidated financial statements under IFRS)

M€	2022	2021
Revenues	**5.3**	**0.7**
Cost of goods and services sold	(4.6)	(0.4)
R&D expenditure	(1.1)	(3.8)
Administrative and commercial expenses	(3.7)	(2.3)
Other income and expenses	0	(0.1)
Operating Income	**(4.1)**	**(5.9)**
Financial income	0.2	0.3
Financial expenses	(0.3)	(0.2)
Financial result	**(0.1)**	**0.1**
Net income	**(4.2)**	**(5.8)**
Net cash flow from operating activities	(3.4)	(6.7)
Net cash used in investing activities	(0.2)	1.3
Net cash flow from financing activities	(0.2)	4.0
Change in cash and cash equivalents	**(3.9)**	**(1.4)**
Cash and cash equivalents at end of year	**4.0**	**7.9**

Details of the main changes in the consolidated financial statements

Since the merger on December 1, 2021, with IRIS Pharma, the Group has generated revenues from Services mainly related to two types of services:

- Pre-clinical activities, representing revenues of €3,977K in 2022 compared to €143K for December 2021,

- Clinical activities representing revenues of €1,275K in 2022 compared to €505K for the month of December 2021.

Costs of goods and services sold amounted to €4,616K in 2022 corresponding to costs associated with pre-clinical and clinical studies performed by IRIS Pharma.

Research and development expenses amounted to €1,107K for the period, compared to €3,838K for the year 2021. The year 2022 saw the continuation of the activities initiated in 2021 marked by clinical studies in renal indications and ophthalmology, and an increase in personnel costs, notably due to the recruitment of employees for the activities related to ophthalmology.

Administrative and selling expenses amounted to €3,661 thousand in 2022 compared to €2,336 thousand the previous year. This increase is explained by the full year effect of the integration of Iris Pharma in the scope of consolidation in 2022, compared to only one month for the year 2021.

After taking into account all these elements, the **operating result** went from a loss of €5,952K on December 31, 2021 to a loss of €4,109K on December 31, 2022.

The **financial result** shows a deficit of 97 K€ at December 31, 2022, compared to a surplus of 130 K€ at December 31, 2021. The 2022 result is essentially composed of gains and losses realized under the liquidity contract.

The **net result** is a deficit of 4,206 K€ at December 31, 2022, compared to a deficit of 5,822 K€ at December 31, 2021.

Cash and cash equivalents amounted to 4,046 K€ at December 31, 2022, compared to 7,935 K€ at December 31, 2021.

2022 highlights

For a limited cash burn, the year 2022 was marked by tangible results both for clinical trials, which all concluded with positive results, and for regulatory advances.

End of the randomized Phase 2a study named RACERS which led to positive clinical results

The randomized Phase 2a study named RACERS, a RAndomized study comparing short-term infusions of CER-001 at different doses to prevent induced acute kidney injury in high-risk sepsis patients, was finalized in 2022. This clinical trial conducted in partnership with the University of Bari and fully funded by the Consorzio per Valutazioni Biologiche e Farmacologiche (CBVF) consortium concluded with positive results for this Phase 2a clinical trial in the treatment of patients with sepsis. These results validated a rapid and sustained reduction in endotoxin levels, and a consequent reduction in the inflammatory cascade compared to the standard of care treatment alone. Endothelial biomarkers demonstrated a significant protective effect of CER-001, as well as several trends of reduced ICU days, reduced need for organ replacement, and improved 30-day survival. No treatment-related side effects were noted during the study.

Continued Clinical Trials in Ultra-Rare LCAT

Building on the positive clinical results of CER-001 in ultra-rare LCAT disease that were published exclusively in the Annals of Internal Medicine in March 2021, ABIONYX Pharma has continued to supply its bioproduct for new Compassionate Access Authorization (CAA) applications in 2022.

Orphan drug designation (ODD) obtained by the FDA

At the end of March 2022, following the Orphan Drug Designation (ODD) obtained for its natural recombinant APOA-I from the European Medicines Agency (EMA), ABIONYX Pharma announced that the Food and Drug Administration (FDA) had granted Orphan Drug Designation (ODD) for the treatment of LCAT deficiency in renal dysfunction and/or ophthalmologic disease. The granting of ODD followed positive results in two compassionate use cases that demonstrated for the first time that APOA-I treatment can reduce lipid deposition in the kidney, slow the decline in kidney function while eliminating the need for dialysis, beneficially remodel lipoproteins, and mitigate visual impairment due to corneal lipid deposition.

Strategic integration of IRIS Pharma for the development of biomedicines in ophthalmology

Thanks to the positive clinical results in the treatment of corneal lipid deposits and the integration of IRIS Pharma, ABIONYX has become a specialist in ophthalmic biomedicines, in addition to renal diseases, with a solid portfolio of drug candidates that can enter the clinical phase and potential development in many ophthalmic indications. IRIS Pharma, now a subsidiary of ABIONYX, remains fully independent in its service activities for the largest pharmaceutical and biotech groups in ophthalmology.

A strategic start to 2023

All the preclinical and clinical results for 2022 and the beginning of this year foreshadow a new acceleration of the development of natural APOA-I in severe renal diseases, which have not seen any breakthrough innovation for a long time, and in ophthalmology, for which the company will present its strategy by the end of March.

About ABIONYX Pharma

ABIONYX Pharma is a new generation biotech company that aims to contribute to health through innovative therapies in indications where there is no effective or existing treatment, even the rarest ones. Thanks to its partners in research, medicine, biopharmaceuticals and shareholding, the company innovates on a daily basis to propose drugs for the treatment of renal and ophthalmological diseases, or new HDL vectors used for targeted drug delivery.

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