
ADOCIA

Announces its Full Year Financial Results 2020 And Provides Corporate Update



ADOCIA

innovative medicine
for everyone, everywhere

- Cash position of € 28.1 million as of December 31, 2020, reinforced by a €7 million by a state guaranteed loan in August 2020.
- Major steps achieved on three promising portfolio projects:
 - Insulin supply from partner Tonghua Dongbao clinically validated; a required step for initiation of Phase 3 in China, Europe and the US.
 - Clinical Phase 1b results in patients with type 1 diabetes support ability of M1Pram to better control postprandial glycemia and reduced body weight in the overweight or obese patients.
 - First patent for a hydrogel scaffold improving cell therapy treatments for people with diabetes.

6pm CET - Adocia (Euronext Paris: FR0011184241 – ADOC), a clinical stage biopharmaceutical company focused the treatment of diabetes and other metabolic diseases with innovative formulations of proteins and peptides, announced today its full year 2020 financial results as of December 31st, 2020. The financial statements were approved by the Board of Directors today and will be submitted for shareholder approval at the next General Shareholders' Meeting on May 20th, 2021.

"We are very pleased to have successfully executed our development plan despite the constraints imposed by the COVID-19 pandemic," said Gérard Soula, President and CEO of Adocia. "The remarkable clinical results obtained in our BC Lispro and M1Pram projects are major steps forward for Adocia. Furthermore, the qualification of the insulin supply from our partner Tonghua Dongbao allows the launch of Phase 3 studies, a major milestone for our company. The results of our M1Pram project demonstrate the benefit of pramlintide in type 1 diabetic patients in the improvement of both blood sugar control and weight control. These results were encouraging and motivated us to swiftly initiate our Phase 2 study. We look forward to further investigating this promising treatment option in our Phase 2 study, as the results of this study should help define the parameters of a future Phase 3 study. Moreover, we are enthusiastic about the first results obtained on the cell therapy project for people with type 1 diabetes. This is a project of great importance for patients that we intend to pursue actively" added Gerard Soula.

Financial Highlights

The following table summarizes the financial statements under IFRS for the years ended December 31st, 2020 and December 31st, 2019:

<i>In (€) thousands, Consolidated financial statements, IAS/IFRS</i>	FY2020 (12 months)	FY 2019 (12 months)
Revenue	841	2 143
Grants, Research tax credit, others	5 992	5 992
Operating revenue	6 833	8 134
Research and development expenses	(22 547)	(23 307)
General and administrative expenses	(5 434)	(6 848)
Operating expenses	(27 981)	(30 155)
OPERATING INCOME (LOSS)	(21 148)	(22 021)
FINANCIAL INCOME (LOSS)	(2 147)	455
Tax	(29)	2 963
NET INCOME (LOSS)	(23 324)	(18 603)

The consolidated financial statements on December 31st, 2020 as well as detailed explanations on the evolution of accounts are presented in the Appendix.

Key Company Results for Full Year 2020

- **Net loss of €23.3 million in 2020** compared to a loss of €18.6 million in 2019, mainly consisted of:
 - Revenue of €0.8 million in 2020, (compared to revenue of €2.1 million in 2019), resulting from the recognition of the initially planned activities by the signature of the license agreements in April 2018;
 - Other operating income of €6 million, resulting mainly from the research tax credit (CIR) generated on 2020 expenses;
 - Total operating expenses of nearly €28 million, a €2.2 million decrease compared to 2019;
 - A negative financial income of €2.1 million, reflecting mainly the financial interest paid on the €15 million loan contracted with IPF Partners in 2019.
- **Cash position of €28.1 million as of December 31st, 2020** (compared to €43.7 million on December 31st, 2019) which includes the state guaranteed loan (PGE) of €7 million granted in August 2020:
 - Over the full year 2020, the net amount of cash needed to finance operations was €22.5 million, compared to €26.7 million over the same period in 2019 which has been restated to be comparable).
 - Financial debts as of December 31st, 2020 up €7 million (PGE), totaled €28.2 million, compared to €21.2 million as of December 31st, 2019. Financial debts consisted of the €7 million state guaranteed loan (PGE) contracted in August 2020 and the €15 million bond issue subscribed to IPF Fund II in 2019, as well as the €6.1 million bank loans to finance the acquisition and renovation of the building in which the headquarters and the research center of the Company are located.

“At the end of 2020, we had a cash position of €28.1 million, which we believe enables us to finance our clinical study program in 2021,” commented Valérie Danaguezian, CFO of Adocia. “We continue to stay focused on our main priorities while maintaining rigorous management of expenses.”

Key Events in 2020 and Perspectives for 2021:

While the COVID pandemic disrupted global context, Adocia has rapidly reacted in order to achieve the objectives set forth:

2020 was mainly marked by the clinical progress made on the combination of prandial insulin and pramlintide (Insulin analog), the bi-hormonal product M1Pram (ADO09):

- In April 2020, clinical results obtained on patients with type 1 diabetes after 3 weeks of treatment, demonstrated that M1Pram enables the restoration of essential functions of physiology during the digestion phase including: improving gastric emptying time recovery, which is abnormally short in patients with type 1 diabetes, inhibiting glucagon secretion (trigger of the endogenous glucose synthesis), and promoting a feeling of satiety. This recovery of a normal metabolism results in better control of post-meal blood sugar levels, with a significant reduction in insulin consumption and weight reduction in overweight / obese patients.
- In September 2020, Adocia announced the results of the extension of this clinical study on patients with type 1 diabetes requiring more than 40 UI/day of insulin and with a longer period of time of treatment (3 months). The primary endpoint of this study was met with the reduction of 69% of post-meal glycemic excursions over four hours vs. Novolog®. This study demonstrated a mean weight loss of 1.6 kg for 24 days with M1Pram treatment (versus an increase of 0.4 kg in the control group for this population). Additionally, a treatment satisfaction questionnaire was submitted to all patients after each treatment period. The results reflect the beneficial impact of M1Pram on individuals, as 87% of them reported an improved appetite control through the M1Pram study medication, and 75% of the patients would recommend it to other people with diabetes.
- In light of these results, Adocia rapidly progressed its clinical program and initiates its Phase 2 study in March of 2021. The study will evaluate the safety and efficacy of M1Pram in 80 patients, assessing weight loss in overweight and obese T1D patients as well as improved HbA1c.

In parallel and considering the significant clinical benefit of an insulin pramlintide combination, Adocia developed a second product based on the BioChaperone (**BC LisPram**) technology. The development of this product was carried on in 2020 and it will be tested in a pump study in the first semester 2021.

During 2020, a major step was achieved with **Tonghua Dongbao (THDB)** on ultra-rapid insulin BioChaperone® Lispro (**BC Lispro**) on the Chinese market, with the filing of a clinical application to the Chinese Reglementary Authorities (Center for Drug Evaluation).

In regard to **BioChaperone® Combo**, co-formulation of glargine (basal insulin) and lispro (prandial insulin), the technological transfer to our Chinese partner is over and the industrialization of the manufacturing process is ongoing. Adocia is currently involved with Tonghua Dongbao on the project of the clinical development and in the preparation of the reglementary application to ensure its commercialization in China, which represents a market with a strong potential.

In 2020, Adocia realized a clinical study called «bridging» which demonstrated that the **BioChaperone Lispro** formulation composed of insulin lispro manufactured by Tonghua Dongbao, had a similar ultra-rapid pharmacokinetic/pharmacodynamic and safety profile, compared with the BioChaperone Lispro formulation composed with insulin lispro, Humalog®. Results from this study complete the dossier for BioChaperone Lispro, employing insulin lispro from Tonghua Dongbao, required for initiation of Phase 3 studies in China, Europe, and the US.

Adocia also developed a new technology in 2020 for cell therapy and developed an innovative stable biocompatible hydrogel scaffold to host and protect pancreatic cell implants. This aims to restore glycemic control without requiring insulin injection and immunosuppressant drugs. An academic collaboration with Pr. Pattou's Inserm Team, a worldwide leader of Langerhans islet transplant in clinical and non-clinical stages, has been established to develop this product in animal models and ultimately in humans. The primary results obtained via this collaboration are promising.

On a financial basis, in the COVID-19 pandemic environment, the Company was granted a non-dilutive loan of € 7 million via a State-guaranteed loan (PGE) by BNP, HSBC, LCL and Bpifrance in August 2020. Its initial term is one year with a 5-year amortization option. Adocia negotiated in parallel with IPF Partners a rescheduling of loan terms (contracted for a total amount of €15 million in 2019) with a differed period of 12 months for an amount of €2 million and issuance of 35 005(BSA) warrants accordingly.

About ADOCIA

[Adocia](#) is a clinical-stage biotechnology company that specializes in the development of innovative formulations of therapeutic proteins and peptides for the treatment of diabetes and metabolic diseases. In the diabetes field, Adocia's portfolio of injectable treatments is among the largest and most differentiated of the industry, featuring five clinical-stage products and three products in preclinical-stage. The proprietary BioChaperone® technological platform is designed to enhance the effectiveness and/or safety of therapeutic proteins while making them easier for patients to use. Adocia customizes BioChaperone to each protein for a given application.

Adocia's clinical pipeline includes four novel insulin formulations for prandial treatment of diabetes: two ultra-rapid formulations of insulin analog lispro (BioChaperone® Lispro U100 and U200), a combination of basal insulin glargine and rapid-acting insulin lispro (BioChaperone® Combo) and one combination of a prandial insulin with amylin analog pramlintide M1Pram. The clinical pipeline also includes an aqueous formulation of human glucagon (BioChaperone® Glucagon) for the treatment of hypoglycemia.

Adocia preclinical pipeline includes three bi-hormonal products: two combinations of rapid human insulin analogues and Pramlintide (BioChaperone® LisPram and BioChaperone® AsPram) and a combination of insulin glargine with Liraglutide (BioChaperone® GlaLira) for the treatment of diabetes.

Adocia recently added a fourth program in preclinical with the development of a hydrogel scaffold for cell therapy in the treatment of type 1 diabetes. A first patent has been filed.

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This press release contains certain forward-looking statements concerning Adocia and its business. Such forward-looking statements are based on assumptions that Adocia considers to be reasonable. However, there can be no assurance that the estimates contained in such forward-looking statements will be verified, which estimates are subject to numerous risks including the risks set forth in the "Risk Factors" section of the Universal Registration Document filed with the French Autorit  des march s financiers on April 22, 2020 (a copy of which is available at www.adocia.com) and to the development of economic

conditions financial markets and the markets in which Adocia operates. The forward-looking statements contained in this press release are also subject to risks not yet known to Adocia or not currently considered material by Adocia. The occurrence of all or part of such risks could cause actual results, financial conditions, performance, or achievements of Adocia to be materially different from such forward-looking statements. This press release and the information contained herein do not constitute an offer to sell or the solicitation of an offer to buy Adocia shares in any jurisdiction.

APPENDIX: Full year results for the year ended December 31st, 2020 – IFRS standards

The following table summarizes the Company's income statement under IFRS for the fiscal year ended December 31st, 2020 and provides a comparison with fiscal year 2019.

<i>In (€) thousands</i>	Notes	FY 2020 (12 months)	FY 2019 (12 months)
Operating revenue		6 833	8 134
Revenue	15	841	2 143
Grants, research tax credits and others	16	5 992	5 992
Operating expenses excluding additions and reversals	14	(26 848)	(28 996)
Additions to and reversals of depreciation, amortization and provisions	19	(1 133)	(1 159)
PROFIT (LOSS) FROM ORDINARY OPERATING ACTIVITIES	14	(21 148)	(22 021)
Financial income		103	1 310
Financial expense		(2 250)	(856)
FINANCIAL INCOME (LOSS)	20	(2 147)	455
PROFIT (LOSS) BEFORE TAX		(23 295)	(21 566)
Tax expense	21	(29)	2 963
NET PROFIT (LOSS)		(23 324)	(18 603)
Base earnings per share (€)	22	(3,3)	(2,7)
Diluted earnings per share (€)	22	(3,3)	(2,7)
GROUP NET PROFIT (LOSS)		(23 324)	(18 603)

Operating income

The Company's operating income resulted from collaboration and licensing agreements and public funding of research costs. In 2020, operating income amounted €6.8 million compared to €8.1 million in 2019, based on the following breakdown:

<i>In (€) thousands</i>	FY 2020 (12 months)	FY 2019 (12 months)
Revenue (a)	841	2 143
Research and collaborative agreements	0	0
Licencing revenues	841	2 143
Grants, public financing, others (b)	5 992	5 992
OPERATING REVENUE (a) + (b)	6 833	8 134

In 2019, revenue resulted in €2.1 million from the initial upfront payment of \$50million (€41.1 million) in April 2018 at the signature of the two partnership and licensing agreement with Tonghua Dongbao. These revenues related to R&D services provided by Adocia to Tonghua Dongbao, are recognized based on progress, in accordance with IFRS 15, by comparison between the costs incurred by Adocia and the total budget estimated to date over the term of the contract.

As of December 31, 2020, the turnover of €0.8 million comes mainly from the licensing agreements signed in April 2018 with the company Tonghua Dongbao Pharmaceuticals and reflects the R&D services provided by Adocia for the transfer and the development of licensed products.

The portion of the initial payment yet to be recognized as revenue, as of December 31, 2020, amounts to € 1.1 million and is recognized as deferred income.

Other operating income mainly consists of the Research Tax Credit which amounted to €6 million as of December 31, 2020 compared to €5.9 million as of December 31, 2019.

Operating expenses

The table below shows a breakdown of operating expenses by function for the fiscal years ended December 31st, 2020 and December 31st, 2019:

<i>In (€) thousands</i>	FY 2020 (12 months)	FY 2019 (12 months)
Research and development expenses	(22 547)	(23 307)
General and administrative expenses	(5 434)	(6 848)
OPERATING EXPENSES	(27 981)	(30 155)

Research and development expenses mainly consisted of the payroll costs of research and development employees, subcontracting costs (including preclinical studies and clinical trials), intellectual property costs and purchases of materials (reagents and other consumables), and pharmaceutical products and other raw materials. In 2020, these expenses amounted to €22.5 million versus €23.3 million in 2019.

The activities in the 2020 financial year focused on the development of the Company's portfolio, especially the clinical development of the M1 PRAM (ADO09) project, combination of insulin prandial and pramlintide (insulin analog).

General and administrative expenses mainly included payroll costs of non-research and development employees, as well as the cost of services related to the management and business development of the Company and its subsidiary in the United States.

General and administrative expenses amounted to €5.4 million in 2020 compared to €6.8 million in 2019. This decrease of €1.4 million is explained by the wind-down of expenses related to the legal proceedings against Eli Lilly, which impacted the fees position in 2019.

Research and Development expenses represented more than 80% of the operating expenses in 2020 compared to 77% in 2019.

The table below shows a breakdown of operating expenses by type of expense for the fiscal years ended December 31st, 2020 and December 31st, 2019:

<i>In (€) thousands</i>	FY 2020 (12 months)	FY 2019 (12 months)
Purchases used in operations	(1 457)	(1 706)
Payroll expense	(11 857)	(13 054)
Share-based payments	(267)	(890)
External expenses	(13 010)	(13 110)
Taxes and contributions	(257)	(235)
Depreciation, amortization & provisions	(1 133)	(1 159)
OPERATING EXPENSES	(27 981)	(30 155)

The cost of consumed materials, products and supplies decreased by €0.25 million between 2019 and 2020, totaling €1.5 million.

Payroll expenses totaled €11.9 million in 2020 compared to €13.1million in 2019, i.e., a decrease of €1.2 million (-9%). The average workforce rose from 138-time equivalents (FTE) in 2019 to 126 FTE in 2020, a decrease of 9%.

The share-based payments line of €0.27 million in 2020 reflects the impact of the plans implemented in previous years. The decrease of the share-based payments (€0.6million) is mainly related to the vesting of several share-based plans in 2020. The 5 new plans put in place in 2020 had a low impact on the item (37.7 K€). In accordance with IFRS 2, these expenses correspond to the fair value of the equity instruments granted to managers and employees. These elements had no impact on the Company's corporate financial statements nor cash position.

External charges include the costs of preclinical studies, clinical trials, subcontracting expenses, intellectual property costs, professional fees and administrative expenses and totaled to €13 million in 2020, at a stable level compared to 2019. This is mainly due to the end of the legal fees incurred for the proceedings against Eli Lilly was balanced by the increase of the R&D external expenses.

Taxes totaled €0.26 million in 2020 compared to €0.24 million in 2019.

Depreciation and amortization totaled by €1.1 million as of December 31, 2020 compared to €1.2 million in 2019.

Net financial income/expense

<i>In (€) thousands</i>	FY 2020 (12 months)	FY 2019 (12 months)
Cost of net financial debt	(1 852)	170
Cash and cash equivalents income	(14)	809
Interest on conditional advances	(2 052)	(416)
Fair value revaluation of IPF's share subscription warrants	214	(223)
Foreign exchange gains and losses	(304)	238
Other financial income and expenses	10	47
FINANCIAL INCOME (LOSS)	(2 147)	455

The negative net financial income amounted €2.1 million as of December 31, 2020 due to the following:

- Interest generated on borrowings related to the subscription of the bond issue with IPF Fund II in October 2019 (€1.7 million);
- Revaluation of the fair value of the warrants granted to IPF Fund II of €0.2 million, with no impact to the Company's cash position;
- Exchange rate loss (€0.3 million).

As a reminder, as of December 31, 2019, the positive financial result of €0.5 million was mainly due to the accrued interest granted by the American Arbitration Association Tribunal within the context of the first phase of the arbitration proceedings initiated against Eli Lilly.

The Company's investment policy focuses on liquidity, the absence of capital risk and, to the extent possible, guaranteed performance.

Corporation tax

The carryforward tax losses, after allocation of the fiscal deficit subject to the standard tax rate for the 2020 financial year, was €164.8 million. This carryforward loss is not limited in time. Since the company cannot determine with sufficient reliability when it will be able to absorb its accumulated tax loss, it did not recognize a deferred tax asset for this loss.

Net profit/loss

	FY 2020 (12 months)	FY 2019 (12 months)
CONSOLIDATED NET PROFIT / LOSS (in euros thousands)	(23 324)	(18 603)
Average number of shares	6 973 639	6 939 148
NET EARNINGS (LOSS) PER SHARE (in euros)	(3.3)	(2.7)
NET EARNINGS (LOSS) PER SHARE FULLY DILUTED (in euros)	(3.3)	(2.7)

The net loss for 2020 amounts to € 23.3 million, compared to a net loss of €18.6 million in 2019. The net loss per share thus amounts to €3.3, compared to a net loss of €2.68 per share in 2019.

Balance sheet analysis

Non-current assets

Non-current assets amounted to €8.7 million at the end of 2020, compared with €9.7 million in 2019. These investments are partially offset by depreciation for the year amounting to €1 million between 2019 and 2020. This decrease reflects the amortization of fixed assets for the period as well as a low level of investment in 2020.

Current assets

Current assets amounted to €36.4 million at December 31st, 2020 compared to €52.2 million at December 31st, 2019, consisting of the following items:

- "Cash and cash equivalents" decreased from €43.7 million as of December 31st, 2019 to €28.1 million as of December 31st, 2020. The €15.5 million variation in 2020 is mainly due to the consumption of cash over the year, which amounted to €22 million, partially offset by the subscription of PGE loans for a total amount of €7 million. In August 2020, Adocia was indeed granted a loan of €7 million from BNP, HSBC, LCL and Bpifrance in the form of a State-Guaranteed Loan (PGE).
- Other current assets amounted to €7.8 million at December 31st, 2020 and consisted mainly of the receivable related to the research tax credit (CIR) of €6 million. At December 31st, 2019, this item amounted to €8 million, of which €5.9 million related to CIR. There is no comment regarding the variation of this item.

Current and non-current liabilities

Liabilities consisted mainly of four items presented on the balance sheet according to their maturity:

- "Trade payables" under current liabilities amount to €4.9 million at December 31st, 2020, compared to €5.3 million at December 31st, 2019.

- "Financial debt" totaling €28.2 million at December 31st, 2020, increasing by €7 million compared to the previous year. This increase is mainly due to the subscription of a state-guaranteed loan (PGE) by BPI, HSBC, BNP and LCL banks for an amount of € 7 million in August 2020.
- "Long-term provisions" mainly comprise provisions of retirement benefits, which totaled €2.2 million for fiscal year 2020 versus €3.1 million for fiscal year 2019.
- "Other liabilities" for 2020 included tax and social security liabilities which amounted to €2.3 million. This item is stable and there is no further comment. In 2020, other liabilities also included €1.1 million, versus €1.9 million last year, in deferred revenue related to the agreements signed with Tonghua Dongbao Pharmaceuticals Co. Ltd, in April 2018.

Cash and financing

Debt financing

Thanks to its research activities, the Company has benefited from reimbursable grants from BpiFrance and COFACE, without bearing any interest, for a total amount of €4.1 million.

As of December 31st, 2020, the outstanding amount of the loans receives from BpiFrance were €0.5 million and relates solely to the repayable advance of €0.8 million received in 2012 for the development of a formulation of fast-acting "human" insulin and the Phase 2a clinical study. In 2015, the Company noted the end of the program and proceeded with the reimbursements provided in the event of commercial failure of the program in 2017 and 2018. An expertise commissioned by BpiFrance was realized in 2020 and should make it possible to close this dossier in 2021.

In addition, the Company uses other financial liabilities to finance the acquisition of lab equipment and materials. Future obligations under these leasing contracts amounted to €0.2 million as of December 31st, 2020.

The Company contracted its first bank loan, in 2016, to finance the purchase of the building that it has occupied since its creation as well as adjoining parking and a second loan, in 2019, to finance building renovations. At the end of 2020, the outstanding capital of these bank loans amounted to €5.1 million.

In 2019, the Company subscribed to a bond issue, with warrants, for a total of €15 million from IPF Fund II, through two tranches of €7.5 million each, on October 11th, 2019 and December 10th, 2019.

In July 2020, in a by the Covid-19 pandemic context, the Company obtained a restructuring of the debt with a new payment deferral of additional 12 months, the final maturity dates of the two tranches remaining unchanged.

The Board of Directors of the Company allocated, in return for this arrangement, to the IPF Fund II SCA SICAV FIAR a total number of 35,005 share subscription warrants (BSA), under terms and conditions similar to those warrants allocated to IPF Fund II SCA SICAV FIAR under the main contract, with an exercise price of the warrants of €7.70.

Finally, in August 2020, Adocia was granted a loan of €7 million from BNP, HSBC, LCL and BpiFrance Banks, in the form of a State -Guaranteed Loan (PGE).

These loans are guaranteed by the French State up to 90% of the amounts due and are not subject to any payment during the first year. At the end of the first year, the repayment of the principal may again be deferred and amortized over a maximum period of 5 years, at the option of the Company. These loans will carry annual fixed interest rates of between 0.25% and 1.75% for the first year.

As of December 31st, 2020, Adocia's financial debt was €28.2 million, with a short-term (less than a year) component of €3 million.

Cash flows

<i>In (€) thousands, Consolidated financial statements, IAS/IFRS</i>	FY 2020 (12 months)	FY 2019 (12 months)
Net cash flow generated by operating activities	(21 854)	(9 655)
Net cash flow in connection with investment transactions	(204)	(2 054)
Net cash flow in connection with financing transactions	6 512	15 529
Changes in net cash	(15 547)	3 820
Cash and cash equivalents at the start of the year	43 661	39 841
Cash and cash equivalents at year-end	28 114	43 661

Net cash flow from operations

For fiscal year 2020, net cash outflows related to operations amounted to €21.9 million compared to a net cash inflow of €9.7 million in the previous year. This change mainly reflects a similar level of expenses as last year ones (after restatement of flows related to legal proceedings against Eli Lilly on 2019).

Net cash flow in 2019 included:

- Collection of \$14.3 million, or €13 million, from Eli Lilly following the favorable outcome of the first part of the arbitration proceedings,
- Reimbursement of insurance of \$4 million, or €3.6 million, following the absence of a gain in the second part of the arbitration against Eli Lilly,

Collection of €3.4 million relating to the corporate income tax claim for year 2014 and the fiscal treatment of the upfront payment paid by Eli Lilly.

Net cash flow from investments

Cash used in investing activities amounted to 0.2 million euros, compared to 2.1 million euros last year. This decrease reflects the low level of investment over the year 2020.

In 2019, the Company had carried out renovation work on two 450 square meter floors intended mainly for the Analysis department's activities (for 1.8 million euros including exterior fittings and furniture).

Net cash from financing investments

In 2020, cash consumption related to investment transactions of €0.2 million is mainly due to the subscription of the PGE loans for an amount of €7 million.

In 2019, cash consumption related to investment transactions was mainly due to the subscription of a bond issue loan by IPF for an amount of €15 million.