Press Release 30 April, 2018



# Lysogene presents its 2017 annual financial report and financial outlook for 2018

**CAMBRIDGE, MA, US, and PARIS, France – April 30, 2018, à 8.30pm CEST –** Lysogene (FR0013233475 – LYS), a pioneering biopharmaceutical company specializing in gene therapy targeting central nervous system (CNS) diseases, today reports financial statements for the 2017 financial year.

LYSOGENE

The audit procedures have been finalized and the annual financial report of the company will be available on April 30, 2018 on <u>www.lysogene.com</u> under Investors> AMF Regulated Information.

	Year endi	Year ending Dec 31st	
	2017	2016	
	in thous	in thousand euros	
Research tax credit	2 568	1 375	
Subventions	104	118	
Other operating income	15	0	
Operating incomes	2 687	1 493	
Operating expenses			
Research and development costs	(15 330)	(6 329)	
General and administrative expenses	(4 573)	(2 453)	
Total operating expenses	(19 903)	(8 782)	
Operating result	(17 216)	(7 289)	
Financial income	136	15	
Financial charges	(712)	(210)	
Financial result	(575)	(195)	
Corporate tax	(3)	-	
Net income	(17 794)	(7 484)	

## Increase of Research and Development activities during the year 2017

#### **Operating Incomes**

The company does not carry out any commercial activity yet and does not generate sales revenue.

Other operating incomes amounted to 1,493 m€ and 2,687 m€, respectively, for the 2016 and 2017 financial years. This increase is related to a higher amount of research tax credit (CIR) over the 2017 financial year, reflecting principally the increase in Research and Development activities and the associated costs. Subsidies mainly correspond to the share of grants recognized as revenue (depending on the progress of the project) on repayable advances granted by Bpifrance Financement.

## **Operating Expenses**

Operating expenses increased between the year ended December 31, 2016 and the year ended December 31, 2017, from 8,782 m€ to 19,903 m€, an increase of 11,121 m€.

This variation is mainly due to the increase of R & D costs (+9.0 million euros) related to:

- contracts for the manufacturing of AAV vectors for the two drug candidates,
- regulatory preclinical studies,
- recruitment of positions in R & D,
- IFRS 2 impact on share-based payments.

as well as increased administrative expenses (+2.1 million euros) between 2016 and 2017.

#### Net income and basic earnings per share

The net loss amounted respectively to (7,484) m€ and (17,794) m€ for the years ended December 31, 2016 and 2017. Earnings per share amounted to (0.91) euros and (1.52) euros for the years ended December 31, 2016 and 2017.

## Equity

Shareholders' equity amounted to 13,821 m $\in$  at December 31, 2017, compared to 5,501 m $\in$  at December 31, 2016, an increase of 8,320 m $\in$  mainly due to the capital increase following the company IPO and conversion of convertible bonds, the impact of share-based payments over the period (+3.2 million euros), and the result of the period.

## Cash flow statement and financial situation

The company's activity is to develop innovative products which implies a research and development phase of several years without turnover, as long as the drug candidates are not approved for marketing authorization and in the absence of revenue from license agreements. The company must therefore find external funding during this period to meet the related expenditures to its research.

Thus, the loss for the 2017 financial year amounts to (17.8) million euros and the retained earnings recognized at 31 December 2017 is (14.7) million euros.

As of December 31, 2017, the company has a net cash position of 14.1 million euros. This level of cash is not sufficient for the company's current operational development plan to finance all activities over the next twelve months (from January to December 2018) and in particular the needs related to the next clinical studies. Available cash as at January 1, 2018 covers the needs of the company until November 2018.

In view of manufacturing delay of drug candidate LYS-SAF302 and the delay of the pivotal trial phase 2/3 now anticipated for the second half of 2018 and not the first semester 2018 (as announced previously <u>on 16th of April, 2018</u>), marketing authorization is now scheduled for the second half of 2021 (compared with the third quarter of 2020 initially envisaged). These revised plan and timings need an additional financing requirement for 2018 that will likely be around 1 million euros and the need for cash for the next twelve months is 17 million euros, i.e. an additional financing requirement of approximately 6 million euros.

The company is studying various options, including (i) a capital increase (private placement, public offering, equity line or other equity instruments) or ii) debt financing (bond issue, repayable loan or venture loan); or (iii) the licensing of one or more of its products, thus providing funds from these collaborations in the form of upfront and milestones.

The accounts are established according to the principle of continuity, in this context, taking into account the probable success of one of these options as well as the possibility for the company to spread the commitment of certain expenditures. There is, however, significant uncertainty about going concern because, if these actions were not realized, the company may not be able to pay its debts and realize these assets in the normal course of business.

#### **About Lysogene**

Lysogene is a gene therapy company focused on the treatment of rare diseases of the central nervous system (CNS). The company has built a unique capability to enable a safe and effective delivery of gene therapies to the CNS to treat lysosomal diseases and other genetic disorders of the CNS. A pivotal clinical trial in MPS IIIA is expected to start in 2018, a phase 1-2 clinical trial in GM1 Gangliosidosis in 2019, while we are currently collaborating to define the clinical development path for the treatment of Fragile X syndrome. www.lysogene.com

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#### Forward looking statement

This press release may contain certain forward-looking statements. Although the Company believes its expectations are based on reasonable assumptions, all statements other than statements of historical fact included in this press release about future events are subject to (i) change without notice and (ii) factors beyond the Company's control. These statements may include, without limitation, any statements preceded by, followed by or including words such as "target," "believe," "expect," "aim," "intend," "may," "anticipate," "estimate," "plan," "project," "will," "can have," "likely," "should," "would," "could" and other words and terms of similar meaning or the negative thereof. Forward-looking statements are subject to inherent risks and uncertainties beyond the Company's control that could cause the Company's actual results, performance or achievements to be materially different from the expected results, performance or achievements expressed or implied by such forward-looking statements. Except as required by law, the Company assumes no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in the forward-looking statements, even if new information becomes available in the future. This press release has been prepared in both French and English. In the event of any differences between the two texts, the French language version shall supersede.