Press Release

2015 annual results

Strong cash position of €43 million and excellent clinical progress

Toulouse, France, Ann Arbor, United States, March 1, 2016 – Cerenis Therapeutics (**FR0012616852- CEREN)**, an international biopharmaceutical company dedicated to the discovery and development of innovative HDL therapies ("good cholesterol") for treating cardiovascular and metabolic diseases, today announces its full-year 2015 financial results, as approved by the board of directors on March 1, 2016. Audit procedures have been performed and certification report is currently being issued.

- **2015 results (selected financial information / IFRS consolidated financial statements)**

in € million	**2015**	**2014**
Revenue	0	0
R&D expenditure	-12.6	-3.1
Administrative, sales and marketing expenses	-2.9	-3.0
Operating income	**-15.5**	**-6.1**
Financial income	1.3	0.7
Financial expense	-2.4	-1.2
Net financial items	-1.2	-0.5
Net income	**-16.6**	**-6.6**
Net income per share (€)	-1.00	-0.50
Net cash flows related to operating activities	-13.7	-3.3
Net cash flows related to financing activities	49.0	0
(Decrease) / Increase in cash position	**35.1**	**-3.3**
Cash and cash equivalents at the end of the period	**43.0**	**7.8**

Jean-Louis Dasseux, founder and CEO of Cerenis, made the following comments: *"2015 was a transformational year for Cerenis with a successful IPO, the addition of four new independent board members who bring a wealth of industry experience and the launch of two clinical trials, a phase II (CARAT) and a phase III (TANGO). This puts us firmly on the path to develop HDL therapy to improve the lives of patients. Clinical results from the LOCATION trial, reported in July 2015, support CER-001's potential, and we are now keen to continue our diligent recruitment efforts in 2016, in order to show the therapeutic appeal of our leading product in post-ACS patients and in treating genetic HDL deficiency. At the same time, we intend to exploit further our portfolio of HDL therapies in 2016, in particular by continuing development work on CER-209, a product intended to help NASH patients showing very high cardiovascular risk, which is a major health problem worldwide. Recent scientific results presented in the conference of the Asian Pacific Association for the Study of the Liver (APASL) in Tokyo show the great potential of this product, and its clinical development strategy should be finalized in 2016."*

Cyrille Tupin, CFO of Cerenis, added the following comment: "*Our solid cash position gives us enough visibility to complete with confidence all clinical developments envisaged at the time of the IPO, relating to the phase-II CARAT trial and the phase-III TANGO trial. These developments will continue to build shareholder value."*

Income statement

The increase in **R&D expenditure** from €3.1 million in 2014 to €12.6 million in 2015 mainly reflects the start of the CARAT clinical trial in Q3-15 and the TANGO clinical trial in Q4-15, in line with the clinical development plan announced at the time of the company's IPO in March 2015.

Clinical trials:

The **CARAT** trial, which is assessing the reduction in atherosclerotic plaque (percent atheroma volume (PAV) reduction) using CER-001 in post-Acute Coronary Syndrome (post-ACS) patients, is a multi-centre phase-II trial involving 292 patients in Australia, Hungary, the Netherlands and the USA. The **TANGO** trial, which is assessing CER-001 for genetic HDL deficiency (FPHA), is also a multi-centre trial involving 30 patients across several sites in Europe, Canada, the USA and other countries depending on the availability of people affected by this rare orphan disease. Lastly, R&D expenditure also includes the LOCATION trial conducted by Cerenis in the first half of 2015, results of which were announced in July 2015 and showed the functionality of CER-001.

Administrative, sales and marketing expenses, which include most staff expenses, totaled €2.9 million, similar to the 2014 figure.

The increase in the **operating loss**, from €6.1 million in 2014 to €15.5 million in 2015, was therefore the direct result of higher R&D expenditure, as described above. That result is fully in line with management expectations: Cerenis' products are currently at the clinical development stage and are not yet generating any revenue.

After taking into account **financial results** of -€1.2 million in 2015 versus -€0.5 million in 2014, Cerenis' **net loss** amounted to €16.6 million in 2015. The increase in financial expense was mainly due to a greater expense related to the IFRS treatment of the BPI repayable advances, and the effect of changes in exchange rates when paying suppliers in foreign currencies (mainly the US and Australian dollars).

Strengthening of the patent strategy

Currently, nine granted patent families protect Cerenis Therapeutics' product portfolio, covering the targeted indications and the production process in various countries. Since the IPO, the Company has successfully expanded the claims and coverage of its main patent families to strategic markets such as the United States, other countries that are members of the European Patent Office (EPO), Mexico and Hong Kong. This strengthening of the international IP strategy particularly concerns CER-001 and CER-209.

CER-001 is covered by several granted patent families, one related to the charged lipoprotein complex that includes a negatively-charged phospholipid, and another associated with the manufacturing process of the negatively-charged complexes. New patents relating to new claims have been successfully recently granted in Mexico, Hong Kong and the United States.

CER-209 has patents related to P2Y13 receptor agonists and their use, particularly as part of the treatment of cardiovascular disease and related metabolic disorders. P2Y13 receptor stimulation emulates Reverse Cholesterol Transport and facilitates better recognition by the liver of mature HDL particles charged with lipids such as cholesterol, resulting in increased bile acid secretion. A new patent relating to new claims for this product and these mechanisms of action has been granted in the United States and gives further protection to CER-209, a promising product dedicated to the treatment of atherosclerosis and associated metabolic diseases, particularly NASH.

Solid cash position of €43.0 million at December 31, 2015

At December 31, 2015, Cerenis had gross cash of €43 million, as announced when the company published its 2015 revenue figures, versus €7.8 million at December 31, 2014. That change is due to the capital increase that took place alongside the company's IPO in March 2015, which was a success, increasing Cerenis' cash position by a net €49 million. The money is being used to finance numerous clinical advances.

- **Significant events occurred since the end of the fiscal year**

Presentation in February of experimental results demonstrating that CER-209 plays an active role in treating atherosclerosis and non-alcoholic steatohepatitis (NASH)

Cerenis Therapeutics featured prominently at the 25th Conference of the Asian Pacific Association for the Study of the Liver (APASL), presenting two posters on CER-209, another of its innovative HDL therapies. Results presented in the first poster show that CER-209 acts as a selective novel agonist of the P2Y13 receptor (P2Y13R), causing an increased uptake of high-density lipoprotein-cholesterol (HDL-c) in the liver, which is associated with stimulation of bile acid secretion. The uptake of large, mature HDL particles loaded with cholesterol by the liver also stimulates de novo synthesis of nascent HDL particles, thereby enhancing the cholesterol efflux capacity of the serum. The overall implication of this increase is not only to allow the removal of cholesterol from atherosclerotic plaques, but also to regulate lipid homeostasis in the liver.

Results presented in the second poster show that CER-209 leads to a marked reduction in overall steatohepatitis and produces considerable decreases in liver enzymes (ALT and AST) in the plasma. These effects suggest the restoration of liver integrity and indicate a strong potential for CER-209 to treat liver diseases such as NASH and non-alcoholic fatty liver disease (NAFLD) associated with cardiovascular diseases.

Upcoming financial reporting: First-quarter 2016 revenue on May 3, 2016

About Cerenis Therapeutics: www.cerenis.com

Cerenis Therapeutics is an international biopharmaceutical company dedicated to the discovery and development of innovative HDL therapies for the treatment of cardiovascular and metabolic diseases. HDL is the primary mediator of the reverse lipid transport, or RLT, the only natural pathway by which excess cholesterol is removed from arteries and is transported to the liver for elimination from the body.

Cerenis is developing a portfolio of HDL therapies, including HDL mimetics for the rapid regression of atherosclerotic plaque in high-risk patients such as post-ACS patients and patients with HDL deficiency, and drugs which increase HDL for patients with low number of HDL particles to treat atherosclerosis and associated metabolic diseases.

Cerenis is well-positioned to become one of the leaders in the HDL therapeutic market, with a broad portfolio of programs being developed.

Since its inception in 2005, the company has been funded by top tier investors: Sofinnova Partners, HealthCap, Alta Partners, EDF Ventures, Daiwa Corporate Investment, TVM Capital, Orbimed, IRDI/IXO Private Equity and Bpifrance (Fund for Strategic Investment) and last March successfully completed an IPO on Euronext raising €53.4m.

About CER-001:

CER-001 is an engineered complex of recombinant human apoA-I, the major structural protein of HDL, and phospholipids. It has been designed to mimic the structure and function of natural, nascent HDL, also known as pre-beta HDL. Its mechanism of action is to increase apoA-I and the number of HDL particles transiently, to stimulate the removal of excess cholesterol and other lipids from tissues including the arterial wall and to transport them to the liver for elimination through a process called Reverse Lipid Transport. Previous Phase II studies have provided important data demonstrating the efficacy of CER-001 in regressing atherosclerosis in several distinct vascular beds in patients representing the entire spectrum of cholesterol homeostasis. The totality of the data to date indicates that CER-001 performs all of the functions of natural pre-beta HDL particles and has the potential to be the best-in-class HDL mimetic in the market.

About CER-209:

CER-209 is the first drug candidate in the category of oral P2Y13 receptor agonists. The P2Y13 receptor is a member of the P2Y receptor family, a well-known receptor family including the P2Y12 receptor which is the target of successful drugs such as the anti-thrombotic agent Clopidogrel (Plavix®). In preclinical studies CER-209 promotes HDL recognition by the liver and increase the activity of Reverse Lipid Transport (RLT), and thus has an impact on atherosclerosis regression. Because of the favorable metabolic effects observed in the liver, CER-209 may also offer a new mechanism for the treatment of non-alcoholic steatohepatitis (NASH).

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