

# **STENTYS 2014 Annual Results**

- Annual revenues up 13%
- Solid cash position of €18.6 million allowing the commercial launch of the new product portfolio
- Accrual for the APPOSITION V clinical trial reduced by almost €1.8 million compared to June 30, 2015

PRINCETON, N.J. and PARIS - March 31, 2015 - STENTYS (FR0010949404 — STNT — PEA PME eligible), a medical technology company commercializing the world's first and only Self-Apposing® coronary stent, today reported its financial results for the year to December 31, 2014, approved by the Board of Directors on March 26, 2015. Audit procedures relative to the consolidated accounts have been carried out and the auditor's report is currently under finalization.

#### 2014 annual results

€ thousands – IFRS*	December 31, 2014	December 31, 2013
Revenues	3,851	3,394
Cost of goods sold	(2,314)	(2,038)
Research & Development	(6,762)	(4,697)
Sales & Marketing	(5,086)	(5,978)
General & Administrative	(2,808)	(2,467)
Other	8	
Current operating loss (before share-based payment and non-current expense)	(13,111)	(11,787)
Share-based payment	609	196
Non-current expense (APPOSITION V)	4,395	0
Operating loss	(18,116)	(11,983)
Net loss	(17,834)	(11,729)
APPOSITION V	(6,818)	(2,391)
Net loss excluding APPOSITION V	(11,016)	(9,338)

<sup>\*</sup> Audited data





The Company's 2014 annual results reflect the following:

- sales continued to grow over the year, rising from €3.4 million to €3.9 million, an increase of 13%. These results were essentially achieved with the former self-apposing stents (PES and BMS), as the renewed portfolio was not marketed until the end of the year.
- current operating costs (before the share-based payment) increased 11.7% year on year. Including the share-based payment and non-current expense, operating costs rose 42.8% and resulted in a net loss of €17.8 million. Excluding all expenses associated with the APPOSITION V clinical trial, the net loss was €11.0 million.

In detail, operating costs (before the share-based payment) were as follows:

- <u>Cost of goods sold</u>: the 13.5% increase is in line with the increase in revenues. Gross margins for 2014 were consistent with gross margins in 2013.
- Research & Development: excluding the costs associated with the APPOSITION V clinical trial recorded during the 1<sup>st</sup> half of 2014 (€2.4 million), R&D expenses increased to €4.4 million, primarily as a result of the development of the new-generation delivery system and the qualification of new suppliers
- <u>Sales & Marketing</u>: the 15% decrease in these expenses was due to a rationalization of spending in this category and to the end of the post-market studies initiated in previous years.
- <u>General & Administrative costs</u>: these costs saw a moderate increase of 13.8% compared with 2013, mainly due to the costs associated with the acquisition in June 2014 of Cappella Peel Away Inc. and its balloon catheter technology.
- Other operational expenses (expenses associated with the termination of APPOSITION V clinical trial enrollment): the non-current expense recorded on June 30, 2014 for the monitoring of 318 patients recruited in this study was €5.3 million and was reduced to €4.4 million based on more accurate estimations of total potential future costs.

At December 31, 2014, STENTYS had a workforce of 39 compared with 38 a year earlier.

# • Solid financial structure

As announced in January, the Company had a solid cash position at December 31, 2014 of €18.6 million, which Management believes provides STENTYS the necessary financial flexibility to carry out the commercial deployment of its innovations over the coming year.

## Recent events

- Broadening of indication for the self-apposing stent to lower-limb artery disease
  A clinical study of 70 patients suffering from critical limb ischemia (CLI) revealed that using the STENTYS
  DES prevented foot amputation in 99% of cases. These results will allow STENTYS to access the peripheral arterial disease market, which is currently estimated at \$1.3 billion (excluding the United States and Japan).
- The self-apposing drug-eluting stent shows its ability to open the heart's main artery. The results of a study in the challenging treatment of the left main coronary artery, published in the peer-reviewed journal 'Catheterization and Cardiovascular Interventions' in January 2015, showed that the STENTYS DES achieved a 100% procedural success rate, 9.3% MACE (major adverse cardiac events) rate at 12 months and, most importantly, larger vessel lumen than second-generation balloon-expandable DES. This study provides further proof of the benefits of STENTYS' technology in the treatment of vessels of varying diameters.
- After almost nine years on STENTYS' Board of Directors following its initial investment in 2006, venture capital firm Sofinnova Partners announced that it stepped down effective March 25, 2015. This brings the total number of Board members to 5.



## Strategy and Outlook

In 2015, STENTYS is beginning a new phase of its commercial development via three successive product launches:

- 1. The self-apposing Sirolimus-eluting stent, STENTYS SES, which obtained the CE mark at the end of October and whose deployment is continuing in early 2015.
- 2. The MiStent SES®, the world's first drug-eluting stent with a rapidly-bioabsorbable polymer coating and sustained drug release. The controlled launch is scheduled in Europe during the first half of the year.
- 3. The new delivery catheter, called Xposition, which allows self-apposing stents to be implanted in the same manner as conventional stents, is expected to be marketed during the second half of the year.

**Gonzague Issenmann, Chief Executive Officer and co-founder of STENTYS, stated:** "During 2014, we laid the groundwork for an expansion and renewal of our cutting-edge product portfolio with the goal of revitalizing STENTYS' development. The discontinuation of the APPOSITION V clinical trial was one of the strategic choices that has enabled us to focus our resources on the product launches that will structure our activity in 2015."

# Upcoming financial publication

STENTYS expects to publish its revenues for the 1st quarter of 2015 on April 16, 2015.

#### **About STENTYS**

STENTYS is developing and commercializing innovative solutions for the treatment of patients with complex artery disease. STENTYS' Self-Apposing® drug-eluting stents are designed to adapt to vessels with ambiguous or fluctuating diameters in order to prevent the malapposition problems associated with conventional stents. The APPOSITION clinical trials in the treatment of acute myocardial infarction showed a very low one year mortality rate and a faster arterial healing compared to conventional stents. The company's product portfolio also includes MiStent SES®, a coronary DES whose new drug delivery mechanism is designed to match vessel response, and is marketed through STENTYS' commercial network in Europe, the Middle East, Asia and Latin America. *More information is available at* www.stentys.com.

#### **Safe Harbor Statements**

This press release contains forward-looking statements about the Company that are based on numerous assumptions regarding the Company's present and future business strategies and the environment in which it will operate in the future which may not be accurate. Such forward-looking statements involve known and unknown risks which may cause the Company's actual results, performance or achievements to differ materially from any future results, performance or achievements expressed or implied by such forward-looking statements. Such factors include, among others, risks associated with the development and commercialization of the Company's products, market acceptance of the Company's products, its ability to manage growth, the competitive environment in relation to its business area and markets, its ability to enforce and protect its patents and proprietary rights, uncertainties related to the U.S. FDA approval process, slower than expected rates of patient recruitment for clinical trials, the outcome of clinical trials, and other factors, including those described in the Section 4 "Risk Factors" of the Company's 2013 Registration Document (document de référence) filed with the French Autorité des Marchés Financiers on October 29, 2014 under number D.14-1026 as such section may be updated from time to time.

#### **STENTYS**

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