STENTYS Reports 2015 Annual Results

- **Annual revenues up 58%**
- **Gross margin up 1,671 bp**
- **48% reduction in the operating loss**
- **Cash position strengthened through the €12.6 million rights issue of March 8, 2016**

PRINCETON, N.J. and PARIS - March 16, 2016 - STENTYS (FR0010949404 — STNT), a medical technology company commercializing the world's first and only Self-Apposing® coronary stent, today announces its annual results for the year to December 31, 2015, as approved by the Board of Directors on March 15, 2016.

- **2015 annual results**

*€ thousands – IFRS**	**December 31, 2015**	December 31, 2014
Revenues	**6,102**	3,851
Cost of goods sold	(2,647)	(2,314)
Research & Development	(3,423)	(6,762)
Sales & Marketing	(6,634)	(5,086)
General & Administrative	(2,709)	(2,808)
Other	0	8
Core operating loss (before share-based payment and other operating expenses)	**(9,311)**	(13,111)
Share-based payment	(250)	(609)
Other operating expenses (APPOSITION V)	56	(4,395)
Operating loss	**(9,505)**	(18,116)
Net loss	**(9,459)**	(17,834)

** 2015 consolidated accounts have been audited and the auditor's certification report is pending.*

The Company's 2015 annual financial statements show an improvement of all operational indicators:

- 58% increase in revenues to €6.1 million, thanks to the positive response from cardiologists to the Xposition product line launched during the 2nd quarter of 2015;

- substantial improvement of the gross margin from 40% in 2014 to 57% in 2015, as a result from the lower manufacturing costs of Xposition compared to those of the previous product;

- 48% reduction in the operating loss to €9.5 million, versus €18.1 million in 2014, owing to the control of operating costs (-9%) and to the termination of the APPOSITION V clinical trial.

In detail, operating costs broke down as follows:

- Cost of goods sold: the decrease in the manufacturing costs of Xposition's delivery catheters, and the economies of scale achieved with some suppliers, lead to piece cost reduction and to a considerable improvement in gross margin in 2015 (+1,671 basis points).

- Research & Development costs: the 49% decrease in R&D costs was essentially due to the end of enrollment in the APPOSITION V clinical trial in July 2014. Design and prototyping expenses were also down compared to 2014, the year when Xposition's new delivery catheter was developed.

- Sales & Marketing costs: the 30% increase was mainly associated with the costs of the DESSOLVE III clinical trial. The expansion of the sales network was achieved by the addition of distributors and sales agents, resulting in a stabilization of personnel expenses.

- General & Administrative costs: their 4% decrease corresponds to a more favorable basis for comparison, given that the acquisition of Cappella Peel Away Inc. in 2014 involved consultancy fees.

At December 31, 2015, STENTYS had a workforce of 33 staff, compared with 40 a year earlier.

- **Strengthened financial structure**

As announced in January when it published its annual revenues, STENTYS had a cash position of €10.7 million at December 31, 2015, compared with €18.7 million at December 31, 2014.

On March 8, 2016, STENTYS successfully carried out a rights issue that increased its cash position by a net amount of €11.3 million (excluding transaction fees).

- **2015 highlights**

- The STENTYS drug-eluting stent achieves excellent results in the treatment of Left Main lesions
  Peer-reviewed journal 'Catheterization and Cardiovascular Interventions' published the results of a study on the treatment of the left main coronary artery with STENTYS DES, showing a 100% procedural success rate, a 9.3% MACE (Major Adverse Cardiac Events) rate at 12 months and larger vessel lumen than second-generation balloon-expandable DES.

- Commercial launch of Xposition S
  STENTYS announced the commercialization of its Sirolimus-eluting self-apposing stent with the new delivery catheter just weeks after it received CE Marking. This launch was backed by the results of the SETUP trial, which showed 100% technical and angiographic success rates with the new system.

- CE Marking for the STENTYS drug-eluting stent in treating BTK arteries
  The STENTYS drug-eluting stent has received CE Marking for the treatment of BTK (Below-The-Knee) arteries, thus becoming the first self-expanding drug-eluting stent for this indication in Europe. This approval follows the results of a study of 70 patients suffering from critical lower-limb ischemia (CLI) for whom the STENTYS drug-eluting stent prevented foot amputation in 99% of cases.

- Enrollment for the DESSOLVE III clinical trial completed
  In December 2015, STENTYS completed the enrollment of 1,400 patients in a trial to compare the MiStent SES® stent, for which it is the exclusive distributor, and Abbott's Xience stent. The final results of this trial are expected during the 1st half of 2017.

- **Strategy and Outlook**

The €12.6 million raised by STENTYS at the start of the year will allow to pursue its strategy focused on two areas of development:

1. Commercial:
   - deployment of the stent portfolio in Europe with its direct sales force and the extension of its network of distributors;
   - expansion in countries not covered by CE Marking by obtaining product approvals.

2. Clinical:
   - Xposition S clinical program, including the GAIN study (randomized study on 300 patients comparing the Xposition S to a conventional drug-eluting stent) and WIN registery (760 patients), in order to obtain reimbursement of the device in France;
   - initiation of a multicenter clinical trial (200 patients in 20 European centers) to evaluate Xposition S efficacy in treating lesions of the left main artery.

Gonzague Issenmann, Chief Executive Officer and co-founder of STENTYS, comments: "*Our 2015 financial results demonstrate good control over our operational expenses while in hyper-growth situation. With the recent round of fundraising, we have the means to continue our growth strategy: commercial development supported by additional clinical evidence to strenghten the continuous adoption of our technology by interventional cardiologists.*"

- **Upcoming financial publication**

STENTYS expects to publish its revenues for the 1st quarter of 2016 on **April 13, 2016**.

About STENTYS

STENTYS is developing and commercializing innovative solutions for the treatment of patients with complex coronary artery disease. STENTYS' Self-Apposing® 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 2014 Registration Document (document de référence) filed with the French Autorité des Marchés Financiers on July 29, 2015 under number D.15-0807 as such section may be updated from time to time.

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