

STENTYS Reports First Half 2015 Financial Results

- Revenues up 35%
- Gross margin up 1,400 basis points to 53%
- 59% reduction in the net loss
- Solid cash position of €12.7 million

PRINCETON, N.J. and PARIS - September 17, 2015 - STENTYS (FR0010949404 — STNT), a medical technology company commercializing the world's first and only Self-Apposing® coronary stent, today announces its half-year results for the six months ended June 30, 2015, as approved by the Board meeting of September 17, 2015.

• 2015 first-half results

<i>€ thousands – IFRS*</i>	June 30, 2015	June 30, 2014
Revenues	2,606	1,936
Cost of goods sold	(1,231)	(1,178)
Research & Development costs	(1,857)	(4,227)
Sales & Marketing costs	(3,424)	(2,784)
General & Administrative costs	(1,325)	(1,524)
Current operating loss (before share-based payments and exceptional expenses)	(5,232)	(7,778)
Share-based payments	(128)	(233)
Non-current expenses (APPOSITION V)	(89)	(5,328)
Operating loss	(5,449)	(13,339)
Net loss	(5,421)	(13,190)

* Review procedures related to the consolidated accounts at the end of June 2015 have been carried out and the review report is currently under finalization.

The Company's financial results for the first half of 2015 are characterized by the following factors:

- the 35% growth in half-year sales to €2.6 million, following the launch of the Sirolimus-eluting stent and the Xposition® line at the end of the period;
- the gross margin improvement, which increased from 39.1% during H1 2014 to 53% during H1 2015, and results from the lower Xposition manufacturing costs than the previous line's costs;
- the 59% reduction in net loss to -€5.4 million, compared with -€13.2 million the prior year, driven by a decrease in operating costs and the termination of the APPOSITION V clinical trial.

In detail, operating costs are broken down as follows:

- Cost of goods sold: productivity gains in stent and coating manufacturing, as well as the manufacturing costs of the balloon delivery system, simpler to produce than the pullback sheath mechanism, contributed to the substantial improvement in gross margin over the first half of 2015 by 1,400 basis points.
- Research & Development: the 56% decrease in R&D spending to €1.9 million was essentially due to the closing of the APPOSITION V clinical trial. Over the first half of 2015, the R&D team focused its activity on the launch of the new balloon catheter system.
- Sales & Marketing: the 23% increase was due to the launch of the DESSOLVE III clinical trial, comparing MiStent SES with Abbott's Xience stent. The expansion of the sales network was achieved through the addition of distributors and sales agents, thus maintaining stable personnel costs.
- General & Administrative costs: the 13% decrease was due to the renegotiation of certain service contracts, as well as a more favorable basis of comparison; during the first half of 2014, the acquisition of Cappella Peel Away Inc. resulted in consultancy fees.

At June 30, 2015, STENTYS had 31 employees, compared with 42 a year earlier.

• **Cash position at June 30, 2015**

As announced in July when the Company published its first-half revenues, STENTYS had a solid cash position of €12.7 million at June 30, 2015.

• **First-half highlights**

- Excellent results of STENTYS drug-eluting stent in the treatment of lower limb artery disease
At the beginning of the year, STENTYS announced the results of a clinical study of 70 patients suffering from critical limb ischemia (CLI) that demonstrated STENTYS' drug-eluting stent prevented foot amputation in 99% of cases. These results open up the peripheral arterial disease (PAD) market for STENTYS, a market currently estimated at USD 1.3 billion outside the United States and Japan.
- STENTYS self-apposing stent allows treatment of the left main coronary artery
In January 2015, the Catheterization and Cardiovascular Interventions journal published a study on the treatment of the left main coronary artery with the STENTYS drug-eluting stent. The results showed a 100% procedural success rate, a 9.3% MACE (major adverse cardiac events) rate at 12 months and, most importantly, larger vessel lumen than with balloon-expandable stents.
- CE Marking for Xposition
At the end of April 2015, the Sirolimus-eluting self-apposing stent with a new and easier delivery system, Xposition, received CE Marking. Its official launch on May 19, 2015 at the EuroPCR conference was supported by the announcement of the SETUP trial results, which demonstrated 100% technical and angiographic success during the initial clinical cases.

• **Strategy and outlook**

Over the coming months, STENTYS will continue to focus its development activities on two strategic areas:

1. Commercial:
 - ramp up of its two complementary stents, Xposition and MiStent SES, in all countries in which the Company has either a direct sales force or a distributor;
 - expected CE Marking for the use of its drug-eluting stents in treating the lower limb arteries.
2. Clinical:
 - continuation of the DESSOLVE III clinical trial which compares the MiStent and Abbott's Xience stent;
 - initiation of new clinical trials for certain high-potential indications.

Gonzague Issenmann, Chief Executive Officer and co-founder of STENTYS, comments: "The first half of the year saw the launch of our new products, which were very well received by cardiologists as illustrated by the increase in revenues, and the improvement of the financial fundamentals. We are now in a position to seize new markets and finalize the clinical demonstration of our technology."

- **Upcoming financial publication**

STENTYS expects to publish its revenues for the 3rd quarter on **October 15, 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 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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