

## STENTYS Reports First Half 2014 Financial Results

- Revenues up 18%
- Solid cash position of €23.1 million
- One-time accrual for the potential future costs of the APPOSITION V trial

PRINCETON, N.J. and PARIS - September 22, 2014 - STENTYS (FR0010949404 — STNT – PEA-PME eligible), a medical technology company commercializing, in Europe, the world's first and only Self-Apposing<sup>®</sup> stent to treat acute myocardial infarction (AMI), today announces its half-year results for the six months ended June 30, 2014, as approved by the Board meeting of September 19.

**Gonzague Issenmann, Chief Executive Officer and co-founder of STENTYS, explained:** "The discontinuation of enrollment in the APPOSITION V trial, which was evaluating the STENTYS bare-metal stent in a pivotal trial for US pre-market approval, was a strategic decision driven by the accelerating market trend of drug-eluting stent usage in AMI treatment, as well as by the excellent clinical results obtained by our drug-eluting stent in the APPOSITION IV trial. This decision has led us to accrue all of the potential future costs associated with the trial, given our commitment to the Food and Drug Administration (FDA) to continue follow up of enrolled patients. From now on, STENTYS can focus all its human and financial resources on sales growth, with the launch of the Self-Apposing Sirolimus-eluting stent, the new delivery catheter and the extension of our international distribution network."

- **2014 first-half results**

€ thousands – IFRS*	June 30, 2014	June 30, 2013
<b>Revenues</b>	<b>1,935.9</b>	1,638.4
Operating costs**:	15,274.8	7,447.2
Cost of goods sold	1,178.4	935.1
Research & Development costs	4,227.4	1,774.1
of which: APPOSITION V	2,434.3	765.1
Sales & Marketing costs	2,784.2	3,145.7
General costs	1,523.7	1,244.5
<b>Current Operating loss (before share-based payments and exceptional expenses)</b>	<b>(7,777.8)</b>	( 5,461.0)
Share-based payments	233.4	347.8
Non Current expenses (APPOSITION V)	5,327.7	
<b>Net loss</b>	<b>(13,190.0)</b>	(5,693.1)

\* Figures subject to a limited review \*\* including cost of sales

The Company's financial results for the first half of 2014 are characterized by two main factors:

- the 18% growth in half-year sales to €1.9 million, achieved exclusively through the current range of active and bare-metal self-apposing stents, which continues to illustrate the popularity of STENTYS' technology amongst cardiologists;
- The strategic decision to discontinue the APPOSITION V trial, which led the Company to record a one-time accrual of €5.3 million corresponding to the trial's potential maximum future costs over the next three years.

In detail, operating costs (before share-based payments) are broken down as follows:

- Cost of goods sold: the 26% increase can be explained by the revenue growth. The gross margin at June 30, 2014 remained close to the figure a year earlier, with a slight erosion of the average selling price due to the growing share of sales through national distributors.
- Research & Development: excluding costs associated with the APPOSITION V clinical trial, which totaled €2.4 million, R&D expenses totaled €1.9 million and were up 78% due to the development of new products, notably the new delivery system, and the cost of registering the Sirolimus-eluting stent.
- Sales & Marketing: the 11% decline in these expenses was a result of the costs of the APPOSITION III clinical trial recorded in H1 2013 accounts – costs that no longer appear in 2014.
- General and Administrative costs: admin costs were up 22% compared with June 30, 2014, notably because of the costs associated with the acquisition of Cappella Peel Away Inc. in the United States.
- Other operating income and expenses: following the announcement of the discontinuation of enrollment in the APPOSITION V clinical trial, the decision was made to record a provision based on the estimated maximum potential future costs associated with this trial, in particular STENTYS' future commitments vis-à-vis the 318 patients already enrolled, the hospitals taking part in the trial and the associated service providers. On the date of closing, these future commitments were estimated at €5.3 million for the coming three years, although these costs could be reassessed downward following future discussions with the FDA regarding the trial's protocol.

At June 30, 2014, STENTYS had a staff of 42, compared with 39 at June 30, 2013.

- **Solid financial structure**

As announced in its press release in July, the Company had a cash of €23.1 million at June 30, 2014.

- **Other first-half highlights**

During the first half of 2014, STENTYS achieved the following important commercial, clinical and strategic milestones:

- Signing of the first distribution partnerships in Asia and Latin America  
After Europe and the Middle East, STENTYS has continued its international expansion by initiating, in January 2014, partnerships with national distributors specializing in cardiovascular products in Singapore, Hong Kong and Malaysia. This expansion of the distribution network also continued at the start of the second half, with the signing of partnerships in three Latin American countries: Argentina, Colombia and Chile.
- Final results of the APPOSITION IV clinical trial  
At the EuroPCR conference held in Paris on May 20, 2014, STENTYS presented the results of the APPOSITION IV clinical trial comparing the Company's Sirolimus-eluting stent to Medtronic's Resolute<sup>®</sup> stent. After nine months, the STENTYS Sirolimus-eluting stent showed no reduction in artery lumen diameter and near perfect arterial healing, demonstrating the stent's efficacy and safety. These results also showed that arteries treated with the STENTYS Sirolimus-eluting stent heal faster than those treated with balloon-expandable drug-eluting stents. STENTYS should receive the CE Mark for this new stent before the end of 2014.

- Acquisition of innovative stent delivery technology  
In June 2014, STENTYS carried out its 1<sup>st</sup> strategic acquisition, buying American company Cappella Peel Away Inc. that developed a self-expanding stent delivery system. This new catheter technology will enable STENTYS self-apposing stent to be implanted in the same manner as a conventional stent, facilitating the intervention for the cardiologist.

- **Strategy and outlook**

Thanks to its direct sales force, its international sales network via distribution partners that will continue to expand and its solid financial resources, STENTYS is well positioned to meet cardiologists' demands with its new-generation drug eluting stent and its innovative delivery system.

- **Upcoming financial publication**

STENTYS expects to publish its revenues for the 3<sup>rd</sup> quarter on October 23, 2014.

### **About the STENTYS Self-Apposing<sup>®</sup> Stent**

The STENTYS Self-Apposing<sup>®</sup> Stent addresses the stent-sizing dilemma that cardiologists are confronted with when treating heart attack patients or patients with atypical artery anatomy. Its flexible, self-expanding design takes the shape of the patient's unique vessel anatomy and apposes to the irregular contours of a blood vessel, in particular after an AMI as the vessel dilates and the clot dissolves. It reduces the risk of malapposition and complications associated with conventional stents in this setting. More than 10,000 STENTYS Self-Apposing stents have been implanted since receiving CE Mark in 2010. The STENTYS Sirolimus-eluting stent should receive the CE Mark during the second half of 2014.

### **About STENTYS**

STENTYS is developing and commercializing innovative solutions for the treatment of patients with acute myocardial infarction (AMI, or heart attack) and complex coronary artery disease. STENTYS' Self-Apposing<sup>®</sup> Stents are designed to adapt to vessels with ambiguous or fluctuating diameters, particularly in the post-infarction phase, in order to prevent the malapposition problems associated with conventional stents. In the APPOSITION III clinical trial, STENTYS stents demonstrated a very low one year mortality rate among 1,000 high-risk AMI patients when compared to recent studies with conventional stents. **More information is available at [www.stentys.com](http://www.stentys.com).**

### **Forward Looking Statements**

This press release contains forward-looking statements about the Company's business. Such forward looking statements 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 2011 Registration Document (document de référence) filed with the French Autorité des Marchés Financiers on August 27, 2013 under number R.13-040 as such section may be updated from time to time.

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