

## STENTYS 2013 Annual Revenues Up 34% From 2012

- Fourth quarter growth up 39%
- Cash position of €31 million at December 31, 2013
- 2014: numerous clinical and commercial expected milestones

PRINCETON, N.J. and PARIS - January 23, 2014 - STENTYS (FR0010949404 – STNT), a medical technology company commercializing the world's first and only Self-Apposing<sup>®</sup> stent to treat acute myocardial infarction (AMI), today announced its consolidated, audited revenues for the fourth quarter and full year 2013.

- 2013 fourth quarter and annual revenues

In € thousands	Annual – 12 months			Quarterly – 3 months		
	2013	2012	% change	Q4 2013	Q4 2012	% change
<b>Revenues</b>	<b>3,393.6</b>	2,530.7	+34%	<b>987.0</b>	707.5	+39%

In the fourth quarter of 2013, STENTYS' revenues rose 39% to €987.0 thousand. This performance can be partly attributed to the growing contribution of sales from the Middle East, where the STENTYS Self-Apposing stent has been well received by cardiologists since its launch in early 2013. Over 2013 as a whole, revenues were up 34% at €3,393.6 thousand.

- A solid cash position at year-end 2013

At December 31, 2013, STENTYS held €31 million in cash, which provides funding for the Company to pursue its current clinical trials and marketing development plans.

- 2014: a robust schedule of expected newsflow

In 2014, STENTYS is anticipating multiple announcements regarding progress made in its clinical program and market expansion.

- ***Release of the APPOSITION IV clinical trial final results***

At the EuroPCR Congress in Paris in May, STENTYS expects to announce the final results of the APPOSITION IV clinical trial, comparing the new STENTYS Sirolimus-eluting stent to the Medtronic Resolute<sup>®</sup> drug-eluting stent. Prior results from the 4-month arm showed faster arterial healing of the STENTYS stent; follow-up data from the 9 month arm will be analyzed to verify whether this key benefit is sustained in the longer term.

- ***Enrollment in the APPOSITION V trial expected to be completed by year-end 2014***

Enrollment in the pivotal FDA-approved IDE clinical trial of the Self-Apposing stent in the United States is progressing in line with the Company's expectations. APPOSITION V compares the STENTYS Self-Apposing stent to the Abbott Multi-Link Vision<sup>®</sup> stent. The 30-day results are expected soon after the completion of enrollment, and future results at 1-year could enable the Company to apply for Premarket Approval (PMA) in the U.S.

- ***Launch of the Sirolimus-eluting Self-Apposing stent***

The Sirolimus drug-eluting stent is expected to receive CE Marking during the second half of 2014. This product is eagerly awaited by the cardiologist community in the region because it combines the benefits of the Self-Apposing platform with a 'limus'-family compound, which currently dominates the drug-eluting stent market.

- ***Develop new markets on a global scale***

As announced earlier this January, STENTYS has signed distribution agreements for its stent in Singapore, Hong Kong and Malaysia. With this opening in Asia, a growing position in the Middle East and a direct sales network in Europe, the Company has a solid basis for growth that it intends to further extend to other high-potential countries and regions of the world, such as Latin America, in 2014.

**Gonzague Issenmann, Chief Executive Officer and co-founder of STENTYS, comments:** *"In 2013 we saw positive clinical results and substantial market developments. Notably we began marketing our products in the Middle East, which has contributed to a solid growth in our annual sales. In 2014, we anticipate continuing this dynamic growth, driven by multiple development projects."*

• **Upcoming financial publication**

STENTYS expects to publish its 2013 annual results on March 13, 2014, after market.

**About the STENTYS Self-Apposing® Stent**

The STENTYS Self-Apposing® 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. The STENTYS Self-Apposing Stent has been marketed in Europe since receiving CE Mark in 2010. The STENTYS Sirolimus-eluting stent is expected to receive CE Mark in H2 2014.

**About the APPOSITION IV Study**

APPOSITION IV is a prospective, randomized, two-arm, multi-center study designed to compare the apposition of the STENTYS Sirolimus eluting stent with Medtronic Resolute® in 150 patients suffering from ST-elevation Myocardial Infarction. Patients will be followed up at either 4 or 9 months (double randomization). The powered primary endpoint is strut apposition at 9 months under OCT. The secondary endpoints are strut apposition at 4 months under OCT and strut coverage at 4 and 9 months. The final results are expected to be announced in Q2 2014.

**About the APPOSITION V Study**

APPOSITION V is an interventional, multi-center, randomized, two-arm clinical trial to evaluate the safety and effectiveness of the STENTYS Self-Apposing® Stent in the treatment of de novo stenotic lesions in coronary arteries in 880 patients undergoing primary revascularization due to ST-elevation myocardial infarction (STEMI) as compared to the Multi-Link coronary system (Abbott Vascular, Inc.). The trial's primary endpoint is target vessel failure (TVF), which is defined as a composite of cardiac death, target vessel recurrent myocardial infarction or clinically driven target vessel revascularization (TVR), at 12 months post-procedure. The powered secondary endpoint is acute stent malapposition and will be assessed by intravascular ultrasound (IVUS) on the first 225 patients. All patients will undergo clinical follow up at 30 days, six months, nine months and 12 months, with an annual checkup through three years. Fifty sites are expected to participate in the U.S. and worldwide. The enrollment of patients started in May 2013. More information can be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

**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's Self-Apposing® 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).**

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, including with respect to a pre-market approval for the Company's BMS, 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 *Autorité des Marchés Financiers* in France on August 27, 2013 under number R.13-040 as such section may be updated from time to time.

**STENTYS**

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