

STENTYS Reports H1 2013 Financial Results

- Improved bottom line on the Company's historical activity
- Dynamic growth in revenues
- Solid cash position

PRINCETON, N.J. and PARIS - 29 August 2013 - STENTYS (FR0010949404 – STNT), a medical technology company commercializing the world's first and only Self-Apposing® stent to treat acute myocardial infarction (AMI), today announced its half-year results for the six months ending 30 June 2013, approved by the Board at its meeting on 28 August 2013.

• Results for the first half of 2013

Given the resource commitment required to conduct the pivotal APPOSITION V study and other market access activities in the US, the Company will now provide a breakdown of historical activity and US pre-marketing activities as well as the consolidated results.

Historical activity (excluding the APPOSITION V study)

<i>€ thousands – IFRS*</i>	30 June 2013	30 June 2012
Revenues	1,638.4	1,149.6
Operating expenses**	(6,682.1)	(6,813.5)
Operating loss	(5,043.7)	(5,663.9)
Net loss	(4,927.9)	(5,598.9)

US pre-marketing (including the APPOSITION V study)

<i>€ thousands – IFRS*</i>	30 June 2013	30 June 2012
Revenues	0	0
Operating expenses	(765.1)	0
Net loss	(765.1)	0

Consolidated income statement

€ thousands – IFRS*	30 June 2013	30 June 2012
Revenues	1,638.4	1,149.6
Operating expenses**	(7,447.2)	(6,813.5)
Operating loss	(5,808.8)	(5,663.9)
Net loss	(5,693.1)	(5,598.9)

*Data subject to a limited review **Including cost of sales

Dynamic growth in half-year revenues: Up 43%

As previously announced on 25 July, revenues totaled €1,638.4 thousand for the first half of 2013, up 43% over the same period in 2012. This comes exclusively from sales of the Company's products marketed in Europe and, for recent months, to hospitals in the Middle East.

Expenses under control in a context of high growth

Historical activity (excluding the APPOSITION V study)

For the first half of 2013, operating expenses (including cost of goods sold) were down 1.9% compared to the first half of 2012, due to the Company's tight controls on expenses.

In detail, operating expenses (before share-based payment) broke down as follows:

- Cost of Goods Sold: Up 49%, consistent with revenues growth. The gross margin over the period remained close to its 2012 level.
- Research & Development: Down 30%, notably following the end of preclinical testing to prepare for the IDE (Investigational Device Exemption) from the US Food and Drug Administration (FDA). As in 2012, the costs of the APPOSITION IV clinical trial have been capitalized (per IFRS rules) and will be amortized when the Company begins to market its new Sirolimus-eluting stent.
- Sales & Marketing: Held essentially stable (up 2%) is the result of a decrease in marketing expenditure associated with the completion of the APPOSITION III clinical trial, which was offset by an increase in personnel costs following further recruitment.
- General & Administrative: Costs increased compared to the same period last year, notably due to recruitment of certain headquarter staff (procurement).

US pre-marketing (including the APPOSITION V study)

Operating expenses of €765.1 thousand are essentially due to APPOSITION V clinical trial costs (recruitment of the US clinical team, contracts with clinical research organizations, etc.) but also administrative and marketing expenses associated with promoting the study and preparing the market.

STENTYS employed 39 staff on 30 June 2013, versus 35 staff on 31 December 2012.

• **Solid cash position**

The Company's cash, €39 million on 30 June 2013, enables STENTYS to advance the APPOSITION V clinical trial and to accelerate the sales deployment for the Self-Apposing stent.

The amount of cash utilized for operating activities was stable for the first half of 2013: €5.9 million compared to €5.7 million during the first half of 2012.

- **Key developments and outlook**

Over the first half of 2013, STENTYS reached major milestones in clinical activities and market development.

Regarding clinical activity, one-year results from the APPOSITION III clinical trial were presented during the American College of Cardiology Scientific Sessions (ACC.13) in March, demonstrating that the STENTYS Self-Apposing stent had the lowest mortality rate among many major heart attack trials. Further data, presented at EuroPCR in May, highlighted the stent's superior performance in many sub-groups as well as the absence of a learning curve. In May, STENTYS enrolled the first patient in its APPOSITION V clinical trial, which should enable the Company to file, by 2015, a Premarket Approval application, which if accepted, would allow it to market its Self-Apposing stent in the United States.

Regarding market development, STENTYS extended its presence beyond Europe by signing, at the end of April, distribution contracts in four Middle Eastern countries where the CE Mark is recognized, thus giving the Company access to stent markets estimated at €160 million.

STENTYS recently obtained approval to expand the Self-Apposing stent's CE Mark to additional indications, allowing it to position the stent in new market segments and to target approximately 10% of all percutaneous coronary interventions in Europe.

Gonzague Issenmann, Chief Executive Officer and co-founder of STENTYS, concludes: *"During the first half-year, for the first time, STENTYS recorded an improvement of its bottom line excluding activities related to preparing for the US market. This very important inflection point is the result of our numerous clinical and marketing successes, and we have high confidence in the continuation of the Company's business plan execution."*

- **Upcoming financial results**

STENTYS expects to publish its revenues for Q3 2013 on 24 October 2013.

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.

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.

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 June 25, 2012 under number R.12-033 as such section may be updated from time to time.

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