

# STENTYS Revenues for the First 9 Months of 2013 Up 32% Over Prior Year

PRINCETON, N.J. and PARIS - October 24, 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 revenues for third-quarter 2013 and 9-months through September 30, 2013.

## Trends in quarterly and 9-month 2013 revenues\*

	9 months			Quarterly - 3 months		
€ thousands	9 months 2013	9 months 2012	% change	Q3 2013	Q3 2012	% change
Revenues	2,406.6	1,823.2	+32.0%	768.0	673.6	+14.0%

<sup>\*</sup> Data reviewed by statutory auditors

Revenues for the third quarter of 2013 totaled €768.0 thousand, up 14% compared to the third quarter of 2012. The substitution of paclitaxel by compounds of the "limus" family, deemed more efficient, on all coronary drug-eluting stents on the market may currently slow down the STENTYS paclitaxel-eluting stent's entry into new accounts and has yielded a more moderate growth rate this quarter. The first clinical results from the STENTYS Sirolimus-eluting stent ("limus" family) will be presented on October 29, and its commercialization outside of the United States is expected after CE Mark approval by the end of 2014.

Over the first nine months of the financial year, STENTYS recorded revenues of €2.4 million, up 32% compared to the same period in 2012.

## · Healthy cash position

On September 30, 2013, STENTYS held €34.5 million in cash, enabling it to pursue the development of its business in international markets and to proceed with the APPOSITION V study in the United States.

## Presentation of new clinical results at the TCT conference

As announced in its recent press release, STENTYS will present 4-month interim clinical results of its Sirolimuseluting stent (the APPOSITION IV study), as well as other results on patient series outside of the AMI indication, at the annual TCT (Transcatheter Cardiovascular Therapeutics) conference, being held from October 27 to November 1, 2013 in San Francisco.

Gonzague Issenmann, Chief Executive Officer and co-founder of STENTYS, commented: "Given the performance of our Self-Apposing stent, which was reinforced recently by its expansion into new coronary indications, we remain confident about our ongoing clinical program. Clinical results obtained to date and the trials that are underway will support continued revenue growth in the coming months and years."

## · Upcoming financial results

STENTYS expects to publish its full-year 2013 revenues in January 2014.



# 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<sup>®</sup> 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 <a href="https://www.clinicaltrials.gov">www.clinicaltrials.gov</a>.

#### **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 August 27, 2013 under number R.13-040 as such section may be updated from time to time.

## **STENTYS**

Stanislas Piot CFO Tel.: +33 (0)1 44 53 99 42 stan.p@stentys.com

STENTYS is listed on Comp. B of the NYSE Euronext Paris

ISIN: FR0010949404 - Ticker: STNT

#### NewCap.

Financial Communication / Investor Relations Dusan Oresansky / Pierre Laurent Tel.: +33 (0)1 44 71 94 93 stentys@newcap.fr

**US: MacDougall Biomedical Communications** 

Charles Liles, Tel.: 781 235 3060

Christine Labaree or Hunter Marshall, Tel.: 650 339 7533

stentys@macbiocom.com

