Svelte Medical Systems Announces Raise of Additional $22M in Private Financing

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NEW PROVIDENCE, N.J.--(BUSINESS WIRE)--Svelte® Medical Systems today announced the close of its latest round of financing in which approximately $22 million of new capital was raised. Along with participation by current investors, the round was lead by CNF Investments and New Science Ventures, bringing a total of approximately $65 million invested into the company since its inception in 2007. Proceeds from this round of financing will be used to complete the DIRECT II study, prepare for commercialization of the Svelte drug-eluting coronary stent Integrated Delivery System (IDS) and Rapid-Exchange (RX) platforms in Europe and expand overall operational infrastructure.

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"We appreciate the confidence our investment partners have in us and will work hard to achieve the milestones necessary to realize commercialization of our drug-eluting stent platforms," said Jack Darby, President and CEO of Svelte Medical Systems. "There are no products presently in the coronary stent market specifically designed to facilitate the trans-radial approach and direct stenting. The low profile of our system, coupled with specialized balloon and drug carrier technologies designed to reduce arterial injury and inflammation, will enhance patient outcomes to address this unmet need."

Somu Subramanium, Managing Partner of New Science Ventures, LLC added, "Our firm is pleased to be partnering with Svelte during this exciting time in the company's evolution. Under the guidance of its experienced management team, Svelte's highly differentiated technologies present a unique opportunity to significantly impact the very large and well-established coronary stent market."

The company plans to commercialize two drug-eluting coronary stent platforms: a fixed-wire Integrated Delivery System (IDS) which navigates the vasculature similar to a traditional guidewire, and a conventional catheter-based rapid-exchange system. The IDS provides the lowest crimped stent profile on the market, ideal for use with the trans-radial approach, and has even been used in interventions using 4 and 5 French diagnostic catheters. Both platforms will incorporate the specialized Svelte balloon and drug coating technologies.

The Svelte balloon technology couples low-compliant balloon material with proprietary Balloon Control Bands (BCBs) which envelop the balloon shoulders to provide a smooth leading edge during delivery and uniform, controlled balloon growth during stent expansion. Designed to facilitate direct stenting, the high-pressure balloon can also be used for multiple post-dilatations, further minimizing procedure time and cost, two well-known benefits of direct stenting.

The Svelte drug coating technology utilizes a new class of bioabsorbable drug carrier composed of naturally-occurring amino acids (PEAs) which provide high mechanical integrity and elicit a reduced inflammatory response compared with competitive (PLGA) technologies. The drug coating is absorbed over approximately 9-months via enzymolysis (enzymatic digestion) rather than hydrolysis (water-based digestion) to avoid bulk degradation and pH change, two common causes of inflammation and activation of the complement cycle found with current-generation technologies.

Results of the randomized, controlled DIRECT II study will be available next year. Commercialization of the drug-eluting stent IDS and RX platforms is planned for early 2015.

Headquartered in New Providence, New Jersey, Svelte Medical Systems (www.sveltemedical.com) is a privately-held company engaged in the development of highly deliverable balloon expandable stents. Statements made in this press release that look forward in time or that express beliefs, expectations or hopes regarding future occurrences or anticipated outcomes or benefits, are forward-looking statements. A number of risks and uncertainties, such as risks associated with product development and commercialization efforts, results of clinical trials, ultimate clinical outcomes and benefit of the company's products to patients, market and physician acceptance of the products, intellectual property protection and competitive product offerings, could cause actual events to adversely differ from the expectations indicated in these forward looking statements.

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