Bullet-proof study design, 140 animals evaluated, exhaustive histopathology, data analysis and reporting... in 32 weeks.

Although the anti-hypertensive drug market is big business ($18 billion annually), about half of hypertensive patients who are on drug therapy do not achieve adequate control of their blood pressure. The door is wide open for more effective hypertension therapies.

"Vessix Vascular came to us with a prototype design looking for our help with animal studies," says James "Butch" Stanley, DVM, DACVP, Director of Pathology for CBSET. "We were challenged to complete all preclinical development in just eight months, and we did."

Uncontrolled hypertension is a huge, underserved clinical market in the U.S., where 1 in 3 adults has hypertension, which translates to about 78 million cases.

In a news release on November 8, 2012, Boston Scientific announced its intent to acquire Vessix Vascular. Below is an excerpt from the release.

Vessix Vascular V2 Renal Denervation System™'

The Vessix System offers the potential for a significant step forward in the treatment of uncontrolled hypertension," said Prof. Horst Sievert, M.D., Ph.D., Director of the CardioVascular Center Frankfurt, Sankt Katharinen Hospital, in Frankfurt, Germany. "In my experience, the system offers ease of use, faster treatment times with decreased patient discomfort and an intuitive approach to renal denervation that leverages the expertise of the interventionalist with balloon catheter technology."

SPONSOR: Vessix Vascular was the venture capital-backed developer of a novel medical device, the V2 Renal Denervation System™, for the nonsurgical treatment of patients with drug-resistant hypertension.

RENAL DENERVATION: An increase in renal sympathetic nerve activity has been shown to be a significant contributing factor in developing chronic hypertension. Renal "denervation" seeks to interrupt the nerve signals between the kidneys and the brain that control the blood pressure response to certain stimuli. But, how best to "shut down" these nerve fibers located in the renal artery without surgery, and how can we know that the treatment is effective, safe and durable?

CHALLENGE: Reduction of kidney norepinephrine (NEPI) is a critical biomarker for determining the efficacy of renal denervation. But, the analytical hurdles present in quantifying NEPI in the sub-endogenous range are daunting. Physiological levels of NEPI are puny — and NEPI is inherently unstable, subject to rapid metabolic and non-metabolic oxidative degradation. Nevertheless, accurate measurement of a decrease in NEPI after neural ablation is essential to reliably compare novel technologies.

SOLUTION: Addressing complex analytical issues, CBSET had to develop a novel HPLC-MS/MS assay that accurately quantifies NEPI concentrations in porcine kidney tissue. The innovative assay is specific, sensitive, stable, robust, and linear over 3 orders of magnitude; indeed, it has significantly upgraded assay performance and data reliability in the sub-endogenous range, allowing assessment of efficacy and aiding in the differentiation and selection of the best treatment.

What the experts are saying:

Raymond W. Cohen, Former CEO
Vessix Vascular, Acquired by
Boston Scientific, November 2012

"CBSET was our preclinical development partner in the best sense of the word, an integral part of our product's success."

Peter Markham, CEO, CBSET

"We are proud to have had Vessix Vascular as a Sponsor, providing support for all phases of its biomedical discovery and development research."

Butch Stanley, MS, DVM, DACVP
Director, Pathology, CBSET

"Our pathologists employed novel histopathology methods to evaluate the time-course tissue response and pathophysiology of the renal arteries, renal nerves, and kidneys following numerous denervation procedures."