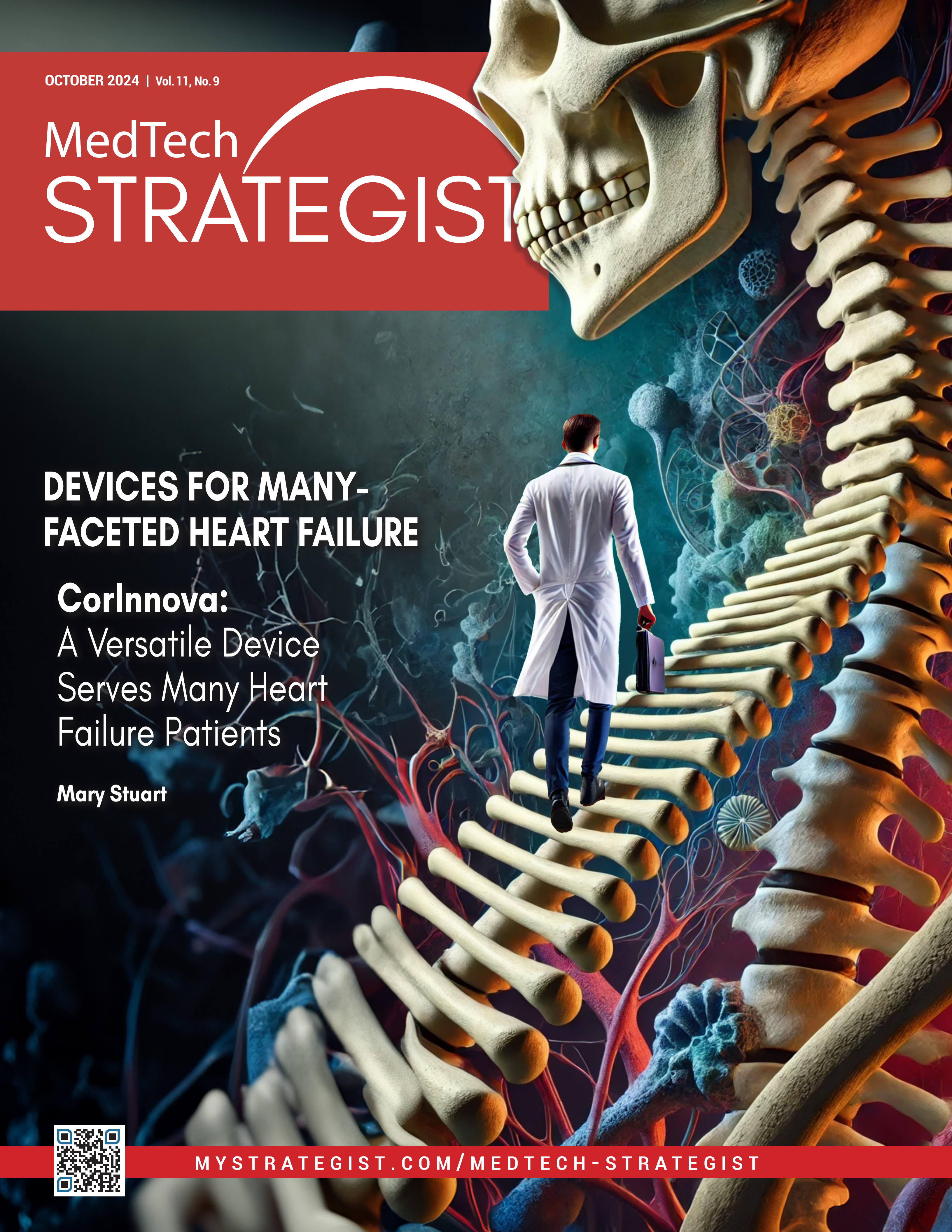
OCTOBER 2024 | Vol. 11, No. 9

MedTech STRATEGIST



DEVICES FOR MANY-FACETED HEART FAILURE

CorInnova: A Versatile Device Serves Many Heart Failure Patients

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some examples include those who are elderly and too frail for a sternotomy; have calcified or small arteries, aortic insufficiency, or stenosis; cannot take anticoagulants because of a previous bleed or stroke risk; have a body size too small for existing devices; or need biventricular support (since LVADs only support one ventricle).

Then there is a whole host of risks associated with the fact that existing pumps come into direct contact with blood, including GI bleeding, a 5-60% rate of bleeding at the access site, a 2-15% rate of stroke within 5 days of use, a 5-13% rate of red blood cell destruction, and a 21-47% rate of kidney dysfunction (according to the company's estimates from published sources).

All existing mechanical circulatory support systems have been designed for HFrEF, but Altman also sees a potential opportunity for his company in HFpEF, where the heart filling or diastolic phase of the cardiac cycle is dysfunctional. During deflation, the CorInnova device provides a low-grade negative pressure to the outside of the heart, which increases the amount of blood volume that flows into the heart during relaxation. "When the heart pumps, the wire frame is drawn inwards, and when the heart relaxes, the wire frame provides suction to pull the heart open," he explains. For now, an unpowered device for HFpEF is a secondary project, which the company has funded through NSF grants.

Because CorInnova's device intrinsically avoids the contraindications that apply to blood-contacting devices, Altman believes that the company's initial opportunity in short-term (less than 5 days' use) cardiac assist is 150,000 patients ineligible for short-term LVADs. These initial short-term cardiac assist markets include acute heart failure or cardiogenic shock, which occur frequently after an MI, and, less frequently, due to other conditions, for example, COVID-19 or post-partum cardiomyopathy. Patients suffering from acute decompensated heart failure could also benefit from minimally invasive mechanical support.

Among those who are medically eligible for support but ineligible for LVADs are many women who are underserved by existing devices because they have smaller femoral arteries, which can preclude them from existing short-term devices. Altman notes that although women represent 50% of heart failure (or 67%, when talking about HFpEF), only one in four receives an LVAD. CorInnova's device can be sized for smaller patients, including women.

Altogether, the company will be serving a $5 billion market in which it is not directly competing with any company, he notes. Looking ahead, the company's future market in chronic cardiac support for end-stage heart failure patients is worth at least another $5 billion. "Ours is the only device that increases output by helping the heart itself pump and do its job better," as opposed to other devices which pump blood through the device and essentially replace the heart's function. "That makes our device much safer and more likely to promote heart recovery, and its market should extend beyond short-term use," asserts Altman.

CorInnova has raised just over $20 million to get to this point, from, as noted, Wellcome Trust, the Texas Emerging Technology Fund, the NSF and NIH, as well as the Texas Medical Center Venture Fund, family offices and angels. Now, the company is beginning to raise $30 million to execute its first human clinical efficacy trial, which will be designed by a team led by cardiologist Joseph G. Rogers, MD, president and CEO of the Texas Heart Institute and a thought leader in heart failure, heart transplantation, and mechanic circulatory assist devices.

Altman pitches future investors: "Our device provides gentle, direct cardiac compression; it gently squeezes the heart, just like a surgeon does," that is, it works by a proven therapeutic mechanism. "It is a breakthrough versus prior art because it is an active device providing systolic and diastolic assist to both ventricles." The company's innovation is protected by 18 issued US patents and three more pending. "We are targeting a large underserved market. We have completed preclinical animal studies demonstrating excellent efficacy and safety, achieved design transfer, and have the assistance of the world's leading heart failure experts to design the clinical trials." The market is large and existing reimbursement is high, he states, adding, "We have a rapid path to human trials and the clinic." And, given that the company is targeting patients who need a short-term device for up to 5 days of use, Altman believes clinical trials will be short and much less expensive than those for other cardiac devices.

A bittersweet testament to the importance of CorInnova's mission came from his father-in-law's cardiologist at Massachusetts General Hospital, who told Altman, "If we'd had this device, instead of having to live on the ground floor and huff and puff up the stairs, your father-in-law could have gone on as he wished for perhaps several years." Like many a medical device innovator before him, Altman says "That's why I get up in the morning."

Posted on MyStrategist.com Oct. 16, 2024