

Paragonix Technologies, Inc., Announces Appointment of Carl Rickenbaugh to the Board of Directors

BRAINTREE, Mass – March 26, 2019 – Paragonix Technologies, Inc. today announced appointment of Carl Rickenbaugh to the Board of Directors, effective immediately. Mr. Rickenbaugh will support several Board initiatives aligned with the ongoing commercial launch of the Paragonix SherpaPak™ Cardiac Transport System^{1,2} and SherpaPerfusion™ Cardiac Transport System^{3,4} in the US and EU⁵. The SherpaPak™ Cardiac Transport System family of products consists of a single-use, disposable device for the hypothermic static preservation and transport of donor hearts. The SherpaPerfusion™ Cardiac Transport System family of products consists of a single-use, disposable device for hypothermic oxygenated perfusion preservation and transport of donor hearts.

William Edelman, Chairman & CEO of Paragonix Technologies commented, "We are thrilled to announce the appointment of Carl Rickenbaugh to the Paragonix Board of Directors. Carl brings deep medical technology industry expertise and perspective, with over 30 years of experience with major companies such as C.R. Bard and Abbott Laboratories. The Board looks forward to Carl's contribution as we build the Paragonix business."

Mr. Rickenbaugh commented, "The Paragonix organ preservation products address a large unmet clinical need in organ transplantation. Based on my decades of experience in the medical device industry, the Paragonix value proposition is incredibly compelling and destined to become the next standard-of-care in heart, lung and kidney preservation. I am excited to join the Paragonix team and support the growth of both SherpaPak™ and SherpaPerfusion™ Cardiac Transport Systems as these products enter the clinical market in the US and in Europe. "

About Carl Rickenbaugh

Mr. Rickenbaugh previously held the position of Vice President of New Business Development at Bard Peripheral Vascular, a major division of C.R. Bard. During Carl's 13 years of leadership at Bard, Carl drove significant game changing acquisitions to build the business, including venture backed Lutonix (Minnesota, drug coated angioplasty), NASDAQ listed SenoRx (California, breast biopsy), and London Stock Exchange listed Clearstream Technologies (Ireland, peripheral and coronary products). Prior to Bard, Carl held multiple positions of progressive commercial and development responsibility, spanning 13 years at various business units of Abbott Laboratories, including critical care medicine, cardiac surgery, anesthesia, cardiac catheterization, interventional radiology, oncology, medical nutrition and vascular surgery. Mr. Rickenbaugh established First Keel, LLC in 2017, which focuses on creating and communicating value from start up to successful destination.

Previous Announcements

Paragonix previously announced February 20, 2018 European Conformity ("CE")⁶ Premarket Clearance for the SherpaPak™ Cardiac Transport System and SherpaPerfusion™ Cardiac Transport System Family of Organ Transport Products

Paragonix previously announced August 8, 2017 Extension of Product Portfolio with the Addition of SherpaPak™ Lung Transport System

Paragonix previously announced April 24, 2017 Presentation of the SherpaPak™ Organ Transport Systems at the American Transplant Congress (ATC) (Chicago, April 29 – May 3, 2017).

Paragonix previously announced March 27, 2017 Presentation of the SherpaPak™ Organ Transport Systems and SherpaPerfusion™ Cardiac Transport System at the 37th Annual Meeting of the International Society for Heart and Lung Transplantation (San Diego, 5 – 8 April 2017).

Paragonix previously announced February 7, 2017 an exclusive distribution agreement with MBA Medical to market Paragonix Technologies' SherpaPak™ Cardiac and Kidney Transport Systems, in the Southern United States.

Paragonix previously announced January 9, 2017 a Presentation of the SherpaPak™ Organ Transport Systems during the ASTS 17th Annual State of the Art Winter Symposium January 26 to 29, 2017 in Miami, FL.

Paragonix previously announced January 4, 2017 an exclusive supply agreement with Sanbor Medical for the Manufacture and Assembly of SherpaPak™ Organ Transport Systems.

About the Paragonix SherpaPak™ and SherpaPerfusion™ Cardiac Transport System

Currently, the availability of heart and lung transplantation is governed by the “ischemic time”, that being, the elapsed time from heart donation to recipient implantation. According to The International Society Of Heart and Lung Transplantation (“ISHLT”) guidelines⁷ for the care of heart transplant recipients, the projected ischemic time should not exceed 4 hours^{8,9}, limiting the distance available to transport a donor heart. Paragonix SherpaPak™ Cardiac Transport System is fully disposable, eliminating problems associated with maintenance, device transport and contamination. The Paragonix SherpaPerfusion™ Cardiac Transport System combines innovative oxygenated perfusion of organs and safe organ storage with the ultimate goal of extending ischemic time to 12 hours, significantly altering the transportation range of donor hearts.

About the Cardiac Transplantation Market

Cardiac transplantation is considered the gold standard therapy for patients in end-stage heart failure¹⁰. With over 6.5 million Americans currently diagnosed with heart failure (HF)¹¹, 10% of which are diagnosed with end-stage heart failure¹², there is a persistent need to provide end-stage heart failure support to this expanding population. Estimates of the prevalence of symptomatic HF in the general European population are similar to those in the United States¹³. In 2017, over 2,000 donor hearts were transplanted in Europe¹⁴.

The annual US economic burden of treating heart failure exceeds \$34.4 billion¹⁵, over 50% of which is due to the cost of hospitalization¹⁶. The financial demands associated with transplantation are considerable. The estimated first year costs for heart transplant are \$997,700, and subsequent annual costs can easily exceed \$30,000¹⁷. In the United States, around 30,000 people die annually from end-stage heart disease. As of February 2018, 3,990 patients in the United States are on the waiting list for a heart transplant¹⁸ and close to 4,000 patients in Europe are on the waiting list for a heart transplant every year¹⁹. In 2017, 3,244 patients in the United States²⁰ and over 2,000 European patients received a live-saving heart transplant¹⁹. These data, however, only seem to represent the tip of the iceberg. Assuming that up to 157,000 people with end-stage heart failure are candidates for transplantation²¹, maximization of donor organ utilization has enormous potential in cardiac transplantation.

About Paragonix Technologies, Inc.

Based in Massachusetts and founded in 2010, Paragonix Technologies, Inc., is a privately held medical

device company innovating the Paragonix SherpaPak™ and SherpaPerfusion™ Cardiac Transport System, a novel, single-use organ preservation device to improve donor organ quality. Paragonix has established a pipeline of donor organ transport devices that address the current donor organ shortage by maximizing donor organ utilization, improving donor organ quality and extending donor organ transport throughout the entire United States.

¹ The SherpaPak™ Cardiac Transport System is protected by patents, both issued and pending.

² The SherpaPak™ Cardiac Transport System has received FDA 510(k) pre-market clearance for heart storage and transport.

³ The SherpaPerfusion™ Cardiac Transport System is protected by patents, both issued and pending.

⁴ The SherpaPerfusion™ Cardiac Transport System is not approved for sale in the United States at this time.

⁵ Paragonix SherpaPak™ Cardiac Transport System and SherpaPerfusion™ Cardiac Transport System received European Conformity (“CE”) Premarket Clearance February 20, 2018.

⁶ The CE mark (*Conformité Européenne*, meaning “European Conformity,” formerly EC mark) according to the European Medical Directive (MDD) is a mandatory conformity mark for medical devices placed on the market in the European Economic Area (EEA). With the CE marking on a medical device, the manufacturer ensures that the product conforms to the essential requirements of the applicable EC medical device directives.

⁷ ISHLT Guidelines for the Care of Heart Transplant Recipients, Task Force 1: Peri-operative Care of the Heart Transplant Recipient (Aug. 4, 2010)

⁸ J Heart Lung Transplant 2001; 20(2):212.

⁹ J Am Coll Cardiol 2004; 43(9):1553-1561.

¹⁰ Datamonitor senior cardiovascular analyst Dr. Sergey Ishin. “Cardiac transplantation continues to be the gold standard for the treatment of end-stage heart failure. However, the number of potential transplants far exceeds the number of donors.” <http://about.datamonitor.com/media/archives/314>

¹¹ <http://newsroom.heart.org/news/latest-statistics-show-heart-failure-on-the-rise;-cardiovascular-diseases-remain-leading-killer>

¹² http://www.heart.org/HEARTORG/Conditions/HeartFailure/LivingWithHeartFailureAndAdvancedHF/Advanced-Heart-Failure_UCM_441925_Article.jsp#.WosY7GNLPjI

¹³ <http://about.datamonitor.com/media/archives/314>

¹⁴ <http://www.transplant-observatory.org>

¹⁵ Circulation 2011;123(8):933-944

¹⁶ Circulation 2007;115(5)

¹⁷ <http://www.transplantliving.org>

¹⁸ <http://optn.transplant.hrsa.gov>

¹⁹ https://ec.europa.eu/health/sites/health/files/blood_tissues_organ/docs/ev_20141126_factsfigures_en.pdf

²⁰ https://unos.org/data/transplant-trends/#transplants_by_organ_type+year+2017

²¹ J Heart Lung Transplant 2011;30:1078-94

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