

Spectral Medical Announces Strategic Joint Venture With Infomed to Accelerate Commercialization of Dimi and Sami Dialysis Devices

Spectral to receive a significant equity stake in the joint venture, while eliminating its need to fund future capital requirements for SAMI and DIMI

TORONTO, Dec. 13, 2022 -- **Spectral Medical Inc. (“Spectral” or the “Company”) (TSX: EDT)**, a late stage theranostic company advancing therapeutic options for sepsis and septic shock, as well as commercializing a new proprietary platform targeting the renal replacement therapy market through its wholly-owned subsidiary Dialco Medical Inc. (“**Dialco**”), today announced it has formed a new joint venture with Infomed SA (“**Infomed**”), a Swiss company dedicated to the development and manufacturing of blood purification devices. The new joint venture company, i-Dialco Inc. (“**i-Dialco**” or the “**Joint Venture**”), will be exclusively focused on advancing commercialization of the SAMI and DIMI dialysis devices in the North American markets.

Key transaction highlights:

- Joint venture expected to accelerate North American commercial rollout of SAMI and DIMI devices
- Infomed to fund all working capital and commercialization costs, as well as planned development, clinical and regulatory activities
- Spectral and Infomed to own 30% and 70% of the joint venture, respectively
- Transaction expected to reduce Spectral’s cash burn by over \$3 million annually
- Eliminates over \$1 million of future minimum purchase orders as well as license fees to be paid by Spectral under the original license agreement with Infomed
- Dedicated management team and board of directors to be appointed for i-Dialco
- Spectral to focus resources and activities on the advancement of PMX and Tigris trial
- Spectral maintains full access to SAMI for potential use with its PMX column through an exclusive, royalty-free license for hemoperfusion treatment

Transaction Details

Dialco previously licensed the SAMI and DIMI technology from Infomed for the North American market and subsequently commenced initial commercialization activities. Under the Joint Venture, Spectral will contribute SAMI and DIMI regulatory approvals, as well as transfer its Medical Device Single Audit Program (MDSAP) certification to i-Dialco. Infomed, an established medical device manufacturer and original developer of the SAMI and DIMI devices, will contribute all hardware, software and certain other intellectual property to further develop the SAMI and DIMI platforms. All prior license fees and minimum purchase requirements for Spectral have been replaced by a zero-cost, license to the technology, granted by Infomed to the Joint Venture. In addition, Infomed has agreed to fund all future development of the i-Dialco business, including working capital and commercialization costs, as well as planned development activities. Spectral will own 30% of the Joint Venture and Infomed will own 70% of Joint Venture.

i-Dialco will focus on increasing penetration within both the acute and chronic dialysis markets. The United States represents the largest dialysis market in the world. The U.S. dialysis market alone was valued at \$26.2 billion in 2021 and is projected to reach \$32.5 billion by 2028.¹ The resources to be contributed by Infomed, given Dialco’s progress to date, are intended to help accelerate commercialization activities, as well as allow for ongoing improvements and enhancements to be made to the systems in a cost-effective manner. The goal of the Joint Venture is to establish SAMI and DIMI as leading dialysis systems in the market, while capitalizing on Infomed’s technology, expertise and resources.

Chris Seto, Chief Executive Officer of Spectral, further noted, “We are very pleased to enter this joint venture with Infomed, which is the ideal partner given their technological and manufacturing expertise, as well as the capital resources they will be contributing to the Joint Venture. We have successfully worked with Infomed for many years and taking this next step with a leading medical device manufacturer illustrates our commitment to accelerating SAMI and DIMI’s growth within large, underserved markets, while maximizing value for our shareholders. Given Infomed’s extensive knowledge and experience in the dialysis space, we believe this new joint venture will allow SAMI and DIMI to reach their full commercial potential.”

“While we have worked aggressively to advance Dialco within the market, we believe this initiative will enable us to reduce our operating costs by over \$3 million annually, in addition to eliminating over \$1 million of minimum purchase orders that would have been required over the next twelve months, per our original licensing agreement with Infomed. Moreover, we will no longer carry the substantial costs of funding the DIMI usability trial or incur future development and commercialization costs for the devices. Through the Joint Venture, we will also eliminate prior license fees to Infomed, which have been replaced by a no-cost perpetual license, thereby increasing product margins within the joint venture. By securing a material ownership stake in i-Dialco, we believe we are maximizing value for Spectral and our shareholders, which we hope to monetize in the future Dialco. This Joint Venture will also enable us to increase our focus on PMX for the treatment of patients with septic shock, including advancement of our Tigris trial, which we believe will be highly beneficial to Spectral and its shareholders. Assuming we are granted FDA approval of PMX, we would also have full access to the SAMI System for hemoperfusion through the Joint

Venture. Overall, we believe the Joint Venture is a significant achievement for the Company and will drive shareholder value," concluded Mr. Seto.

Olivier Favre, Chief Executive Officer of Infomed SA, commented, "We are excited to embark on this joint venture, as we believe the DIMI and SAMI systems hold tremendous market potential, which should benefit both Spectral and Infomed. Spectral has already significantly advanced the commercialization of these devices, and we believe that with a dedicated management team to be appointed, as well as additional resources, we can help accelerate the commercial rollout. Additionally, we look forward to implementing further technology enhancements to support commercialization, while advancing the usability trial for regulatory approval of DIMI within the sizable North American home hemodialysis and peritoneal dialysis markets."

The SAMI System

The SAMI System offers flexible dialysis modalities in hospital or clinical settings, including continuous renal replacement therapy, prolonged intermittent renal replacement therapy, sustained low efficiency dialysis, slow continuous ultrafiltration, hemoperfusion and therapeutic plasma exchange. The SAMI System is an open platform design, specifically intended to assist health care providers to deliver therapy safely and efficiently. SAMI's built in intelligence reduces complexity, while increasing efficiency and reducing consumable cost, as well as delivering customized therapy. The SAMI system has received 510(k) regulatory clearance in the United States as well as Health Canada approval.

The DIMI System

The DIMI System is designed for the treatment of treat patients with acute and/or chronic renal failure, with or without fluid overload using hemodialysis, hemodiafiltration, hemofiltration and/or ultrafiltration in hospital or clinical settings. The portability, flexibility and simplicity of the DIMI system facilitates dialysis in a wide variety of settings including hospitals, clinics, and skilled nursing facilities. The DIMI System has received 510(k) regulatory clearance in the United States as well as Health Canada Approval. Dialco is actively seeking FDA approval for home hemodialysis and peritoneal dialysis use.

¹Source: <https://www.fortunebusinessinsights.com/u-s-dialysis-services-market-105704>

About Spectral

Spectral is a Phase 3 company seeking U.S. FDA approval for its unique product for the treatment of patients with septic shock, Toraymyxin™ ("PMX"). PMX is a therapeutic hemoperfusion device that removes endotoxin, which can cause sepsis, from the bloodstream and is guided by the Company's Endotoxin Activity Assay (EAA™), the only FDA cleared diagnostic for the risk of developing sepsis.

PMX is approved for therapeutic use in Japan and Europe, and has been used safely and effectively on more than 340,000 patients to date. In March 2009, Spectral obtained the exclusive development and commercial rights in the U.S. for PMX, and in November 2010, signed an exclusive distribution agreement for this product in Canada. In July 2022, the U.S. FDA granted Breakthrough Device Designation for PMX for the treatment of endotoxemic septic shock. Approximately 330,000 patients are diagnosed with septic shock in North America each year.

Spectral is listed on the Toronto Stock Exchange under the symbol EDT. For more information please visit www.spectraldx.com.

Forward-looking statement

Information in this news release that is not current or historical factual information may constitute forward-looking information within the meaning of securities laws. Implicit in this information, particularly in respect of the future outlook of Spectral and anticipated events or results, are assumptions based on beliefs of Spectral's senior management as well as information currently available to it. While these assumptions were considered reasonable by Spectral at the time of preparation, they may prove to be incorrect. Readers are cautioned that actual results are subject to a number of risks and uncertainties, including the availability of funds and resources to pursue R&D projects, the successful and timely completion of clinical studies, the ability of Spectral to take advantage of business opportunities in the biomedical industry, the granting of necessary approvals by regulatory authorities as well as general economic, market and business conditions, and could differ materially from what is currently expected.

The TSX has not reviewed and does not accept responsibility for the adequacy or accuracy of this statement.

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