Current Agreements

Dealdoc

Development and licensing agreement for Virtue Sirolimus-Eluting Balloon (SEB

Terumo
Orchestra BioMed

Jun 13 2019

Development and licensing agreement for Virtue Sirolimus-Eluting Balloon (SEB

Companies:	Terumo Orchestra BioMed
Announcement date:	Jun 13 2019
Amendment date:	Oct 28 2025
Deal value, US$m:	35 : sum of upfront and equity payments

Details

Announcement date:	Jun 13 2019
Amendment date:	Oct 28 2025
Industry sectors:	Medical device
Brand name:	Virtue Sirolimus-Eluting Balloon
Compound name:	Sirolimus
Exclusivity:	Exclusive
Asset type:	Product
Therapy areas:	Cardiovascular Cardiovascular » Coronary artery disease
Technology types:	Devices Drug delivery » Parenteral » Infusion Drug delivery » Targeted Drug delivery » Transmucosal Implant Small molecules
Deal components:	Development Licensing Termination
Stages of development:	Formulation
Geographic focus:	Worldwide

Financials

Deal value, US$m:	35 : sum of upfront and equity payments
Upfront, US$m:	30 : upfront payment
Milestones, US$m:	n/d : clinical and regulatory milestone payments
Royalty rates, %:	n/d : share meaningfully in future commercial revenues of through royalties and per unit payments
Equity, US$m:	5 : equity commitment

Termsheet

October 2025

Terminated

July 2019

Terumo has secured exclusive global development and commercialization rights to Virtue Sirolimus-Eluting Balloon (SEB) for percutaneous coronary interventions by entering into a strategic partnership with Orchestra BioMed.

Terumo will make a one-time, up-front payment of USD 30 million and an equity commitment of USD 5 million to Orchestra BioMed.

Terumo will also make substantial future clinical and regulatory milestone payments to Orchestra BioMed.

Terumo will also make a strong commitment to finance and execute a global clinical program in collaboration with Orchestra BioMed to gain regulatory approval for commercial sale of Virtue SEB in multiple markets and indications.

Upon commercialization, Orchestra BioMed will share meaningfully in future commercial revenues of Virtue SEB through royalties and per unit payments as the exclusive supplier of its proprietary sustained-release formulation of sirolimus used in Virtue SEB.

Orchestra BioMed retains the rights to develop and license technology used in Virtue SEB for clinical applications outside of coronary and peripheral vascular interventions.

Press Release

October 2025

Terminated

July 2019

Terumo Enhances Coronary Interventional Product Portfolio By Securing Exclusive Global Rights to Orchestra BioMed's Virtue® Sirolimus-Eluting Balloon (SEB) through Global Strategic Partnership

First and only non-coated drug-eluting angioplasty balloon that delivers a proprietary bioabsorbable, sustained-release formulation of sirolimus

TOKYO, June 13, 2019 /PRNewswire/ -- Terumo Corporation (TSE: 4543), a leading global medical device manufacturer, today announced that it has secured exclusive global development and commercialization rights to Virtue® Sirolimus-Eluting Balloon (SEB) for percutaneous coronary interventions by entering into a strategic partnership with Orchestra BioMed, Inc., a biomedical innovation company providing high-impact solutions for large unmet needs in procedure-based medicine.

Under the terms of the agreement, Terumo will make a one-time, up-front payment of USD 30 million and an equity commitment of USD 5 million to Orchestra BioMed. Terumo will also make substantial future clinical and regulatory milestone payments to Orchestra BioMed.

Terumo will also make a strong commitment to finance and execute a global clinical program in collaboration with Orchestra BioMed to gain regulatory approval for commercial sale of Virtue SEB in multiple markets and indications.

Upon commercialization, Orchestra BioMed will share meaningfully in future commercial revenues of Virtue SEB through royalties and per unit payments as the exclusive supplier of its proprietary sustained-release formulation of sirolimus used in Virtue SEB.

Orchestra BioMed retains the rights to develop and license technology used in Virtue SEB for clinical applications outside of coronary and peripheral vascular interventions.

Virtue SEB is the first and only non-coated drug-eluting angioplasty balloon that delivers a proprietary bioabsorbable, sustained-release formulation of sirolimus, the gold standard drug for preventing restenosis following a percutaneous interventional procedure. In April, the U.S. Food and Drug Administration (FDA) granted Virtue SEB Breakthrough Device Designation for treatment of coronary in-stent restenosis (ISR), which may expedite its development and regulatory review for this challenging cardiovascular condition that represents more than 10% of total interventional coronary procedures and for which available treatment options are limited. In a prospective study of very challenging ISR patients, Virtue SEB demonstrated excellent angiographic results at six months as well as outstanding clinical outcomes out to three years. Orchestra BioMed plans to conduct a near-term U.S. registrational trial for ISR.

"We are excited to partner with Orchestra BioMed and secure global rights to Virtue SEB, which we intend to make a flagship therapeutic product that strongly compliments our broad US and global portfolio of interventional solutions. We believe Virtue SEB is an important innovation that has the potential to address key unmet needs in the field of interventional vascular therapy while fitting seamlessly within current clinical practice and workflow," said James Rushworth, CEO of Terumo Medical Corporation (North America) and Chief Commercial Officer of the Interventional Systems Division of Terumo. "The highly differentiated, non-coated design of Virtue SEB demonstrates Orchestra BioMed's deep knowledge of the needs of interventional cardiologists and its capability to deliver innovative solutions that have the potential to improve patient outcomes."

Virtue SEB strengthens the current cardiovascular product offering of Terumo Intervention Systems, Terumo Corporation's largest division, which includes a complete, solution-based product portfolio used in advanced coronary and peripheral endovascular treatments, with market-leading solutions for vascular access, lesion access and intervention. Orchestra BioMed and Terumo are seeking to make Virtue SEB

the first drug-eluting balloon approved for coronary use in the U.S. and Orchestra BioMed expects to initiate a U.S. registration trial for Virtue SEB in ISR under an Investigational Device Exemption (IDE) from the FDA within the next year. Virtue SEB is currently not approved in any market, but Terumo and Orchestra BioMed plan to conduct trials to support global regulatory approvals in indications including ISR, small coronary vessels, peripheral artery disease below-the-knee and other indications. Terumo and Orchestra BioMed's objective is to commercialize Virtue SEB in the U. S., Japan, China, and other markets.

"We are delighted to be aligning with Terumo, which has a rich history of global leadership in medical devices. Terumo has a proven global distribution and operations infrastructure with the sales and marketing expertise necessary to make Virtue SEB broadly accessible to physicians and patients worldwide, pending regulatory approvals." said David Hochman, Chairman and Chief Executive Officer of Orchestra BioMed. "This strategic partnership is a major milestone for Orchestra BioMed that validates our differentiated strategy to focus on the development of high-impact therapies while leveraging alliances with established market leaders, like Terumo, to drive global commercialization of our products."

About Terumo Corporation Tokyo-based Terumo Corporation is one of the world's leading medical device manufacturers, with approximately US$6 billion in sales and operations in more than 160 nations. Founded in 1921, the company develops, manufactures and distributes world-class medical devices, including products for use in cardiothoracic surgery, interventional procedures and transfusion medicine; the company also manufactures a broad array of syringe and hypodermic needle products for hospital and physician-office use. Terumo contributes to society by providing valued products and services to the healthcare market, and by responding to the needs of healthcare providers and the people they serve. Terumo Corporation's shares are listed on the first section of the Tokyo Stock Exchange (No. 4543, Reuters symbol <4543.T>, or Bloomberg 4543: JP) and is a component of the Nikkei 225, Japan's leading stock index.

About Orchestra BioMed Orchestra BioMed is a biomedical innovation company providing high-impact solutions for large unmet needs in procedure-based medicine. The company partners with established market leaders to drive global commercialization of its products, establishing multiple long-term potential revenue streams and supporting further product development. Its current product pipeline was organically developed and features Virtue® SEB for the treatment of artery disease, the leading cause of death worldwide, and BackBeat Cardiac Neuromodulation Therapy (CNT) for the treatment of hypertension, the leading contributing risk factor for death worldwide. Orchestra BioMed's business model optimizes capital efficiency and cash flow by developing therapies with a high probability of success that fulfill a specific need, fit within clinical workflow and deliver health-economic value. Orchestra BioMed is led by a multi-disciplinary team with a long track record of successful product development.

Filing Data

Not available.

Contract

Not available.