

ASX ANNOUNCEMENT

13 July 2026

Vectus Engages Cardinal Health Regulatory Services as US Regulatory Agent for FDA Submissions

Vectus Biosystems Limited (ASX:VBS) (Vectus or the Company) is pleased to announce it has formally engaged Cardinal Health Regulatory Services (CHRS) as its United States (US) Regulatory Agent, which will act as the primary point of contact for all Food and Drug Administration (FDA)-facing regulatory activities for Vectus' lead compound, VB0004, and, potentially, its other pipeline assets as they advance.

Under the engagement, CHRS will facilitate and prepare all FDA-facing communications, interactions and submissions on behalf of the Company, including the Orphan Drug Designation Request, pre-Investigational New Drug (pre-IND) communications and the IND application for VB0004 in idiopathic pulmonary fibrosis (IPF).

CHRS is a leading US regulatory affairs consultancy with deep expertise in FDA submissions and drug development strategies. The engagement of CHRS as Vectus' US Regulatory Agent establishes the US regulatory pathway for VB0004.

The Company's Chief Executive Officer and Chief Technology Officer (CEO and CTO), Dr Tara Speranza said: "Appointing CHRS as our US Regulatory Agent is an important milestone in establishing a clear regulatory pathway for VB0004 with the FDA. Its extensive experience in regulatory strategies and submissions will be invaluable as we advance preparations for our US development programme. This represents another important step toward bringing our first-in-class oral therapy to patients living with IPF, where there remains a significant unmet medical need."

VB0004 is Vectus' first-in-class oral Natriuretic Peptide Receptor C agonist in development for the treatment of IPF. Vectus has completed a Phase Ia clinical study in healthy volunteers establishing a favourable safety and pharmacokinetic profile. US regulatory activities are now underway to establish the foundation for future clinical development in the US.

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Chairman

Dr Tara Speranza
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This announcement was authorised by the Board of Directors

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About Vectus Biosystems Limited

Vectus Biosystems Limited (ASX:VBS) (Vectus or the Company) is an Australian clinical-stage biotechnology company developing novel therapies for fibrotic diseases, with an initial focus on advancing its lead compound, VB0004, for the treatment of idiopathic pulmonary fibrosis (IPF), a progressive, and often fatal, lung disease with significant unmet medical need. VB0004 is a first-in-class antifibrotic candidate that has demonstrated the ability to reverse established fibrosis in pre-clinical models, and has successfully completed Phase Ia clinical studies, establishing a favourable safety and pharmacokinetic profile.

Beyond IPF, the Company is advancing a broader pipeline of antifibrotic assets targeting cardiovascular, renal and liver fibrosis, leveraging a platform approach to address diseases driven by pathological tissue scarring. The commercial potential of the platform has been externally validated through a licensing agreement with an international biotechnology company for one of Vectus' renal fibrosis assets, showing a pathway for potential future milestone and royalty revenues.

The Company will continue its clinical development with an ambition to create shareholder value through the advancement, partnering and commercialisation of innovative therapies that address significant unmet needs in fibrotic disease.