ASX ANNOUNCEMENT

16 November 2026

Encouraging FDA Pre-IND feedback for VB0004 in IPF

HIGHLIGHTS

- The U.S. Food and Drug Administration's (FDA) written responses have been received from the Division of Pulmonology, Allergy and Critical Care (DPACC).
- The feedback addresses Vectus' chemistry, manufacturing and controls (CMC), and nonclinical and clinical questions supporting the planned Phase Ib / IIa study of VB0004.
- The FDA's responses are supportive and provide practical guidance as the Company finalises its Investigational New Drug (IND) package.

Vectus Biosystems Limited (ASX:VBS) (Vectus or the Company) is pleased to announce that it has received the FDA's written responses to its Type B Pre-IND meeting for VB0004, Vectus' first-in-class oral therapy being developed for idiopathic pulmonary fibrosis (IPF).

The Company submitted its Pre-IND briefing package to the FDA in October 2026 seeking its views on the CMC packages for both the drug substance and drug product, the nonclinical package supporting the proposed dose range, the design of the planned Phase Ib / IIa study, and the proposed regulatory pathway for VB0004 in IPF.

The FDA's written responses are supportive of Vectus' development programme and provide practical guidance that the Company will incorporate into the IND package.

Vectus' Chief Executive Officer and Chief Technology Officer (CEO & CTO), Dr Tara Speranza, commented:
"This is an important step for VB0004. The FDA's feedback is encouraging and gives us a clear path for the IND. We asked the Agency direct questions across manufacturing, toxicology and the Company's clinical plan, and the answers will shape the package we submit. Our focus now is to complete the IND and move VB0004 into its first study in patients with IPF."

Vectus will incorporate the FDA's feedback into the VB0004 IND, which is being prepared with the Company's U.S. regulatory agent, Cardinal Health Regulatory Sciences. The IND will support the planned Phase Ib / IIa study, which will commence in Australia.

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Chairman

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This announcement was authorised by the Board of Directors.

About Vectus Biosystems Limited

Vectus Biosystems Limited (ASX:VBS) 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 preclinical 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.