



NEWS RELEASE

# Donaldson Announces Integrated Lentiviral Vector Manufacturing Platform Development

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The first phase of a multi vector manufacturing platform solution

MINNEAPOLIS--(BUSINESS WIRE)-- Donaldson Company, Inc. (NYSE: DCI), a leading worldwide provider of innovative filtration products and solutions, announced its Isolere Bio (Isolere) and Univercells Technologies businesses are developing an integrated upstream and downstream platform for viral vector manufacturing. The first phase will focus on lentivirus (LV) manufacturing, concentrating on improving recoveries with a scalable process while keeping the manufacturing footprint small.

"This manufacturing platform promises to establish a solution that accelerates process development timelines and reduces manufacturing complexity in the production of accessible cell and gene therapies worldwide," said Andrew Dahlgren, Donaldson Life Sciences president.

Univercells Technologies' scale-X™ fixed-bed bioreactor has demonstrated high yields of infectious LV in perfusion mode. Isolere's IsoTag™ LV affinity purification reagent enables non-chromatographic purification of LV vectors with high functional recoveries, high purity, decreased unit operations and reduced total processing time. The IsoTag LV reagent confers additional stabilizing properties to the LV vectors that may be advantageous when used in conjunction with the scale-X bioreactor.

"For the first phase of the manufacturing platform, we are starting with LV given the growing demand for this vector, as current infectious virus recoveries are low and the virus is unstable," said Kelli Luginbuhl, Isolere's founder and general manager. "Achieving extended, low-shear perfusion culture in the scale-X bioreactor platform, together with the IsoTag LV's in situ virus stabilization, will improve yields and lower costs."

Isolere's pipeline of IsoTag reagents currently is focused on offering affinity purification solutions for adeno-associated virus (AAV), LV and positive-strand RNA viruses (ssRNA). These reagents combine tailored affinity ligands

with liquid-liquid phase separation to sequester target biologics from complex solutions into large droplets. These droplets are concentrated and purified via tangential flow filtration using familiar equipment and off-the-shelf consumables.

Mathias Garny, Univercells Technologies' general manager, said, "scale-X technology is a demonstrated bioreactor platform for rapid process development and scale-up of virus manufacturing. The design of the scale-X fixed-bed enables extended low-shear perfusion operation as well as significant reductions in host cell proteins and host cell DNA. Unlike other bioreactors, both suspension and fixed-bed, this bioreactor is directly scalable from bench to commercial-scale. It is now in use at CDMOs worldwide for clinical trial manufacturing, and the first commercial product produced in the scale-X bioreactor will launch later this year."

"Donaldson is a new entrant into the bioprocessing space, having made selective and strategic acquisitions over the past three years," added Dahlgren. "A key element in our strategy is to acquire innovative companies such as Isolere and Univercells Technologies that together can make a significant difference in the manufacturing of complex biologics, increasing the availability of these life-changing medicines worldwide."

#### About Donaldson Company

Founded in 1915, Donaldson (NYSE: DCI) is a global leader in technology-led filtration products and solutions, serving a broad range of industries and advanced markets. Diverse, skilled employees at more than 140 locations on six continents partner with customers - from small business owners to R&D organizations and the world's largest OEM brands. Donaldson solves complex filtration challenges through three primary segments: Mobile Solutions, Industrial Solutions and Life Sciences. Additional information is available at [Donaldson.com](https://www.donaldson.com).

#### About Donaldson Bioprocessing

Donaldson Bioprocessing is dedicated to advancing biopharmaceutical technologies through its subsidiaries of Isolere Bio and Univercells Technologies, among others. Isolere Bio specializes in IsoTag™ reagents and filtration processes for streamlined biopharmaceutical manufacturing, while Univercells Technologies focuses on innovative biomanufacturing solutions for cell and gene therapy research and commercial manufacturing. For more information, visit [IsolereBio.com](https://www.isolerebio.com) and [UnivercellsTech.com](https://www.univercellstech.com).

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