

PRESS RELEASE



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FOR IMMEDIATE RELEASE

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DevPro Biopharma and Bespak Complete Early Feasibility Studies for New Groundbreaking Albuterol Inhaler

Ventolin®-equivalent pMDI utilizes near-zero global warming potential propellant

BASKING RIDGE, NJ, & HOLMES CHAPEL, UK, May 7, 2024 - DevPro Biopharma and Bespak have announced the completion of early feasibility studies on DP007, a new formulation of albuterol in a pressurized metered dose inhaler (pMDI) which shows comparable performance to Ventolin® HFA but with a significant reduction in greenhouse gas emissions. This breakthrough pMDI is being developed by DevPro Biopharma, a respiratory-focused clinical development accelerator, and Bespak, a leading contract development and manufacturing organization (CDMO) focused on orally inhaled and nasal drug-device combination products. Clinical studies are planned to be initiated by the end of the year to fast-track its development, as the pharmaceutical industry begins to accelerate its transition to climate-friendly respiratory care.

The preliminary results will be presented on May 18, 2024, at the 2024 Respiratory Innovation Summit, hosted by the American Thoracic Society (ATS) during their 2024 International Conference at the San Diego Convention Center, San Diego, CA.

The new formulation has the potential to revolutionize the treatment of respiratory disease by reducing the global warming potential (GWP) impact of albuterol inhalers such as Ventolin, the most commonly prescribed inhaler type globally. It is expected to be commercialized by mid-2027 to meet the requirements of the US phasedown of fluorinated gases under the American Innovation and Manufacturing Act of 2020.⁽¹⁾

As many as 384 million people globally suffer from chronic obstructive pulmonary disease (COPD), and about 262 million people suffer from asthma.⁽²⁾ Most of these patients are treated using pMDIs that have a high GWP due to the use of greenhouse gases known as hydrofluoroalkanes (HFAs) as propellants. Greenhouse gas emissions challenge efforts to keep the global temperature rise at or below 2°C this century, and regulation is being tightened across the world as a result.

The innovative formulation is being developed by Bespak at its Research Triangle Park, NC research facility under the terms of an exclusive agreement with DevPro Biopharma. The new formulation contains Honeywell's Solstice® Air (HFO-1234ze(E) cGMP), a hydrofluoroolefin (HFO) propellant that has 99.9% less global warming potential than current HFAs and is in clinical development for pMDI products. This announcement follows an [earlier announcement](#) of the commercial partnership between Bespak and Honeywell to speed the development of near-zero GWP inhalers.

Colin Reisner, CEO of DevPro Biopharma, said, "Albuterol pMDIs account for approximately 45% of all pMDIs used worldwide, contributing substantially to global warming. In the US, about 60 million prescriptions are written annually

for albuterol pMDIs producing emissions equivalent to more than 200,000 passenger vehicles. There is an urgent need to develop a low-GWP albuterol pMDI to reduce the environmental impact of the life-saving inhalers patients need, without sacrificing performance or ease-of-use. Working with Bespak, we are excited about the results we have seen with DP007 showing comparable performance with Ventolin HFA. Based on our own market research, it has the potential to generate peak sales in excess of \$500 million USD annually.”⁽³⁻⁷⁾

Chris Hirst, CEO of Bespak, commented, “We’re committed to leading the transition to low-GWP propellants in pMDIs to help halt the global warming caused by greenhouse gases. Bespak has a long history in the development, scale-up, and clinical and commercial supply of inhalers and our goal now is to transition as many pMDI products as possible to meet the requirements of evolving global legislation. We believe in not only leveraging our own skills and capabilities, including our expertise in valves, actuators, and dose counters, but also working together across the industry to achieve this goal. Building on our partnership with Honeywell, we are proud to partner with the experienced team at DevPro Biopharma on this exciting development.”

Reisner added, “This is a low risk, high reward development program with opportunity for a major reduction in global warming. We have assembled a world-class team of experts from Bespak and DevPro Biopharma who have developed the plan together for the next phase of the program to quickly de-risk the asset. We are encouraged by interest in the program and look forward to speaking with potential investors at ATS 2024 Respiratory Innovation Summit.”

DevPro Biopharma is inviting expressions of interest from investors and pharmaceutical organizations in the next phase of the development program. Interested parties should contact Lin Ling:
lling@devprobiopharma.com.

For further information and interview opportunities with Bespak, contact Sarah Guinane at Notch Communications: sarah.guinane@notchcommunications.co.uk.

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Bespak

Bespak is a global contract development and manufacturing organization (CDMO) focused on inhaled and nasal drug delivery devices and drug-device combination products. The company’s service offering spans early-stage feasibility, analytical services, and product development, from pilot-scale, through to clinical supply and commercial-scale drug product fill-finish, device, and component manufacturing. The company has made significant investments in commercial-scale and pilot-scale filling equipment for the manufacture of pMDIs using low GWP propellants and is the first CDMO to manufacture a pMDI at commercial scale with HFO-1234ze. Visit [Bespak.com](https://www.bespak.com) for more information.

DevPro Biopharma

DevPro Biopharma LLC is a respiratory-focused, fully integrated clinical development company with the mission to design, develop, and deliver molecules into medicines. The DevPro Biopharma team has collectively contributed to more than 50 approved products or label expansions. DevPro Biopharma is actively conducting studies in cystic fibrosis, idiopathic pulmonary fibrosis, progressive pulmonary fibrosis, asthma, and chronic obstructive pulmonary disease (COPD). Visit [DevProBiopharma.com](https://www.devprobiopharma.com) for more information.

References:

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6. Greenhouse Gas Emissions from a Typical Passenger Vehicle, US EPA, <https://www.epa.gov/climate-hfcs-reduction>.
7. DevPro Biopharma data on file.

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