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OCTOBER - 2020

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Iconovo

**TOP
DRUG
DELIVERY
DEVICE**

SOLUTION PROVIDERS

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*The annual listing of 10 companies that are at the forefront of providing
Drug Delivery Device solutions and impacting the industry*

Iconovo

An Experienced Partner for the Development of Inhalation Products

Asthma, chronic obstructive pulmonary disease (COPD), and other respiratory illnesses are emerging as a severe global health problem. According to the National Institute of Health (NIH), over eight percent of all adults and over nine percent of all children have asthma, and COPD is the third leading cause of mortality after cancer and heart disease in the country. Several reports suggest that patients would benefit from appropriate medications delivered by inhalation as the drug travels faster to the affected area without being diluted in the systemic circulation. However, the regulatory procedures and demonstration requirements prove to be a significant deterrence for the speed to market of these products, especially for the generic products. Despite strict regulations in place, the regulatory regimes across the globe are slowly opening up to the idea of fast-tracking the generic drugs' approval process. The Hatch-Waxman Amendments established bioequivalence as the basis for approving generic copies of drug products, allowing the FDA to approve applications to market generic versions of brand-name drugs without repetitive and costly clinical trials.

A Sweden-based pharmaceuticals company, Iconovo is capitalizing on the relaxed regulatory scenarios by developing ready-to-use inhalation products – inhaler devices and dry powder formulations – and assists in clinical trials and registration for generic drug and pharmaceutical companies. Possessing a unique combination of engineering and pharmaceutical expertise, the company renders an integrated development process that enables it to develop devices and formulations in a shorter time-frame

cost-efficiently, meeting the rigorous ISO 13485-standard. “We are one of the few independent companies in the world that develops and supplies both the inhalation device and the dry powder formulation along with the analytical testing, documentation, and all the supporting requirements related to the product,” states Dr. Orest Lastow, CTO and founder, Iconovo. He further says, “For organizations developing inhalation products, we shorten the product’s time to market, while reducing the project risk and development cost at the same time.”

The company has four proprietary inhaler platforms—ICOres, ICOpre, ICOcap, and ICOone. ICOres is Iconovo’s flagship product with dual reservoirs that deliver up to 180 doses of mono or combination therapies, either carrier-based formulations or active pharmaceutical ingredient (API). Besides, the product also has a dose counter and an inhalation feedback feature, making it easier for the users to receive and keep track of the doses. Lastow sheds light on an exclusive development and licensing agreement for the development of a generic Symbicort product and adaptation of the ICOres device with Amneal Pharmaceuticals LLC, a leading generics manufacturer. Lastow informs, “When we signed the deal with Amneal, we only had early prototype versions of the device, now we have successfully performed the first clinical trials and are in the process of setting up the large-scale commercial manufacturing of the device.”

Iconovo’s another product ICOcap is an easy-to-use inhaler designed to have equivalent function, handling, and performance of branded capsule inhalers on the market, both in vitro and in vivo. The third product ICOpre is a pre-metered dry powder inhaler for carrier-based or



Orest Lastow

spray-dried formulations with simple three-step user operation—open-inhale-close. It is designed for combination products and contains two times 30 individually sealed doses for a month’s supply and has a dose counter to check the remaining doses. Finally, ICOone is a single dose disposable dry powder inhaler for simple, cost-effective, and discreet use. The product is the perfect replacement for injections, eliminating the need for any refrigeration and risk of syringes with contaminated blood.

Established in 2013, Iconovo boasts of a highly proficient and experienced team of people with expertise in several aspects including, device development, formulation development, analytical testing, and regulatory project management. The company caters to not only experienced players with in-house capabilities, but also the newcomers in the inhalation product arena. Currently, the company is eyeing to find a partner for the delivery of its ICOpre platform. Also, Iconovo plans to enhance its workforce and products in the coming years with royalties from the existing products. 