

Flerie's portfolio company Xspray Pharma provides update on FDA process for Dasynoc®; observations at contract manufacturer delay approval

Flerie AB's (publ) portfolio company Xspray Pharma has announced that it will be resubmitting its New Drug Application (NDA) for Dasynoc® once observations raised by the U.S. Food and Drug Administration (FDA) at its contract manufacturer have been addressed. These observations are unrelated to the production line used for Dasynoc, but the FDA is pausing approvals of new products at the facility until the corrective actions have been completed. Xspray Pharma is working closely with both the manufacturer and the FDA to expedite the process and enable a resubmission.

"Whilst the response from the FDA delays the anticipated approval of Dasynoc, we remain confident in Xspray Pharma's ability in conjunction with their contract manufacturer to successfully navigate the process effectively. At the same time, Xspray Pharma's robust technology platform and the continued progress across its broader pipeline demonstrate the depth of opportunity and confirm our conviction in our portfolio company's long-term potential," says Ted Fjällman, CEO of Flerie.

Read Xspray Pharma's full press release here:

https://xspraypharma.com/modular_finance_pressmeddelande/xspray-pharma-providesupdate-on-the-fda-process-for-dasynoc-observations-at-contract-manufacturer-delay-approval/

Flerie's holding in Xspray Pharma amounts to 18%.

For more information:

Ted Fjällman, CEO Email: <u>ir@flerie.com</u>

Flerie in brief

Flerie is an active long-term life science investor, with a broad and diversified portfolio of innovative companies based on pioneering science. We invest in product development and commercial growth opportunities globally alongside other leading investors, focusing predominantly on private companies that are otherwise difficult to access. Flerie's active ownership model, broad network and resources support and accelerate the development of the portfolio projects, creating value for shareholders. Flerie AB's ordinary share is listed on Nasdaq Stockholm with the ticker FLERIE. For further information please visit www.flerie.com

Attachments

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