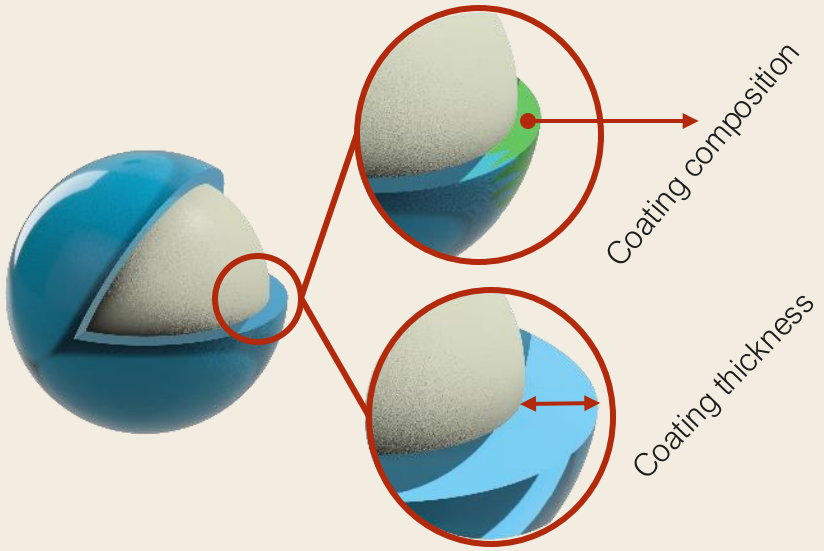
Once-monthly GLP-1 formulation using the PharmaShell drug delivery system

PODD 2025

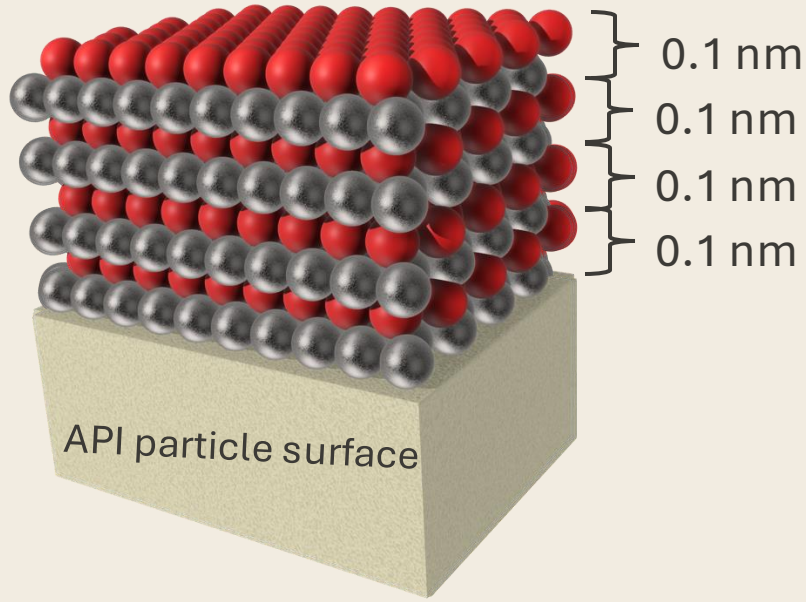
PharmaShell®

- Tailoring of depot length and release profile by adjusting the ALD parameters such as composition and thickness
- Drug release for 1 or 3 months or potentially longer, regardless of the API's half life
- No change to the Active Product Ingredient (API)
- The coating protects the API



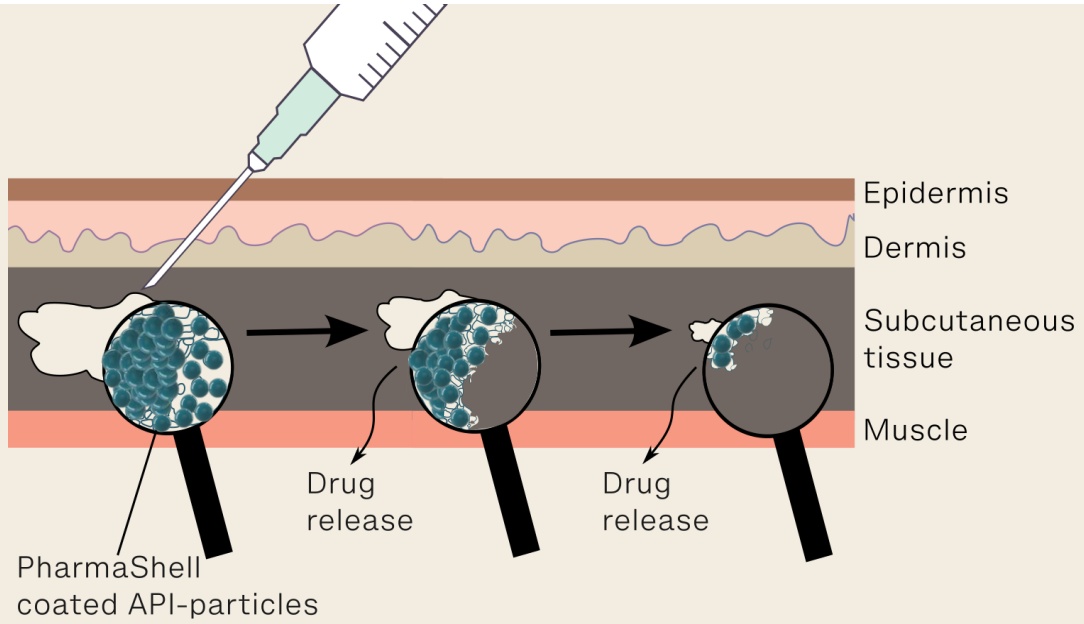
PharmaShell® by Atomic Layer Deposition (ALD)

- PharmaShell® coating consists of inorganic oxides applied on API particles using ALD
- ALD is a gas phase technique to coat surfaces
- Gentle process also for peptides and mAbs, operates at dry conditions, close to room temperature
- Coating thickness in the nanometer range allows for a very high drug load
- No post-process purification steps needed



PharmaShell® release mechanism

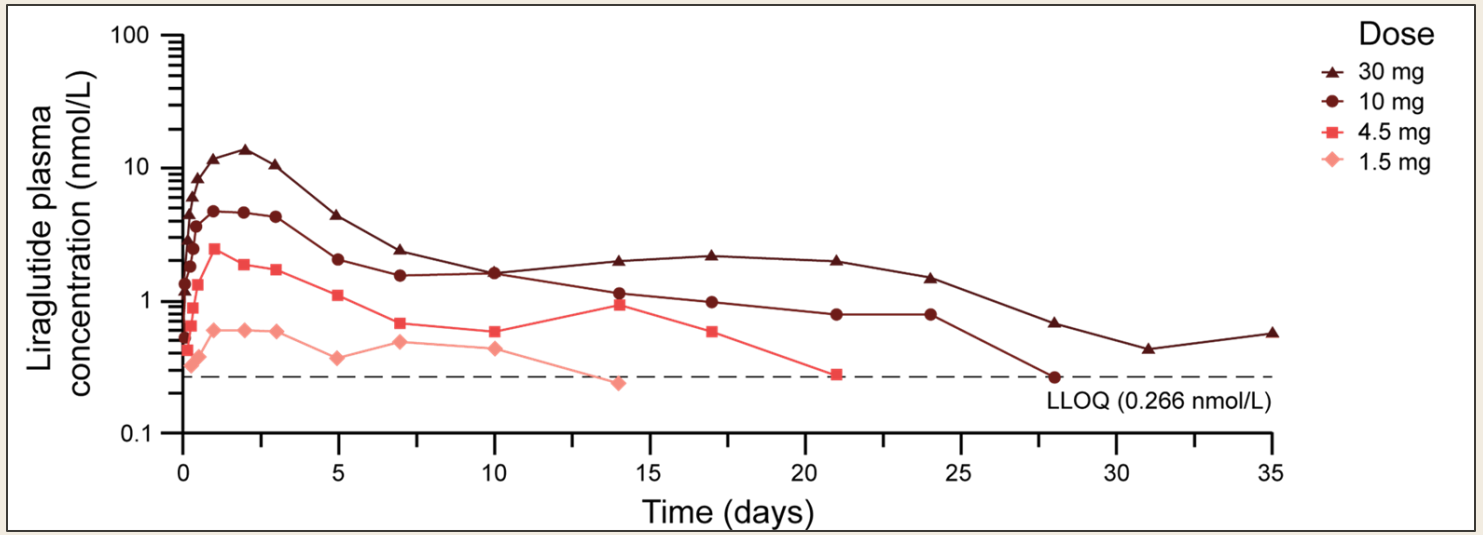
- PharmaShell® formulation prepared as a suspension
- After injection, PharmaShell coated API particles gradually dissolves, exposing the API to the systemic circulation
- The coating is dissolved into its ions and eliminated via urine and feces



Thin Gauge Needles (30G) and low injection volume with >150 mg/mL concentration)

Proof of concept - NEX-22 – liraglutide with PharmaShell® shows clinical exposure over 36 days

85th American Diabetes Association , Chicago June 22th, Poster 1975-LB



- Phase 1 results in GLP-1 naïve participants with Type 2 Diabetes
- The first tested PharmaShell formulation of liraglutide
- Release of liraglutide over 36 days after a single subcutaneous injection
- Dose linearity in exposure and Cmax
- Optimized formulations to improve Cmax to Ctrough in preclinical studies

Repeated dosing simulation of PharmaShell® semaglutide in humans

- based on an optimized liraglutide formulation in rat

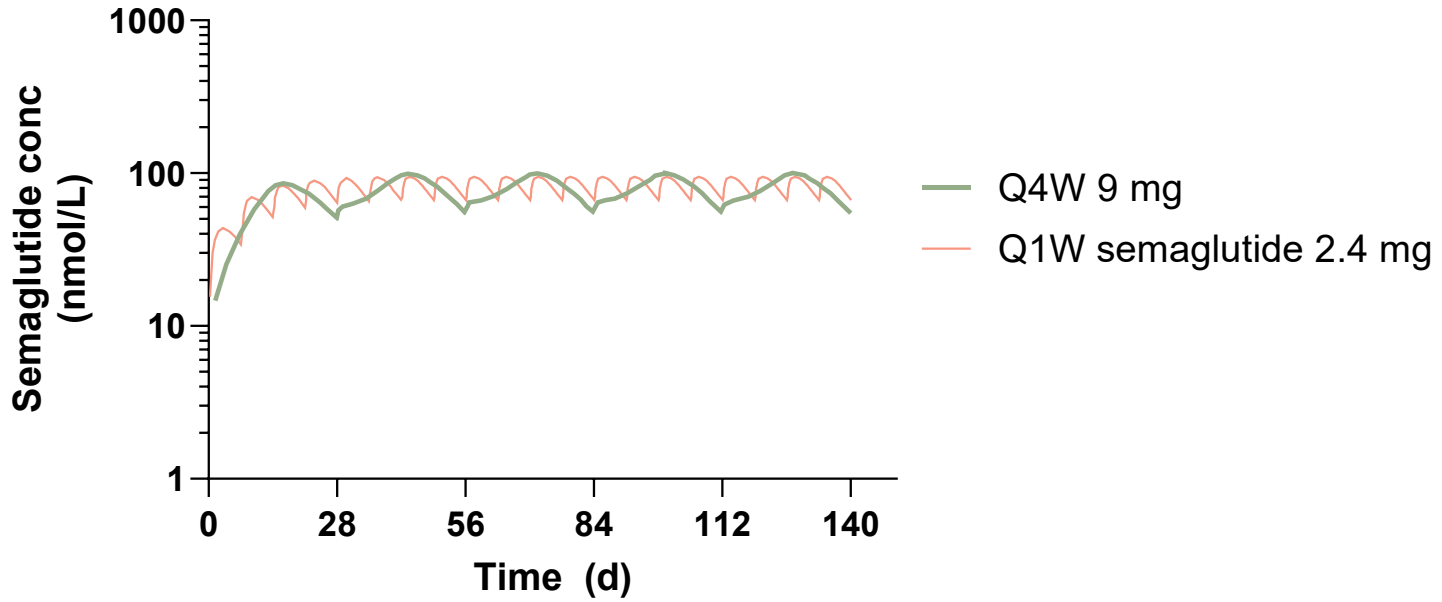
PharmaShell® semaglutide peak to trough ratio at steady state is predicted to 1.8

	Cmin (nmol/L)	Cmax (nmol/L)
9 mg	55	100

Wegovy peak to trough ratio at steady state 1.7–1.9 (half-life ~1 week)

Wegovy*	Cmin (nmol/L)	Cmax (nmol/L)
2.4 mg	61	102/118

*https://www.ema.europa.eu/en/documents/assessment-report/wegovy-epar-public-assessment-report_en.pdf Table 9 and 10



Terminal sterilization

PharmaShell® enables terminal sterilization

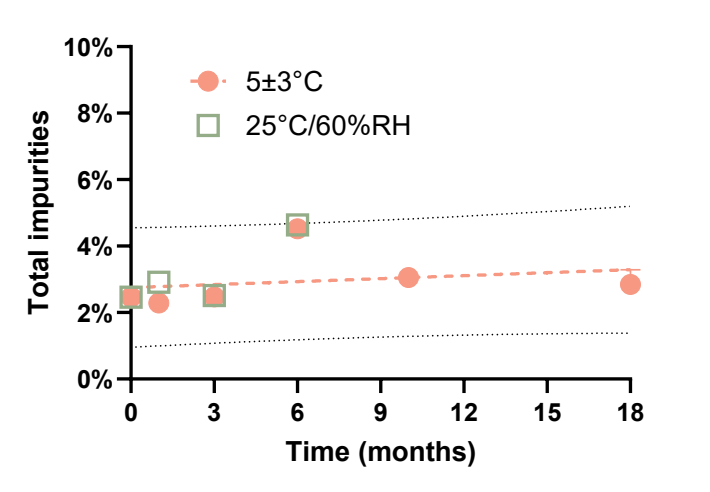
Limited formation of impurities during gamma irradiation:

- Gamma irradiation at a dose of 20 kGy resulted in 3% additional impurities (40% less impurities for coated compared to uncoated liraglutide)
- PharmaShell® process is bioburden reducing and protects the API enabling an even lower irradiation dose
- Reducing the irradiation dose to 8 kGy (following ISO11137-2 method 2 to reach a SAL of 10^{-6}) decreases degradation, limiting impurity formation to about 1.5%

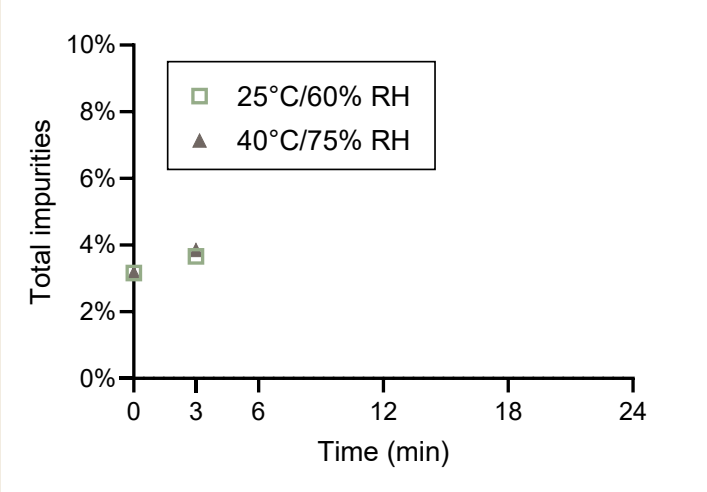
Room temperature storage

PharmaShell® protects API during storage

- Gamma irradiated coated peptides can be stored at room temperature.
- PharmaShell coating preserves product quality and efficacy without the need for cold storage requirements



Real-time data for 6 mo in 25°C/60% RH

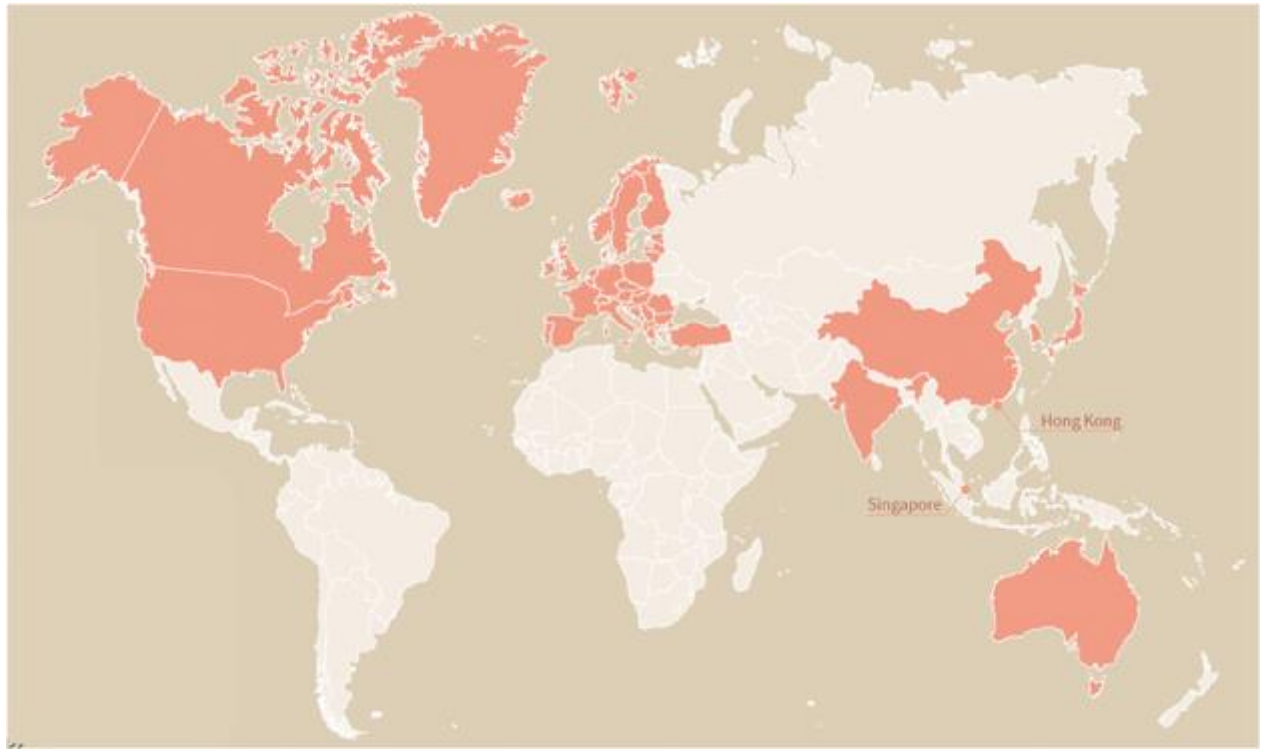


Accelerated data for 3 mo in 40°C/75% RH

Patent portfolio

14 patent families, with granted patents and/or pending patent applications in or in respect of up to 50 countries, having normal expiries dates extending up to 2046

- 8 on general formulations/products
- 2 on project specific products (NEX projects)
- 1 on ALD reactor for upscaling
- 3 on methods for producing PharmaShell.



New inventions patented by Nanexa are crucial enablers on both a laboratory and commercial scale. By protecting these inventions through intellectual property rights, Nanexa will be able to defend its strong market position in the field well into the future.

Thank you for listening!

Come and meet us at Booth **#128**

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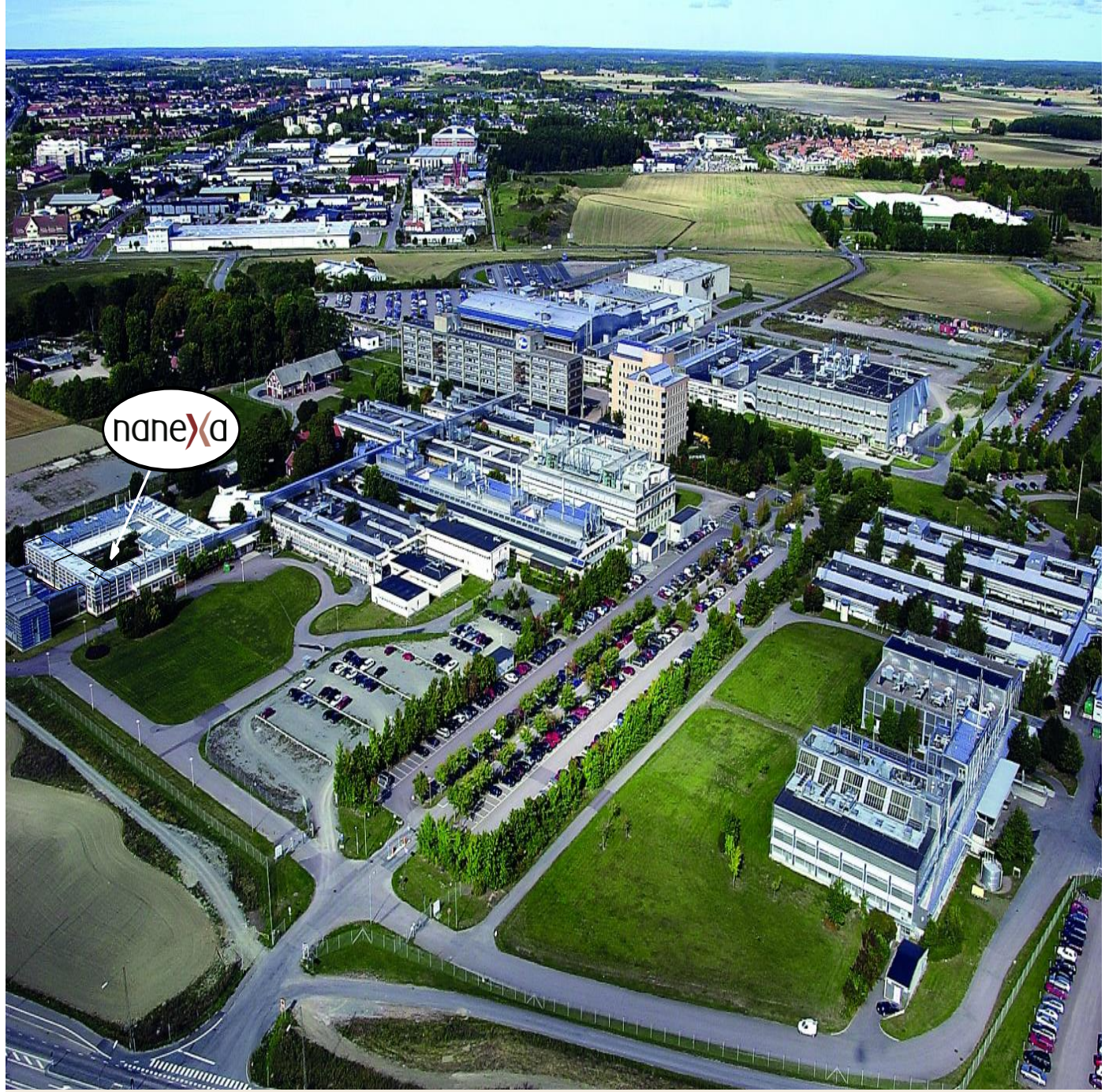

Nanexa located on former Pharmacia-Upjohn / Pfizer site in Uppsala, Sweden