## What Does it Take to Manufacture Oligonucleotides?

<u>Oligonucleotides</u> have emerged as a new drug modality originally targeting rare diseases. Today, they are delivering on their promise, showing their potential for common diseases that affect a larger number of patients. Bachem recognized this shift and the need to manufacture oligonucleotides on a large scale to meet the market demand.

Daniel Samson, Head of Oligonucleotides at Bachem, explained that "by nature, rare diseases were the first targets, but we see more and more trends towards larger indications, larger populations. This generates a lot more demand, and more capacity is needed. In addition, big pharma companies are getting more and more excited. So, that's certainly a trend. We'll have both rare diseases of small indications, but also large indications."

The company saw an opportunity to expand its existing <u>manufacturing capacity</u> and expertise in large-scale active pharmaceutical ingredients (APIs) by building facilities to produce oligonucleotide APIs. However, this change in scale and high demand bring new challenges related to capacity, sustainability, supply chain, cost, and quality.

Daniel Samson, Head of Oligonucleotides at Bachem, says:

"When it goes to later clinical phases or even commercial demand for large indications, we talk almost about metric tons of one single molecule and that's a completely different story than in terms of equipment, trains, how to manufacture that."

Bachem recognizes this and is meeting these challenges with investments in new <u>facilities</u>, people, and innovations. With our expertise in peptide drug development and commercialization, we have been able to exploit synergies in technology and know-how. As a first mover in the industry, we are pioneering the implementation of automation, new methods, and technologies for synthesis and purification, such as continuous chromatography on a commercial scale.

"We are hiring a lot of people and we train them. We are operational for quite a while now and have already manufactured several oligonucleotides for our customers. [...] For the mid and longer term, we invest a lot of CapEx (capital expenditures) in the construction of a new building, new equipment and, innovation as well. [...] Innovation helps, especially for larger scale, in decreasing the process mass intensity, the carbon footprint, and the solvent consumption. For example, we implemented continuous chromatography, which is [...] absolutely one of the methods of choice to save solvent and at the same time have a very powerful separation."

Our goal is to become one of the leading CDMO for peptides and oligonucleotides by offering our customers a full package of end-to-end services for their compounds, from process development and analytics to regulatory affairs and commercialization.

"We are ready to grow. We invest heavily into a new building and an additional site. We will provide the capacity and at least some of the oligonucleotides will go very big. So, that's our ambition to provide those"

## **About Bachem**

Bachem is a leading, innovation-driven company specializing in the development and manufacture of peptides and oligonucleotides. With over 50 years of experience and expertise Bachem provides products for research, clinical development and commercial application to pharmaceutical and biotechnology companies worldwide and offers a comprehensive range of services. Bachem operates internationally with headquarters in Switzerland and locations in Europe, the US and Asia. The company is listed on the SIX Swiss Exchange.