

# FEATURE SERVICE

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## mRNA Therapeutics – Why WACKER Is Investing in this Future Technology

**Vaccines based on mRNA protected humanity against a worst-case scenario during the Covid-19 pandemic. These mRNA therapeutics will soon be able not just to protect against various virus infections, but also to heal cancer. WACKER is building an mRNA technical competence center in Halle to cover future demand.**

Until just a few years ago, mRNA therapeutics were only familiar to specialists. Today, most people at least know the term “mRNA vaccines” as a result of the coronavirus (SARS-CoV-2). “The high demand for new and, above all, rapidly available vaccines has shown the potential of this technology. The biopharmaceutical sector has experienced a major boost,” said Dr. Guido Seidel, managing director at Wacker Biotech. He compared the situation with the amazing rise of antibodies just a few decades ago: “There were a lot of skeptics in the 1980s who dismissed any potential for this technology. Today, highly-specific antibodies are used in standard therapies for numerous diseases.” The same point, he explained, had now been reached for mRNA technology: “Proof of concept” has been achieved. Whether this technology works in other indications still has to be demonstrated. “Very likely we will be able to treat or even prevent

numerous diseases in 20, 30 years with mRNA-based medication,” added Seidel confidently.

More research, more demand, more business – WACKER is moving with the current rise in demand and has decided to expand the Wacker Biotech GmbH site in Halle to become an mRNA technical competence center. The WACKER Group focuses all its biopharmaceutical activities within its Wacker Biotech subsidiary. Ground was broken at the beginning of July 2022. The new production building at the Halle, Saxony-Anhalt site will be up and running within two years and some 200 people will work there. Plans are for four production lines which will exclusively manufacture mRNA biopharmaceuticals. This means that Wacker Biotech will greatly increase its production capacity based on its current site capacities in Jena and Halle (Germany), and in Amsterdam (NL) and San Diego (USA). “It is no longer possible to conceive of medical biotechnology not being used in patient treatment. Almost half of all newly approved medicines are now biopharmaceuticals<sup>1</sup>”, Seidel underlined. According to experts, the percentage of mRNA therapeutics will continue to rise.

### **How mRNA vaccinations work**

The foundation stone was laid by vaccine development during the current pandemic. In just a few months, numerous biotechnology companies developed vaccines against the SARS-CoV-2 virus. The main constituent is mRNA. The abbreviation stands for messenger RNA (messenger ribonucleic acid). While previous vaccines usually consist of virus particles or fragments

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<sup>1</sup> <https://www.vfa-bio.de/vb-de/aktuelle-themen/branche/biotech-branche-wachstum-beschaefigte.html> (German-language link only)

of such particles, mRNA vaccines take a slightly different path: They consist of a detailed blueprint of the special proteins in the pathogen, also known as antigens. In the coronavirus, for instance, this is the spike protein that protrudes from the surface of the virus, providing it with a striking appearance. Packed in a lipid envelope, the genetic message is delivered into the muscle cells at the injection point. The cells build the corona protein, present it to the immune system which then recognizes the antigen as an intruder and starts to produce antibodies against it. Should the body one day be infected with the actual pathogen, it is then suitably equipped and can effectively combat the intruder.

**mRNA is DNA's  
little sister**

In order to understand what is so unusual about mRNA, you need to look inside the cell nucleus. This is where the DNA, containing the human genetic information, is stored. It holds the complete information for the blueprint of the human body. Each gene codes for a protein. These genes determine the characteristics of every life form. It has been 60 years since it became clear that cells produce a copy of the genes in order to translate the information in a protein. Whenever the body requires a specific protein, the required gene is translated in a mRNA. The mRNA transfers the blueprint for the protein from the cell nucleus to the ribosomes. The ribosomes in the cells then produce the required protein. The DNA remains protected in the cell nucleus.

It has now become possible for the first time to use these mRNA vaccines to create therapeutic agents based on mRNA on a large

scale. Over 12 billion vaccinations<sup>2</sup> worldwide up until June 2022 have shown that mRNA vaccines work effectively, are well tolerated and can be efficiently produced. Many were astounded at how rapidly the appropriate vaccinations became available in such huge volumes. This rapid development was made possible because many building blocks for mRNA vaccine had already been created, emphasized Seidel. He is himself a biochemist and has been familiar with the research and production of biopharmaceuticals for more than 20 years. “That production ramped up so fast is because the spike sequence mRNA could be conceived, designed and synthesized so rapidly, relatively speaking, compared to cancer therapeutics that companies have been researching so intensively to date.”

That this experience has resulted in numerous ideas for further vaccines based on the same principle is a logical conclusion: The US biotech company Moderna is also working, amongst other things, on a quadruple vaccine against the influenza virus. The company even intends to create a form of “autumn vaccine” that combines different vaccines against various respiratory diseases such as COVID-19, influenza and RSV.<sup>3</sup>

### **Numerous application areas for mRNA**

There is a lot to suggest that mRNA therapeutics will also find a use in the future for other indications. Biontech founder Ugur Sahin believes that his company will introduce multiple products to combat cancer and infectious diseases over the next three to five years.<sup>4</sup> “You can use mRNA anywhere in the body where

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<sup>2</sup> <https://de.statista.com/statistik/daten/studie/1195157/umfrage/impfungen-gegen-das-coronavirus-nach-laendern-weltweit/> (German-language link only)

<sup>3</sup> <https://www.modernatx.com/research/product-pipeline>

<sup>4</sup> <https://www.pharmazeutische-zeitung.de/mrna-krebstherapeutika-in-drei-bis-fuenf-jahren-133527/> (German-language link only)

proteins are functioning incorrectly or where proteins are needed to activate the immune system, for instance, the vaccination against the coronavirus – but hopefully also against cancer”, said Seidel. Possible application areas for mRNA therapeutics could be autoimmune diseases, cardiovascular diseases and in regenerative medicine.

Developers are placing a lot of hope in cancer treatment in particular. The challenge for a cancer vaccination is that cancer cells often hide and therefore avoid being destroyed by the immune system. The mRNA vaccine is intended to induce the immune system to recognize tumor cells as “foreign” again and effectively fight them. The mRNA vaccine therefore receives the blueprints of important components of individual tumors, for instance a surface protein. The resulting protein or peptide then activates the immune system which combats the cancer cells. “The key step here is to rapidly produce a suitable active ingredient from the tumor data”, said Seidel, adding that mRNA was predestined for this as it can be relatively rapidly designed and produced.

**WACKER for the  
pharmaceutical  
industry**

As is often the case during the development of new medicines, numerous actors are essential: While pharmaceutical companies drive research forward, contract manufacturing organizations such as Wacker Biotech ensure that the new active ingredients can be produced in large quantities. As a contract development and manufacturing organization (CDMO), the company produces active ingredients for the market and clinical testing on behalf of pharmaceutical and biotech companies. “The rapid success in vaccine production would hardly be possible without companies

**Building up  
mRNA expertise**

like us”, said Seidel. As a full service producer of biologics, Wacker Biotech has 20 years of experience in the sector of microbial systems. Core competencies include the production of pharmaceutical active ingredients, live bacteria and vaccines – lately also based on mRNA. Wacker Biotech has built up an international portfolio of customers over the years. Business is growing steadily.

The biotech company recognized the potential in mRNA therapeutics early on: “We have been intensively expanding our expertise and production capacities for mRNA therapeutics since 2018,” said Seidel. The various sites cover different specialist areas of the manufacturing processes: In Amsterdam for example, they know how to package the highly sensitive molecules into tiny lipid spheres. Plasmid DNA is produced in San Diego as the raw material for mRNA therapeutics.

WACKER eventually decided to focus all these mRNA competencies at one site: “Together with our partner, CordenPharma, our Halle site will in the future cover the complete manufacturing process of mRNA active ingredients,” said Seidel. While Wacker Biotech takes over the production of mRNA derived from plasmid DNA and the preparation of the mRNA active ingredient with lipid nanoparticles (LNP), CordenPharma is to produce the lipids for the LNP preparation and take over the sterile filling and packaging of the mRNA vaccine.

Four new production lines will be set up in Halle for this purpose. Approximately half of the production capacity will be reserved for

**Pandemic preparedness  
plan for the German  
Federal Government**

the German Government within the framework of the pandemic preparedness plan contracts. Seidel said that “The concept of a ‘warm facility’ will be followed here: Systems will be operational and be maintained in a state of full readiness. If we receive the order from the German Government to produce mRNA vaccine, we can start production within a very short time.” The aim is to be optimally prepared for a future pandemic and thus avoid any supply bottlenecks like those that occurred at the start of the coronavirus pandemic. Seidel is very proud that WACKER will be producing mRNA vaccines for the Federal Government if needed: “We are very happy that we have invested in this technology over the years – and are now playing in the front row.”

If needed, Wacker Biotech and CordenPharma can supply Germany with 80 million vaccine doses per year. The plan is to use the remaining production capacity in Halle to contract manufacture mRNA therapeutics. The first products will emerge from the Halle plant from mid-2024. Wacker Biotech is already putting out feelers for customers who could in the future produce in Halle. Seidel’s dream? To be present when the new technology will also be able to heal cancers in the future. “It is so exciting to imagine that we will one day be able to contribute towards improving the fight against tumors in a truly wide range of cancer indications, and to heal patients in a highly specific manner.”



Wacker Biotech manufactures active pharmaceutical ingredients under contract to pharmaceutical and biotech companies for the market and for clinical studies (photo: WACKER).



As a contract manufacturer, Wacker Biotech US Inc. in San Diego operates a specialized fermentation line for manufacturing and purifying plasmid DNA (photo: WACKER).





Guido Seidel is the managing director of Wacker Biotech and responsible for the biopharmaceutical sector at WACKER (photo: WACKER).



From development to dispensing: at WACKER's Amsterdam biotech site, active ingredients can be dispensed into their final packaging for shipment to the customer. The vials then undergo one last quality control step (photo: WACKER).



Bacteria at Wacker Biotech in Halle produce pharmaceutical proteins in stainless steel tanks known as fermenters. The site is being expanded into an mRNA technical competence center, scheduled to start up in 2024 and featuring a new technology (photo: WACKER).

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**The Company in Brief:**

WACKER is a global chemical company with some 14,400 employees and annual sales of around €6.21 billion (2021).

WACKER has a global network of 26 production sites, 23 technical competence centers and 52 sales offices.

**WACKER SILICONES**

Silicone fluids, emulsions, rubber grades and resins; silanes; pyrogenic silicas; thermoplastic silicone elastomers

**WACKER POLYMERS**

Polyvinyl acetates and vinyl acetate copolymers and terpolymers in the form of dispersible polymer powders, dispersions, solid resins and solutions

**WACKER BIOSOLUTIONS**

Biotech products such as cyclodextrins, cysteine and biologics, as well as fine chemicals and PVAc solid resins

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