

# PRESS DOSSIER 2021

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Algenex is a Spanish biotechnology company founded in 2005. The Company specialises in the production of proteins using insect chrysalis to manufacture vaccines, therapeutic molecules, and diagnostic reagents.

Producing proteins for the manufacturing of vaccines and biotechnology products in general through insects is a faster, cheaper, and simpler alternative than conventional production in traditional bioreactors, which require greater investment.

Algenex is to date the most advanced company in terms of production of biologicals using living bioreactors. Its CrisBio technology, which uses insect chrysalis as biofactories in combination with baculovirus vectors, is patented and semi-industrialized, allowing the production of vaccines antigens, therapeutic molecules, diagnostic reagents and other biotechnology products in a fast, scalable and cost-efficient way.

### Protein production process

Proteins are at the core of innovation in new therapeutic products and vaccines. Proteins are complex molecules formed by amino acid sequences that cannot be chemically synthesised, thus requiring living cells that grow in bioreactor complexes to be obtained. The sequence, conformation and modifications that give functionality to proteins must be carried out by the biosynthetic machinery in cells and cannot be developed chemically.

The synthesised genes, from the sequences of the different pathogen or organism genomes, are incorporated into the DNA to generate baculovirus vectors responsible for programming the cells of the chrysalis used as biofactories by means of molecular biology techniques.

When the baculovirus vector infects the insects' cells, the desired product is generated inside the insect. It is then extracted, purified and formulated appropriately to obtain the end product (vaccine, therapeutic molecule, diagnostic reagent or other biotech product).

Proteins are commonly used to produce:

- Vaccines
- Therapeutic molecules (antibodies, replacement proteins)
- Diagnostic reagents
- Hormones
- Enzymes

Algenex combines in its technological platform baculovirus vectors widely used in the industry to produce insect cell cultures and insect pupae, the natural host of these viruses. Thus, the baculoviruses, manipulated in the laboratory and completely harmless to humans and animals, properly program the cells that make up the pupae to produce the necessary proteins in large quantities.



#### CrisBio® platform

Algenex has developed a disruptive alternative technology that harnesses nature to create protein manufacturing tools in a simple, scalable, and cost-effective manner: The CrisBio® platform.

CrisBio® is a technological platform that combines the baculovirus vectors widely used in the industry to produce natural bioreactors in Trichoplusia lepidopterous ni (the cabbage looper), in insect cell cultures and insect chrysalids, which are the natural hosts of these viruses. This platform enables simplified conventional processes, near-unlimited linear scalability, and a significant reduction in investment and operating costs.

Insects are bred in a modular, semi-automatic system patented by Algenex, and grow in incubation chambers under specific conditions. The entire life cycle of the insect is approximately three weeks, moving from the larval stage to the chrysalis in just two weeks. CrisBio® is a semi-automatic process that allows scalability by minimising manual work. Silk is automatically separated from the chrysalids and collected and deposited by a robot in disposable labelled trays (using RFID) and automatically inoculated the baculovirus vector by another robot. The process is capable of achieving unprecedented productivity for a baculovirus vector-based technology.

Depending on the antigen and the established immunisation dose, an infected chrysalis can produce between 10 and 80 vaccine doses. This will depend on the productivity of each molecule and the dose used in the vaccine. It may also produce enough antigen to diagnose thousands of patient sera. In short, Algenex has developed the biology and engineering of a unique process that goes from the mass breeding of these insects to their robotic infection with a vector, which has also been improved by the company. This vector is responsible for properly programming insect cells that are in optimal physiological production conditions. As mentioned above, the process is extremely simple and robust, while at the same time rapid in the development of new, scalable and economical molecules, with application to any biotechnology product, including next-generation vaccines.

## An ally for pharmaceutical companies

Algenex makes its technology available to third parties through development agreements and licenses to pharmaceutical companies that want to develop biotechnological products without the need for major investments.

Originally, the developments carried out by Algenex have been linked to the veterinary field, with a particular experience in the vaccine area. The first vaccine was licensed in 2015 to the Italian company Fatro and is in the process of registration by the European Medicines Agency (EMA). This has been followed by licenses to other companies in the animal health sector that are at different stages of development.

In the field of human medicine, Algenex works with different companies, researching influenza antigens, SARS-CoV-2, and human papillomavirus to develop effective and affordable vaccines in developing countries or in the event of a pandemic.



#### **About Algenex**

Algenex is a Spanish biotechnology company that currently employs 20 professionals, many of which are doctors in different fields of biomedicine. There are 6 men and 14 women in their staff.

In September 2020, the company completed a round of private funding worth € 7.4 million, which has involved the entry of Columbus Life Science Fund II as a shareholder. This fund is specialised in investing in innovative early-stage and high-growth opportunities in the Spanish biotechnology sector. Currently, 50% of the company is owned by a private fund in Luxembourg, 19% by Columbus, and 31% by other investors, founders and the companies' leadership team.

Its new headquarters in Tres Cantos were inaugurated in September 2020. The facility has an initial capacity for the production of up to 1.7kg of recombinant protein, enough to formulate around 50 million vaccine doses per year.

Algenex has extensive experience in the development of veterinary products and has been selected as one of the 20 companies with the greatest impact on animal health by the organisations IHS and Stonehaven Consulting in their March report "Disruptors and Innovators 2020 report".

Its first animal vaccine is currently being validated by the European Medicines Agency (EMA). It also has other vaccines in development against viral diseases for several species at different stages. The Company expanded its reach into human pharma in 2019 and is conducting animal studies in two indications (COVID and pandemic influenza), with data expected in 2Q 2021.

## **COVID-19** applications

Until now, Algenex had used its technology to manufacture animal vaccines. However, as early as 2019, they undertook a proof of concept on the influenza vaccine, using an avian strain that had the potential of becoming a pandemic. The company thus proved its ability to manufacture a vaccine candidate in just 4 months and showed the functionality and full safety of this vaccine in animal models. From this experience, Algenex is now evaluating the possibilities for using CrisBio® in pandemic-fighting developments such as SARS-CoV-2.

Algenex' production system is applicable to 40% of vaccine candidates currently in clinical development. This system has two key advantages: Linear and near-unlimited scalability, which would enable the market to be supplied quickly; and the low cost of production, which would allow the development of a vaccine that could be implemented in vaccination campaigns around the world, including developing countries.



#### Más información:

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