Plattform Life Sciences
Technologie – Finanzierung – Investment

DEFENCE THERAPEUTICS

Stock Portrait

Sector

Biotechnology / Immuno-Oncology

1,97 EUR
(Tradegate)

Market Capitalization: EUR 96,2 mln

10th September 2023

Defence Therapeutics Inc.

Industry: Biotechnology
Area: Immuno-Oncology/Vaccination
ISIN: CA24463V1013
WKN: A3CN14
Symbol: DTC
Listed: Toronto, Tradegate, Frankfurt
Segment: Regulated Unofficial Market
Number of shares: 48.844 mln
Member of the Executive Board: Sebastien Plouffé (CEO)
Director: Dr. Moutih Rafei (CSO)
Stock exchange listing: CSE since 05/21

Current price: 1.97 EUR
Market capitalization: 96,2 Mi o. EUR

High/Low (12 months): 3,40 / 1,01 EUR

Corporate

Defence Therapeutics is a Canadian biotech company specialized in the development of vaccines and the improved delivery of drugs into diseased cells. The company relies on a **platformtechnology** that will serve as the basis for various solutions. With its patented **Accum technology™,** Defence Therapeutics offers a platform for so-called antibody-drug conjugates (ADCs).

Shareholder structure

(Booth 14. August 2023; Source: DTC)
Company founders, HNWIs and **management:** 82%, **free float:** approx. 18% off

Relevant company appointments

Festival of Biologics in Basel, CH
10 - 12 October 2023

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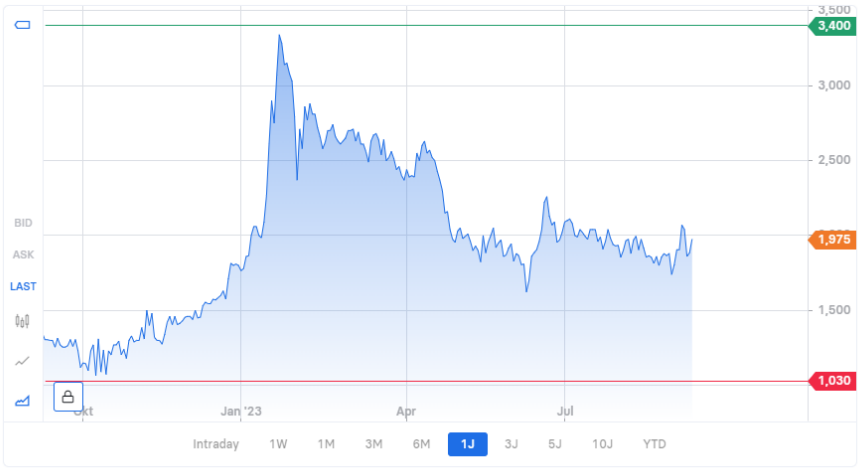
Profile

Defence Therapeutics (DTC) is a Canadian biotech company specialized in the development of vaccines and improved delivery of drugs (cancer therapeutics and antibody-drug conjugates – AKA ADCs) into diseased cells. The company relies on a platform technology that will serve as the basis for various solutions. With its patented **Accum technology™**, Defence Therapeutics offers a platform for ADCs. In this process, a specific active ingredient is combined with an antibody by means of a linker and thus reaches exactly where it is supposed to act.

DEFENCE THERAPEUTICS INC. (German Exchange; Tradegate 08.09.2023)



(Source: www.Stock3.com of 08.09.23)

Defence Therapeutics has data showing that Accum™ can significantly increase the effectiveness of certain therapies in combination with immune-checkpoint inhibitors. Immune-checkpoint inhibitors are specifically used in oncology to block inhibitory receptors involved in halting inflammation. On the one hand, Defence Therapeutics specializes in **the effective transport of active substances into diseased cells using ADCs** and acquired the Accum platform™ for this purpose in 2017. Furthermore, Defence Therapeutics is active in the field of immuno-oncology and has set itself the goal of developing vaccines against cancer.

		DISCOVERY	PRE-CLINICAL		PHASE 1-2023
PRODUCT	**INDICATION**	**RESEARCH & DEVELOPMENT**	**NON-GLP**	**GLP**	**Q2**
Cell Vaccine					
ARM	Solid Tumors				
Protein Vaccine					
AccuVAC-PT007	Cervical Cancer				
AccuTOX					
AccuTOX-001	Melanoma, Breast				
AccuTOX-IN001	Lung Cancer				
ADCs					
AccuADC-001	Breast				
mRNA Vaccine					
AccuVAC-mRNA001	Undisclosed				

(The pipeline of Defence Therapeutics; Source: Company Presentation Q1-2023)

The global immuno-oncology market

In the field of immuno-oncology, the aim is to activate the immune system to fight cancer. The body's immune system plays the greatest role in the defense against diseased cells. Particularly in recent times, there has been significant progress in research in this therapeutic direction. Today, our understanding of the interaction between cancer cells and the immune system has been sufficiently researched to take advantage of the effects. According to current knowledge, the human immune system works in two ways: non-specific against all pathogens or specifically with the help of adaptive immunity . **In the latter branch, immune-checkpoint blockers come in handy as they help in activating the immune system to mount potent and specific antitumoral responses.**

Analysts at Research and Markets estimate the market potential in the field of immuno-oncology at a total volume of USD 48.9 billion by 2027. In 2020, the market was only USD 17.3 billion. So, the annual growth rate until 2027 is equivalent to 16% (CAGR).

(Source: www.researchandmarkets.com)

ADCs on the rise

Experts at Emergen Research also predict that the **market for ADCs will reach a total volume of more than USD 20 billion by 2028**. The analysts have identified intensive research, and the growing importance of antibody therapies as well as the increasing use of complex active ingredients as growth drivers. All of this is necessary because the population in industrialized countries is getting older, and with it the need for therapies is increasing. Many large pharmaceutical companies have also discovered a promising market for ADCs. In September 2020, the Merck Group invested more than USD 150 million in the manufacturing capacity at the Madison (USA) site to enable large-scale production of ADCs. **ADCs have gained a lot of attention over the past decade and recent regulatory approvals demonstrate their potential use as targeted therapies.** The segment is promising and thrives on the high level of research activity in the oncology sector.

(Source: https://www.emergenresearch.com/industry-report/antibody-drug-conjugates-market)

The drug enhancer platform Accum™ in mRNA vaccinations

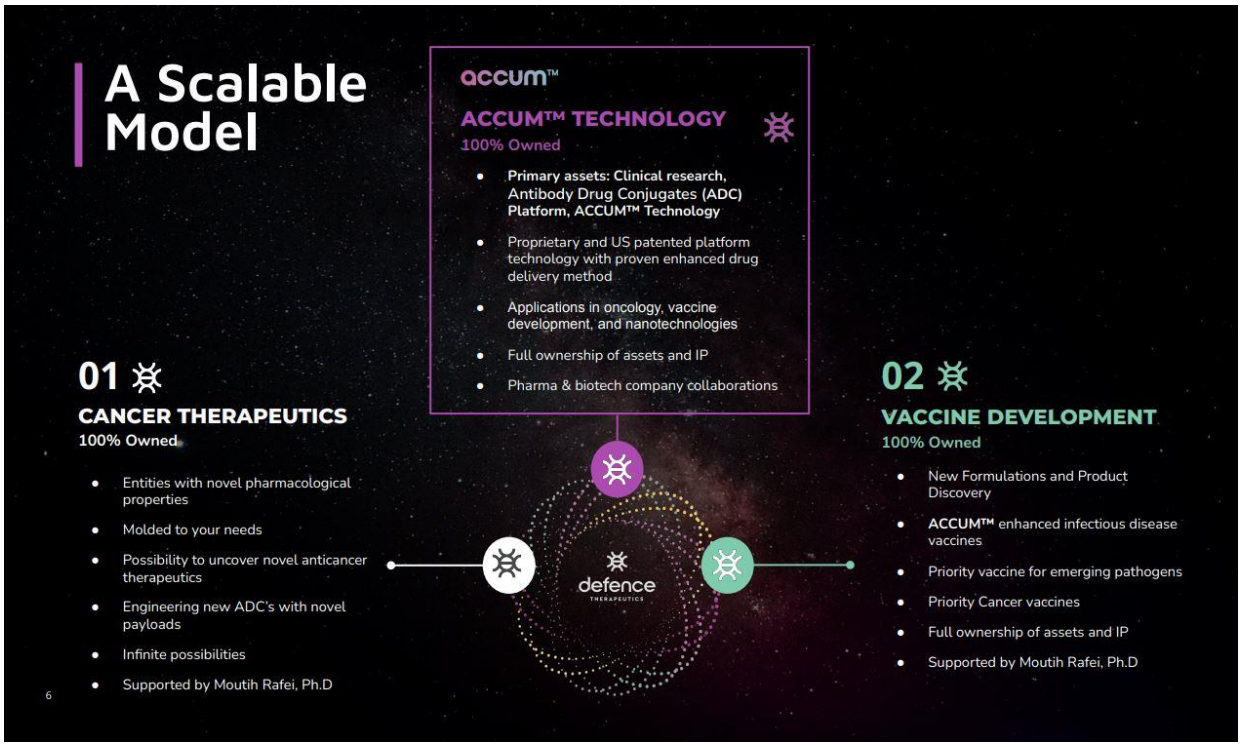
In recent years, Defence Therapeutics gradually came closer to finding solutions to fight cancer. The patented active ingredient enhancer Accum™ is suitable for delivering effective drugs and vaccines precisely into malignant cells. In this way, extremely effective active ingredients can be used without the risk of side effects being too great. After the detailed preparatory work of the past few months, the first mRNA vaccines against cancer are in reach, which can be combined with the active ingredient enhancer Accum™.

mRNA technology has also become known to the general public in the wake of the successful vaccines against Covid-19 from BioNTech and Moderna. One of the advantages of using this method, which has been researched for many years, is its flexibility. As a result, mRNA vaccines can be produced and adapted relatively quickly. Defence Therapeutics is investigating the efficacy of its drug enhancer in mice by administering vaccinations with or without the Accum™ additive. The experience gained from these experiments can usually be transferred to humans. Of course, the process in humans is regulated by several stages of approval.

In contrast to conventional vaccines such as proteins, mRNA vaccine manufacturing do not involve great expenses because they can be quickly synthesized. **To put it simply, mRNA vaccines carry the genetic blueprint encoding a protein derived from a given pathogen, which when delivered and expressed in a host, enables the body to produce protective antibodies.**

Therapeutic mRNA vaccines against cancer, such as those envisaged by Defence Therapeutics, represent therefore an obvious and strategic option to pursue. According to some experts, vaccinations against cancer in particular are considered promising. According to Defence Therapeutics, the tests using the Accum TM platform are carried out in two stages: In the first stage, mice are given an mRNA vaccination containing the blueprint for a foreign antigen, once with and once without Accum™. Over a period of six weeks, blood is then taken from the mice every two weeks and the concentration of antibodies is measured.

According to the hypothesis of Defence Therapeutics, mice that received a combination of mRNA and Accum™ should have a higher concentration of antibody titers because the mRNA blueprint should be better implemented due to Accum™ activity. **In a second study, the company is focusing on antineoplastic efficacy.** This refers to relieving symptoms and prolonging lifespan, especially in the treatment of cancer. For this purpose, solid T-cell lymphomas are transplanted into mice, on the surface of which an experimental antigen is located. Subsequently, the animals receive a so-called prime boost injection of the Accum mRNA vaccine™ and tumor growth is followed thereafter..



(Source: Company presentation Defence Therapeutics; March 2023)

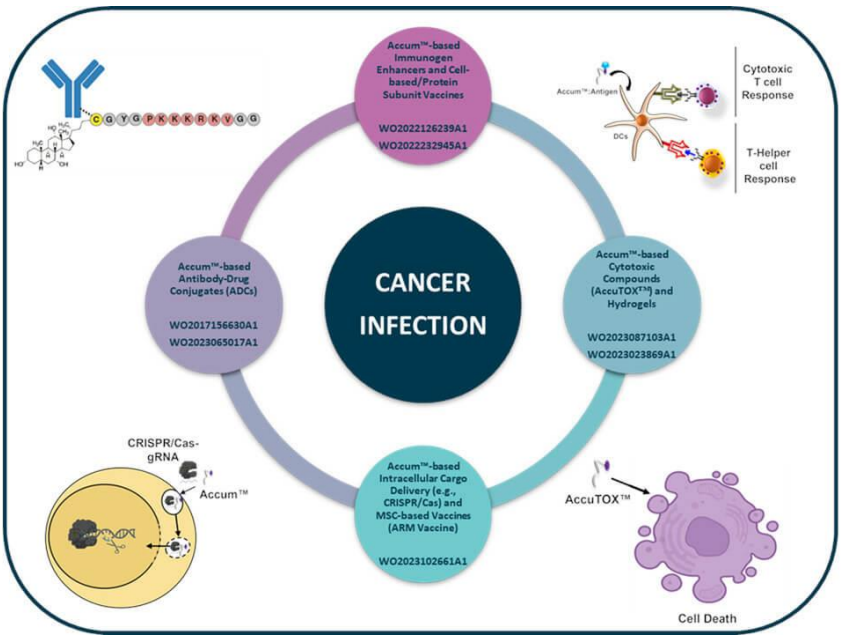
When pharmacologists are asked about the communicated study design, their response was that the company's plans sound plausible If the vaccination works in phase 2 of the study (ongoing studies), the immune cells will produce therapeutic antibodies against the chosen antigen. These antibodies dock onto the protein on tumor cells and mark it so that other immune killer cells are attracted to destroy the tumor.

Is Accum™ technology the missing link?

According to Defence Therapeutics, there are two programs run in parallel. **In an overview of all Defence Therapeutics projects published at the end of February,** the **mRNA program is still in the development stage. The ARM vaccine and AccuTOX™ program are much further along.** The former is a cell vaccine against established tumors, whereas the latter is a chemotherapeutic agent to be intratumorally administered in skin, breast or lung tumors. Both projects are moving to phase 1 studies before the end of 2024. Defence Therapeutics has already identified the "City of Hope" hospital in the greater Los Angeles area as a site for testing AccuTOX™ , through which all applications to the US Food and Drug Administration (FDA) can now be submitted.

If you look at the product pipelines of Moderna and BioNTech, you will find numerous projects related to cancer, but also infectious diseases such as RSV, CMV, EBV or HIV. The study design of these companies already underlines the current scientific consensus that it is often the combination of different approaches and the use of assistive technology that ultimately leads to success. In addition to mRNA technology, BioNTech, for example, is also focusing on cell therapies and antibodies. For example, BioNTech's product candidate BNT411, a so-called small-molecule immunomodulator, addresses intracellular tumor targets to stimulate a wide range of immune cells. **The ultimate goal is to improve existing treatments for cancer therapies.**

A look at the activities of renowned biotech companies shows that Defence Therapeutics has taken an approach with its Accum technology™ that is also followed by the "big names in the sector": Any measure that improves the effectiveness of biological agents is welcome in **the industry.** In connection with the ARM cell vaccine against solid tumors, the company is already on the verge of a clinical trial in humans. The protein vaccine against cervical cancer caused by HPV, which is combined with Accum™, is also already advanced. **Defence Therapeutics' mRNA project could also cause surprises before the end of 2023.**



(Source: Company presentation Defence Therapeutics; Q2 2023)

"Although it is a promising technology, mRNA vaccines have not yet reached their full potential. By conjugating mRNA with Accum™, we expect to improve the immunogenicity of the vaccine, resulting in a strong immune response."

The latest developments in the second quarter

(Image: Dr. Moutih Rafei; CSO, DTC)

In June, Defence Therapeutics successfully expanded its patent portfolio. To this end, the company has applied for global protection of its **Accum technology™** for intracellular administration of various drugs and vaccines, including polynucleotides, recombinant proteins and nucleoprotein complexes according to the PCT standard. It is an international treaty on the protection of intellectual property, which will ultimately results in national patents in all Member States. 157 countries around the world have acceded to the PCT Treaty.

But what exactly do the patents cover? What are polynucleotides or nucleoprotein complexes? In a broad sense, they are chains of amino acids that make up genetic information such as RNA or DNA. Proteins that can bind to RNA or DNA are also included. The patent filed by Defence Therapeutics therefore covers Accum's™ property as an active ingredient enhancer for mRNA vaccines as well as its property as a carrier of procedures such as CRISPR (Clustered Regularly Interspaced Short Palindromic Repeats). CRISPR is a method that is also called "gene scissors". This makes it possible to remove defective genetic information from existing DNA and replace it with new information.

In principle, the process works on all organisms and led to the Nobel Prize in Chemistry in 2020 for the two discoverers Jennifer Doudna and Emmanuelle Charpentier. Despite the progress that the method is making in various projects, the transport of the "gene scissors" into the interior of the cell is still considered a major challenge. Currently, the most widespread way is to use inactivated viruses as transport carriers. Nanoparticles, such as liposomes, can also protect the "gene scissors". However, all processes are considered error-prone and, such as nanoparticles, are not yet mature enough. This is where Accum technology™ comes into play. As is so often the case in biology, the combination of several assistive technologies could ultimately lead to an increase in the effectiveness of biotechnological methods, such as CRISPR.

Specifically, the patents cover the role of Accum™ as a classic ADC. To put it simply, the ADC piggyback on drugs and smuggle them into affected cells. The second area of application includes the property of Accum™ to be extremely toxic in potentized form and to induce premature cell death in affected cells – such as cancer. **In the experiments with mice, Defence Therapeutics has already shown that the extent of lymphoma decreases significantly when this form of Accum™ (AccuTOX™) is administered and the survival rate is increased.** Furthermore, it has been observed that AccuTOX™ forms hydrogels after dissolution and subsequent incubation in various aqueous solvents – Defence Therapeutics also sees room for further innovation in this.

Towards Phase 1 Trial for AccuTOX™

It appears that AccuTOX™ could become Defence Therapeutics' first compound to be transferred to a Phase 1 trial. AccuTOX™ is an anti-cancer agent based on the versatile Accum™ technology. The patent obtained protects Accum™ as a drop-in technology that enhances the immunogenicity and performance of virtually any cell- or protein-based vaccine and covers both prophylactic and therapeutic vaccines against cancer and infectious diseases. **Defence Therapeutics sees the rapid patent grant as a testament to the solid scientific foundation of its technology.** The patent is intended to be the basis for the worldwide protection of the technology. This would also open up the possibility of licensing Accum™ for other uses, either generating cash flows or attracting partners to explore further opportunities around the technology.

In mid-June, the company successfully announces its own production of AccuTOX™. In order to be able to properly submit all applications to the U.S. Food and Drug Administration (FDA), Defence Therapeutics had already secured the services of the City of Hope University Hospital near Los Angeles months ago. With the production of drug-grade AccuTOX™, all requirements for the start of the Phase 1 study will soon be met. Prior to any clinical trial of active ingredients, drug regulators require rigorous manufacturing and quality control testing. In order to meet these requirements, Defence Therapeutics has commissioned Biopeptek Pharmaceuticals, a service provider, to carry out this preparatory work.

"This is an important milestone for Defence's AccuTOX program™. With the successful completion of the manufacturing and release trials, Defence is now on the final step towards applying for the IND application for a Phase I clinical trial of AccuTOX™ as an injectable agent for the treatment of melanoma," said Sébastien Plouffe, CEO and President of Defence.

(Image: Sébastien Plouffe, CEO Defence Therapeutics)

Update on current developments

The collaboration with the French nuclear medicine specialist Orano is also promising. As a first step, Defence has successfully combined an active ingredient from Orano with Accum™ and made it usable. The next steps are about modifications. The joint findings remain the property of both companies. From today's perspective, it is possible to achieve all the stones by mid-2024. It is not yet clear whether Accum™ will ultimately be out-licensed. .

The comparative study on mRNA vaccines in conjunction with Accum™, which was announced a few months ago, is progressing: Results should be available by the end of the year. This holds potential for new vaccines, but also for projects that were already considered to have failed and could become competitive again thanks to Accum™. Many biotech projects appear in a new light with the current state of knowledge. **Collaborations with larger biotech companies are therefore quite conceivable.** The important thing now is that the project with City of Hope Hospital will lead to a rapid implementation of the Phase 1 study. The same applies to the ARM vaccine project against hard-to-cure cancers.

Equity Story: The vision is now NASDAQ

Defence Therapeutics has promising projects and, thanks to its platform approach, is not starting from scratch in the development of new vaccines. For the company, this starting position offers time savings in the development of new vaccines. With the fight against cancer, Defence Therapeutics has committed itself to an important field of research for the benefit of humanity. If experiments with mice succeed (as shown so far), Defence Therapeutics would have a blockbuster vaccine in its portfolio – parallels to BioNTech could then hardly be denied. The versatile Accum technology™ also offers the prospect of a licensing business that could become extremely lucrative thanks to revenue or profit-sharing.

The company's perspective depends primarily on the success of the research. Thanks to the platform approach and the possible licensing business, this potential is very large – provided that Defence Therapeutics' products establish themselves on the market. The Phase 1 studies on the two vaccine candidates against cancer planned for the coming months will mainly revolve around safety aspects in the study design. Safety is one of the biggest risks in the approval process of ADCs. **The outcome of the Phase 1 studies is therefore likely to point the way forward for Defence Therapeutics.**

The company is constantly pushing ahead with the development of its numerous projects. While AccuTOX™ and the ARM vaccine are about to enter phase 1 trials, Defence is testing its active ingredients in an increasing number of diseases. In particular, the testing of the ARM vaccine for cancer variants that are difficult to cure, such as pancreatic cancer, is likely to be closely watched within the biotech community. In view of Accum's™ versatility and the advancing patent protection, it cannot be ruled out that the company, which is currently valued at around EUR 91.3 million, will attract the attention of major players in the biotech and pharmaceutical sectors. Defence Therapeutics shares have bounced back a bit after a furious start to 2023. The current fears of recession and growing interest rate concerns are weighing on the biotech industry in particular. **However, for investors who seek an investment opportunity in cancer treatment, the current market cap of Defence Therapeutics Inc. seems to be an attractive entry level.**

Risk note: The **reported free float** is approx. 18%, which remains very small, i.e. that stronger fluctuations must also be expected in the ongoing price determination. The company has so far been almost exclusively equity-financed, the market capitalization also illustrates the corresponding enterprise value. A peer group comparison with other companies in the industry is not expedient due to the diversity of research approaches.

For a **performance comparison,** the NASDAQ Biotechnology Index (. NBI) ca be used. The development of this broad sector has been minus 3.1% since the beginning of the year (as of 8th of Sept 2023). As a suitable industry overview for listed biotech companies in the DACH region, we refer to the GoingPublic Life Sciences Biotech & Co Basket. **(See also: https://www.goingpublic.de/?s=Biotech+Basket)**

Note on further financing: Defence Therapeutics is not currently making any sales, as it is completely in the research and development phase. The company raises the necessary funds for this through regular capital increases. With liquidity of just under CAD 3 million as of the second quarter of 2023, the projects are well secured until 2024. The company is thinking about significantly broadening its investor base. Cooperation with large biotechs or pharmaceutical companies should also be considered, but not necessarily. A listing on the NASDAQ is being sought in order to make the stock investable for institutional investors.

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All images are taken from the website and presentations of Defence Therapeutics.

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