

IMMUTELL

A novel way to diagnose diseases

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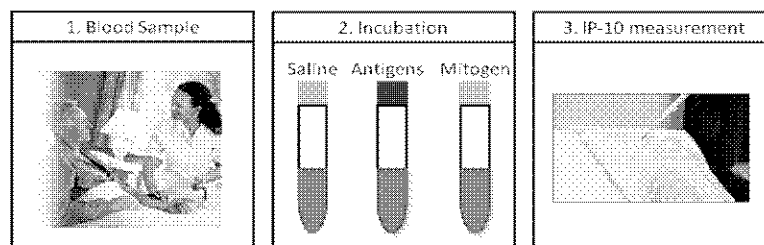
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Executive Summary

IMMUTELL's mission is to develop, produce and market Cell Mediated Immune Response diagnostics to help combat diseases that are difficult to diagnose. A preliminary estimate puts the pre-money value at 3 million USD with exit possibility after 5 years for investors. The purpose of this business plan is to raise 1 million USD in exchange for at 25% equity stake in IMMUTELL.

Product

We have invented a novel method for diagnosing diseases. Our invention is based on the principle of recognition by cells of the immune system. We have utilized this biological principle to develop a method of diagnosing diseases, ranging from infectious diseases to autoimmune diseases and cancer.



Blood is drawn into three tubes: one contains salt water (negative control), one contains antigens, and one contains a cell stimulant (positive control). The blood samples incubate for 18-24 hours during which the antigens stimulate the cells to produce IP-10. Afterwards IP-10 production in samples is measured on an analysis platform (e.g. by using ELISA technique or a dip stick, similar to a pregnancy test). Immutell is currently developing a manufacturing technique that will make it possible to coat the test kit tubes with a minimal use of antigens, in effect enabling an additional competitive advantage.

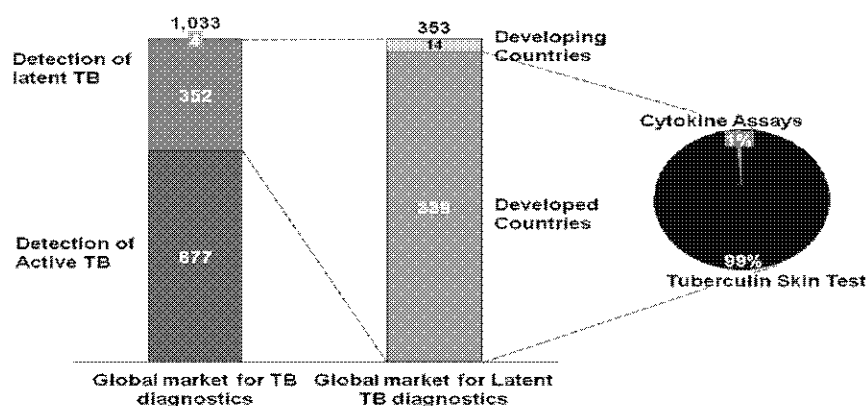
Intellectual Property

Our technology builds on the same biological mechanisms that lie behind the effect of vaccination. For example, if an individual is infected or vaccinated, cells of the immune system will remember the foreign molecules (antigens) and upon repeated exposure, the cells will respond by secreting effector molecules. Using a multiplex approach, we have screened a large panel of immunological effector molecules and identified two molecules (IP-10 and MCP-2) that are secreted antigen-specifically and in high amounts. The essence of our invention is that IP-10 and MCP2 are absent if there is no recognition, and present in high amounts if there is recognition. This generates a strong almost binary response. We have demonstrated the principle using TB and Chlamydia infection, and by stimulation with disease-specific antigens it is theoretically possible to diagnose all conditions with an inflammatory component i.e. infections, autoimmune conditions (e.g. arthritis, diabetes) and cancer. The invention is protected by a patent with claims:

An immunological method comprising the steps of (A) incubating a sample obtained from a mammal with a test-antigen, (B) determining the IP-10 level in said sample, and (C) comparing the determined IP-10 level with a reference-level, thereby determining whether said mammal has previously encountered the test-antigen by generating an immunological reactivity to the test-antigen. This IPR is now owned by Hvidovre Hospital but the ownership of the patent will be transferred to IMMUTELL by giving Hvidovre Hospital an equity stake.

Market Opportunity & Customers

The greatest market potential for the IP-10 test lies in the developed countries where focus is on diagnosis and treatment of latent tuberculosis infection in order to prevent active TB disease. As seen in the following figure the current dollar market value of the TB diagnostic market in developed countries is ca. 340 million USD per year of which the majority consists of the use of the ca. 100 year old technology, the Tuberculin Skin Test.

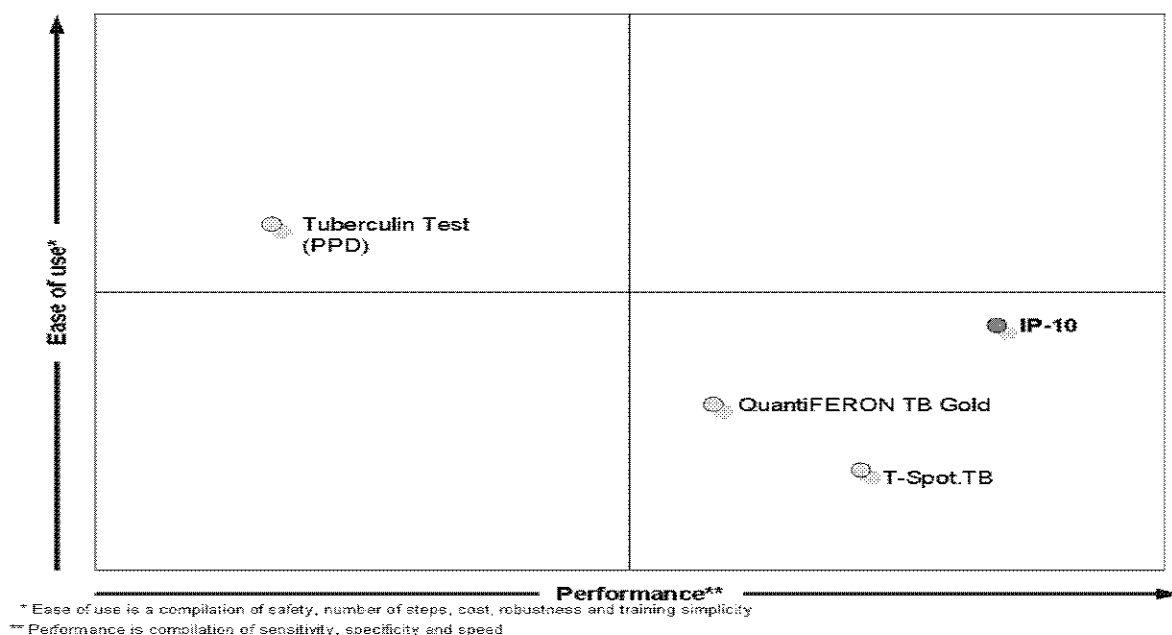


Breakdown of Global TB diagnostic market (numbers in USD Million) (Diagnostics for Tuberculosis: Global demand and market potential, WHO report 2006)

It is estimated that the total number of tuberculin skin tests carried out annually in Europe is 7 million. Initially the European markets will be pursued as part of IMMUTELL's growth strategy, where health care providers (public and private hospitals and clinics) and immigration authorities are considered to be potential high volume users.

Why is the IP-10 test unique?

The IP-10 test is faster, more sensitive and is less labour intensive than the currently available cytokine assay solutions (QuantiFERON TB GOLD and T-Spot.TB). Furthermore, the IP-10 test has high sensitivity, high specificity and is not compromised by immunosuppression and active TB, in addition it works well in children. The primary alternative, the Tuberculin Skin Test, though inexpensive, has serious technical and logistic problems: it requires patient follow-up within 72 hours, it relies on subjective measurement and interpretation of test result, and it has a very low specificity in people that are vaccinated and/or exposed to other mycobacteria than the tuberculosis strains that cause human disease.



Team

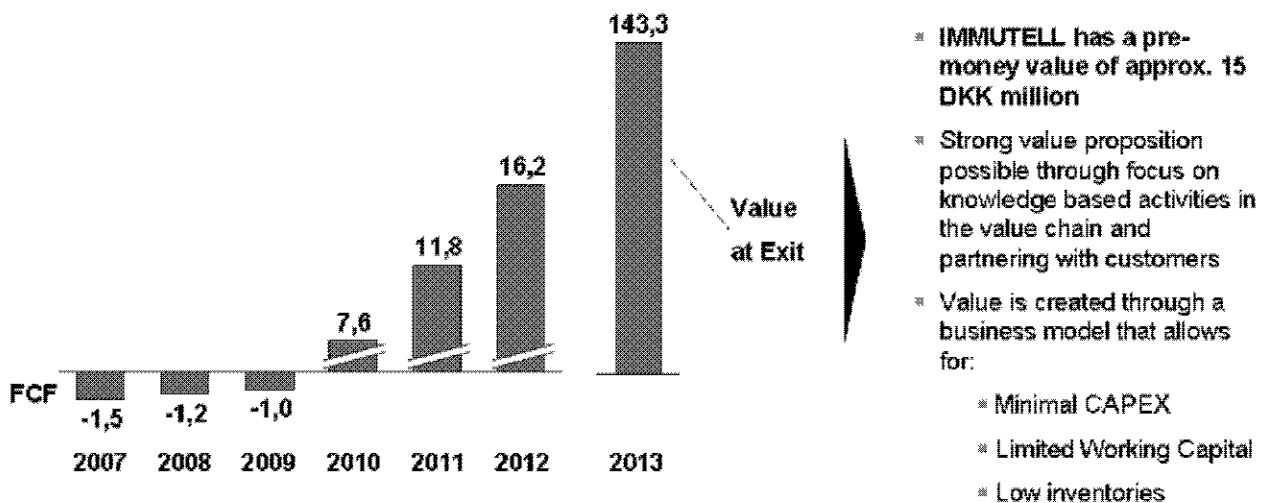
The team has a broad set of skills and experiences covering initial start-up phase needs.

	Education	Experience	Contribution
John Agerholm	<ul style="list-style-type: none"> ▪ MSc International Business student, ASB,AU ▪ BSc Business Administration & German, ASB,AU 	<ul style="list-style-type: none"> ▪ Intern, Siemens ▪ Intern, Bavarian Chamber of Commerce, Munich 	<ul style="list-style-type: none"> ▪ Strong entrepreneurial skills ▪ International expansion & business systems understanding
Martin Klint Hansen	<ul style="list-style-type: none"> ▪ MSc Finance student, ASB,AU ▪ BSc Business Administration & Economics, ASB,AU 	<ul style="list-style-type: none"> ▪ Intern, McKinsey & Co. ▪ Analyst assistant, Quantitative Research, Jyske Bank 	<ul style="list-style-type: none"> ▪ Strategic and financial understanding ▪ Analytical skills
Jesper Eugen Olsen	<ul style="list-style-type: none"> ▪ PhD in HIV prognostics, University of Copenhagen ▪ MSc in Biochemistry, University of Copenhagen 	<ul style="list-style-type: none"> ▪ CSO, Virogates ▪ Laboratory Research Director at Clinical Research Centre at Hvidovre Hospital 	<ul style="list-style-type: none"> ▪ Business development & IP law skills and experience ▪ Technological and product development expertise
Pernille Ravn	<ul style="list-style-type: none"> ▪ Phd, Copenhagen University Hospital ▪ Doctor of Medicine (MD), University of Copenhagen 	<ul style="list-style-type: none"> ▪ 13 years experience within TB immunology and clinical TB diagnosis ▪ 11 articles within the area 	<ul style="list-style-type: none"> ▪ Clinical and technological expertise ▪ Significant network of TB specialists and researchers
Morten Ruhwald	<ul style="list-style-type: none"> ▪ Phd student at Copenhagen University Hospital ▪ Doctor of Medicine (MD), University of Copenhagen 	<ul style="list-style-type: none"> ▪ 10 years of research within immunology ▪ Phd thesis on the prognostic and diagnostic value of different biomarkers 	<ul style="list-style-type: none"> ▪ Clinical and technological expertise ▪ Experience with IP law

Additional industry and functional expertise will be recruited as soon as funding is available. For the crucial steps in the validation and value transfer protocols of the IP-10 platform IMMUTELL will seek consultancy from Engineer, PhD. Jan Kyhse-Andersen. Rikke Thygesen is in charge of communication and marketing.

Valuation and Investor's Exit Possibilities

A preliminary rough estimate of IMMUTELL's pre-money value is 3 million USD (15 million DKK). This is based on an initial strategy of focusing on developing, manufacturing and marketing the IP-10 TB diagnostic tool to healthcare providers and immigration authorities within Europe.



Note: Discount rate of 70% used; Exit multiple of 2,3 EV/SALES based on data extract from AMADEUS & ZEPHYR;

Distributors have to sign up for a defined number of kits, thereby generating an early income for IMMUTELL