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Sementis – Revolutionising the Vaccine Industry

Groundbreaking Sementis SCV technology is poised to revolutionise the vaccine industry and make a significant contribution to the quality of life of people worldwide.

A working vaccine for Peanut Allergy is just one of the many applications made possible by Sementis' revolutionary platform technology.

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Executive Summary

Revolutionising the vaccine industry

Sementis has proprietary platform and manufacturing technology, which together have the potential to revolutionise the vaccine industry and make a significant medical contribution to the world.

A platform (or 'vector') is simply a virus that acts as a carrying vehicle for antigens (i.e. proteins) from various diseases. Genes for antigens from a disease are inserted into the platform with a view to transforming the platform into a vaccine for whatever has been inserted into it.

The body's immune system reacts to the transformed platform and produces immunity to the disease whose antigens are now being presented by the platform, as well as immunity to the platform itself.

Sementis' platform is called Sementis Copenhagen Vector (SCV), which is the old smallpox vaccine called vaccinia which originated from the cowpox virus.

Sementis has genetically altered the vaccinia virus to make it completely safe and more immunogenic. Genes for antigens from other diseases are inserted into the Sementis SCV platform, creating a vaccine for that disease.

Rabies was eliminated in Europe using exactly this approach with the 'native' vaccinia virus. Sementis has simply made the vaccinia virus completely safe and more effective through genetic manipulation.

Sementis has proven the effectiveness and total safety of the SCV platform in animals. The results have now been published in a peer review journal.

Executive Summary Continued

Sementis SCV platform can be used for any number of diseases and conditions. People with conditions that hitherto had no effective vaccine or other solution will now have hope. There is also the potential to substantially improve current vaccines in terms of their effectiveness and availability.

Game changing manufacturing technology

Sementis' game changing manufacturing technology, combined with the SCV proprietary platform technology, will mean that cost effective solutions will now exist where previous economics may have been too challenging. Potentially, tens of millions of vaccines could be manufactured in weeks.

This can be applied as a global solution and highly effective rapid response to Pandemics and Bio-Terror.

Sementis intends to work with CSIRO to bring this game changing manufacturing technology to fruition.

A vaccine for Peanut Allergy

Initially, Sementis focused on allergies and developed a vaccine for Peanut Allergy. This is a unique strategy in an array of possible treatments being explored by companies worldwide. However, Sementis' solution is expected to be far superior as it results in a *cure*, not just toleration to peanut allergens. Extensive proof of concept results in human blood and animals, to date, are extremely encouraging and strongly suggest the vaccine will work. Proof of concepts studies are expected to be completed in the next few months and human trials are expected to begin late 2018. Sementis' other allergy vaccine products in development include the treatment and cure of cat allergies.

It has been estimated that the potential revenue for a solution to food allergies in the U.S. alone is around $US20 billion per year. Peanut Allergy would contribute to 30% of that revenue. The stakes are high and Sementis believes it is in the best position to provide the solution.

Executive Summary Continued

A dual vaccine for mosquito borne diseases

Sementis has also focused on mosquito borne diseases, namely a dual Zika and Chikungunya vaccine. Successful proof of concept experiments are complete and trials are expected in late 2018. This should give Sementis a foothold in the infectious disease space, which is a major part of the vaccine market.

This dual vaccine is a world first where the concept of two (or potentially more) vaccines in the platform will only require one manufacturing process, as opposed to a multiple manufacturing process for conventional combination vaccines.

Sementis is finalising the proof of the game changing manufacturing technology where a live vaccine can be manufactured from the biotechnology gold standard cell substrate. This will be a first in the vaccine industry. This means that Sementis will be able to manufacture millions of doses at literally a fraction of the cost of conventional methods and importantly, in a matter of a few weeks (not many months as is currently the case). This technology is expected to coincide with the progression to human trials in late 2018 for both the Peanut Allergy and the combined Zika/Chickungunya vaccines.

Sementis is also exploring the use of our technology for other potential vaccines, including cancers and a dual Hepatitis A and B, amongst others. Potential collaborations and partnerships are possible going forward.

The Vaccine Industry

Vaccines have historically been a small part of the Pharmaceutical Industry. However, this has changed in the last decade with growth in the vaccine market outstripping the rest of the industry.

The global vaccine market is expected to reach $US 48 billion by 2021 from $US 32 billion in 2016 – a CAGR of 8.3 % ***(a)***. Other studies expect double digit growth ***(b)***. These numbers would be a substantial underestimate should Sementis successfully launch a vaccine for Peanut Allergy.

There is general agreement that the growth in the vaccine market is driven by:

- High prevalence of disease
- Rising government funding for vaccine development
- Increasing investment by companies developing new vaccines
- Increasing focus on immunization programs

Advances in technology are dramatically expanding the *possibilities of vaccine treatments* (e.g. cancer).

Advances in manufacturing technology are expected to *change the economics of vaccinations*.

(a) Vaccines by Technology, Disease Indicator, End User and Type – Forecasts to 2021. Markets and Markets, August 2016
(b) Global Human Vaccine Market 2016-2020. Research and Markets, January 2016

Panic and neglect to investing in health security: financing pandemic preparedness at a national level (2017). International working group on financing preparedness. Supported by the World Bank and Welcome Trust

Vaccine Industry - Historical Background

In the late 1700s, it was observed that milk maids were immune from smallpox. It was eventually discovered that they had cowpox, and this is what was giving them smallpox immunity.

Hence the vaccine industry was born, with the word 'vaccine' Latin for "from Cows".

The cowpox virus used as a vaccine, called 'vaccinia', has been successfully used as a smallpox vaccine for over two hundred years. Being a replicating virus it can have some serious side effects in a tiny fraction of individuals (death in very rare cases). However, with smallpox killing one in three it was then worth the risk.

In the 1990s, genes for rabies antigens were inserted into the vaccinia virus (Copenhagen Version) and inserted into meat and fed to animals in Northern Europe. The theory was that the new virus should give the animals immunity from not only smallpox but also rabies.

It *worked* - as follow up studies over the past twenty years have proven.

The obvious question was why not use this *proven technology* as a platform for all sorts of diseases and why not in humans? The only problem to be solved was the safety issue, where the original vaccinia virus can have adverse effects (sometime severe) on a tiny fraction of recipients.

Enter Sementis

Sementis Revolutionary Platform Technology

The Sementis platform is called Sementis Copenhagen Vector (SCV), which is a delivery mechanism for antigens (proteins) from diseases to initiate an immune response to both the SCV (or 'virus') and the disease in question.

The SCV is essentially the old smallpox vaccine, which was used to eradiate rabies in Northern Europe as a vectored vaccine and smallpox worldwide. However, it it has been genetically altered to be:

- **Perfectly safe** - it doesn't multiply to give side effects that were seen during the smallpox vaccination campaigns of 1950s, 60s & 70s.
- **More immunogenic** – it makes it more visible to the immune system, thereby making it more active, which increases the effectiveness of the vaccine.

Genes for antigens from other conditions/diseases are inserted into the SCV platform thus making a vaccine against both smallpox and that conditions/disease.

In principle there are literally dozens of conditions/diseases that the platform could accommodate to create a vaccine for these conditions/diseases.

Does the SCV platform work and is it safe?

The SCV platform has already been proven to work. There is extensive proof of its effectiveness, dating back to the rabies eradication. In addition, every one of Sementis' proof of concept studies confirms the effectiveness of this approach in animals.

Sementis has also proven the complete safety of the SCV platform, *as it doesn't multiply upon vaccination*.

A peer reviewed publication describes in detail the results of SCV's proof of concept trials, as a true non replicating platform.

Sementis proof of concept trials have also confirmed the powerful immunogenic properties of the SCV platform, which only requires *a single shot vaccination strategy*, where most vaccines require priming and boosting strategies. This is extremely important as many vaccines have questionable consistency and efficacy.

Trials in humans are the next step but as the vaccinia virus has been used in humans as a smallpox vaccine for over 200 years, its effectiveness and properties are well understood.

With SCV, we will have eliminated the side affects that were seen with the original smallpox vaccine. Hence there are high expectations that human trials will simply confirm this previous success.

Why SCV is superior to other platforms

Many other platforms have been altered substantially to make them non replicating/non harmful. After all, these platforms are viruses and shouldn't be replicating in the body.

However, this attenuation process can make them less effective as a platform as lack of multiplication/replication often equates to poorer immune responses.

Sementis SCV, on the other hand, has been genetically altered to make it unable to multiply but also be *more immunogenic.*

In addition, unlike other platforms, SCV can carry a big payload. Many genes for different antigens can be added. This means SCV can handle more complex antigen combinations and also cover two (and possibly more) disease targets in the one SCV vaccine. This is different to the classical combination vaccines, which consist of multiple different vaccines that first need to be manufactured separately before mixing into the same bottle. SCV bypasses this by only requiring one manufacturing process (a single batch run) to create a vaccine that covers multiple diseases.

There are also significant game changing manufacturing advantages, which are unique to Sementis SCV. Hence, the combination of the SCV platform and its manufacturing technology makes it truly revolutionary and unique. SCV is the only live viral vaccine that can be manufactured in the industrial gold standard biotechnology-friendly cell substrate that enables rapid scale up.

Sementis game changing manufacturing technology

Currently, manufacturing vaccines can be a highly complex process, often using thousands of eggs in the vaccine production process. This is expensive, time consuming, results in batch to batch variation and much can go wrong.

More recently, there have been a number of innovations. The respected Roots Analysis report on global vaccine contract manufacturing has noted the recent technological advances which they concluded to be "far superior" to the traditional egg based methods. They noted that there is a move away from "conventional roller bottles" to more advanced methods of virus production.

Sementis is at the leading edge of every one of the many technological advances noted in the report.

In fact, it has advanced beyond those developments, such that there is a multiple improvement in efficiency of production (at least 10 times over even the more advanced methods). This is achievable through the combination of the SCV platform and our manufacturing technology.

For instance, Sementis will be able to produce tens of millions of vaccine doses in a 500 litre Bio-Reactor in a space of a few weeks by increasing vaccine yields from smaller batch production sizes, thus improving the time to produce and cost of production. To put this into perspective, to produce SCV based vaccines from a 500L bioreactor would require a production room the size of a CEO's office, but the manufacturing of currently registered viral vaccines of the same yield would require a production room the size of a warehouse and take many months. Even the most advanced can't come within a fraction of Sementis's capacity and in the same time frame.

This will change the economies of the vaccine manufacturing industry. In fact, other vaccine producers with vectors are teaming up with the new manufacturing companies because of the multiple efficiency improvements. Sementis is way beyond all that and has it all in the one company.

Sementis does not need to pay out royalties to gain access to the new technology.

Pandemics and Bio-Terror are a clear and present danger. Sementis has the solution

The World Bank report on Pandemic Preparedness has found that "the world's investment in Pandemic Preparedness and response remains woefully inadequate…The result is the world remains scarily vulnerable…It is inevitable the world will see another pandemic in the not too distant future". (**a**)

Bio-Terror is also a real threat. Experts have warned we are in the midst of a bio scientific revolution which makes building and using biological weapons more deadly and increasingly easy.

Sementis SCV technology can make a vaccine to protect for most, if not all, of the pandemic and bio-terror threats and when combined with the manufacturing technology, can potentially make tens of millions of vaccines in weeks.

We believe this may be the world's best and only effective solution.

It is important to note that the SCV platform is a safe and more efficient version of the original *proven* smallpox vaccine.

(a) Panic and neglect to investing in Health Security" Financing Pandemic Preparedness at a National Level(2017). By international working group on financing preparedness. Supported by World Bank and Welcome Trust

Business Strategy

- Products under development
  - Allergies – Peanut and Cat
  - Mosquito Diseases – Zika and Chikungunya
  - Future Products
- The Next Eighteen Months
- Patents

Sementis Strategy: Optimizing the SCV technology

Core Technology

- Totally attenuated live viral vector platform (SCV)
- Novel production method (SCV-CHO cell substrate)

Allergies

- Therapeutic vaccination approach
- Desensitization by switching allergen-specific Th2-allergic response to allergen-specific Th1 benign immune response

Peanut — **Ready for clinical development**

Cat — **In Pre-clinical Proof-of-concept phase**

Cancers

- Therapeutic vaccination approach
- Breaking immunological tolerance to Prostate specific antigens

Prostate — **Antigen design phase**

Mosquito borne diseases

- Prophylactic Protective vaccines
- Induction of protective immunity

Chikungunya — **Ready for clinical development**

Zika — **Ready for clinical development**

Allergies - Size of the market

An academic paper produced by JAMA Pediatrics in the U.S. has estimated that caregivers would be willing to pay an incredible $20.8 billion annually ($3504 per year per child) for food allergy treatment. Peanut was the most common food allergy (28.7%). They concluded “research to develop an effective food allergy treatment and cure is critically needed”. (**a**)

Peanut Allergy is on the increase. It occurs in about 1 in 50 children and 1 in 200 adults. Peanut is the most likely food to cause anaphylaxis and death. It had been estimated that there is one death for every 200 episodes of anaphylaxis. (**b**)

Children who are allergic to peanuts and other nuts are at increased risk of anaphylaxis compared with those who are allergic to other foods such as eggs and milk. One in five children with a food allergy will have a severe reaction requiring emergency medical attention, and this is most often triggered by peanut. (**b**)

The numbers are huge and clearly, having a solution to Peanut Allergy is worth many billions of dollars in revenue. Sementis believes that a working vaccine for Peanut Allergy would likely also pave the way for vaccines for various other food allergies, as the science is identical.

(a) JAMA Pediatr 2013;167(11):1026-1031.doic:10.1001/jamapediatrics.2013.2376
(b) http://www.slhd.nsw.gov.au/rpa/allergy /resources/allergy/peanutallergy.pdf

Peanut Allergy - Theory and results

Peanut and other allergies result from the immune system reacting to the peanut allergens as if it was a parasitic invader. The immune system releases an attack on the invader in the form of chemicals (histamines etc.). This is known as a TH2 response. It is these chemicals that cause the allergic reaction.

Sementis' approach is to re-adjust the immune response so that it is non harmful.

Genes for peanut allergens are inserted into the SCV and because it is a live virus and not a parasite, the immune system undergoes what is termed a peanut-specific non-allergic TH1 response, which is *non harmful*! It is well founded that the immune system responds in a TH1 way to a live virus. Also, it is well established that TH1 response dominates the TH2 response - effectively telling it to "stand down". This is not theory, but proven multiple times in peer reviewed studies and experiments over many years.

Sementis peanut vaccine induced response will *switch off* the harmful peanut-specific allergic TH2 response. Hence, theoretically, the Sementis solution should lead to a cure. This is opposed to 'tolerating,' which is the current treatment for allergies. Even when it works, full blown allergy usually returns within a 5 to 10 year time frame.

Sementis has undertaken proof of concept experiments with its peanut vaccine in peanut allergic human blood (outside the body) and in peanut sensitized mice. As expected, in ALL cases the 'switch' has taken place. Furthermore, immune memory is induced so the solution should be permanent.

We have completed our critical proof of concept experiments and the results are extraordinarily exciting in that the practice is meeting the theory. We are currently completing further confirming proof of concepts experiments before publishing our results in peer reviewed publications which we expect to be in the next few months. We expect to be in human trials in the latter part of 2018.

Peanut Allergy: other competing approaches

With potentially many billions of dollars of revenue on offer, competition for a solution is intense.

Sementis is the only company developing a true vaccine that will result in a *cure for peanut allergy*. The are many companies developing toleration methods for the treatment of peanut allergy and other allergies. However, the Sementis approach is different in that our vaccine will re-educate the immune system NOT to react to peanut proteins as allergens thereby preventing an anaphylactic response upon ingesting a peanut.

The current treatment for peanut allergy and also for all other allergies involve a method of inducing tolerance to small amounts of allergens. These methods involve a long process and sometimes risky by inadvertently setting off an unwanted allergic response. These approaches suffer from some or all of the following problems:

1) they are intense and costly to administer
2) require high maintenance – a missed treatment step can rend the treatment up to that stage useless (e.g., 1 year of treatment maybe lost if the subsequent ongoing treatment is interrupted!)
3) not a long term solution. i.e. the "cure" is only short lived.
4) the treatments have safety concerns, exposure to the small tolerating doses can inadvertently set off an allergic reaction
5) because the process is lengthy (i.e. around 18 months) compliance is low, i.e., occasional treatment interruptions and dropouts
6) In the early stages of the treatment most patients will feel ill, i.e., nauseous and sometime vomiting, hence high rate of drop outs from the treatment course are often observed

Mosquito Borne Diseases

Sementis SCV platform is ideally suited to providing a vaccine for many infectious diseases.

Over the past decade, there has been an increasing prevalence of the emergence of mosquito borne diseases.

This has focused world governments' and world health authorities' attention to seeking a solution.

Zika has been a particular concern, given the impact on unborn babies and the fact it can be sexually transmitted.

Chikungunya, whilst less well known, has also raised serious concerns about its spread to many regions in the world. Chikungunya infection can lead to debilitating arthritic symptoms that can persist beyond 6 months and often require hospitalisation

The Zika and Chikungunya viruses are carried by the same mosquito and hence, tend to appear in the same regions at around the same time where a person can be infected by both viruses from a single mosquito bite.

Mosquito Borne Diseases Continued

Sementis has developed a world first dual Zika/Chikungunya vaccine to prevent both diseases in one vaccination. We aim to enlist an NGO to fund a clinical trial to test our Zika/Chikungunya vaccine.

Extensive proof of concept experiments in animals have shown the effectiveness of the dual vaccine in protecting against both Zika and Chikungunya in one shot. Most importantly, the results show protection for the unborn baby from mothers previously vaccinated with our dual Zika/Chikungunya vaccine.

A peer reviewed published paper with the results is expected shortly.

Also, the vaccine has been shown to protect against a related Australian mosquito borne disease called Ross River Virus

The importance of this division of our business is that it would put us on the map in this space and be the 'go to' company when outbreaks of infectious diseases occur. Sementis would be the only company to have the technology to produce an effective vaccine quickly as well as being **able to manufacture millions of doses in weeks.**

Our next step is to develop our universal manufacturing process for all of our SCV vaccines, produce vaccine batches and then undergo toxicology studies in preparation for trials in late 2018.

Future Developments

Sementis SCV platform technology and manufacturing technology is poised to be utilised for a whole array of diseases and conditions. We will explore the opportunities and may enter into partnerships and/or license agreements regarding the SCV platform.

Over the past few years there has been significant progress in using immunogenicity to treat cancers. The SCV platform is ideally suited to taking these developments to the next step.

Sementis will be exploring the Pandemic/Bio-terror opportunities, as the SCV platform and manufacturing technology is ideally suited as a potential global solution.

Sementis may explore the possibility of numerous disease targets for 'one shot' vaccination strategies. This could potentially change the economics of existing vaccines as well as open up the possibility of numerous multi-disease 'one-shot' vaccines that only require a single production run, as opposed to multiple production runs of different vaccines to formulate into a combination vaccine.

The Next Eighteen Months

Sementis needs to complete the development of the manufacturing process, manufacture clinical batches of the vaccines, and carry out toxicology studies before we can begin human clinical trials. This process can be complicated, bureaucratic and time consuming.

The development of the manufacturing process and cell line development can be done in parallel and once finished will be used to manufacture all SCV-based vaccines, i.e., SCV universal manufacturing process. This development is expected to take around 6 to 9 months.

Sementis is working with NGO's with potential financial support for the development of Master Cell Bank for our SCV-substrate and intends to work with CSIRO to develop and validate a SCV vaccine manufacturing process.

Once completed, toxicology would begin for both Peanut and Zika/Chikungunya vaccine and is expected to be finished mid to late next year, making both ready for use in human clinical trials.

During the next year Sementis will be searching for the best partners to undertake the trials for each product. In the case of SCV-Zika/Chickungunya vaccine, Sementis would be looking for NGO funding to undertake the clinical trial. In the case of the SCV-Peanut vaccine, a financial partner or a sizable capital raising would be needed to fund a human clinical trial. It may be that Sementis decides to list on a stock exchange at this point.

It also anticipated that, over the next six months, more peer reviewed publications will appear detailing our proof of concept work in a number of areas, including the platform, peanut allergy and the mosquito diseases. This should establish the Sementis brand in the market and it is our intention to have discussions within the industry to examine possible collaborations. Different divisions may take different directions.

Sementis will keep an open mind as to all possibilities but it would be expected that a liquidity event would occur within the next eighteen months.

Meanwhile, after the proof of concept is finalised over the next few months, we expect to begin work on a dual Hepatitis A and B vaccine and determine what other diseases/conditions to begin developing vaccine solutions. Sementis will also work on making the manufacturing process even more efficient. We believe that further development of our manufacturing technology could result in another two to three-fold productivity increase over the coming year.

Research/Collaborations/Grants

University South Australia (UniSA)

- Sementis has a long standing relationship with UniSA where it uses the labs and pays for a number of scientists to undertake research and animal trials under the guidance of our Chief Scientific Officer, Paul Howley.

- ARC-Linkage: $362,000 for a 3 year period; Post-Doc salary and consumable costs

- Science and Industry Endowment Fund STEM+ Business Industrial Research Fellowship Award: $300,00 for a 3 year period; Post-Doc salary and consumable costs

QIMR Berghofer Medical Research Institute

- Advance Queensland Research Fellowship Award; $300,00 for a 3 year period Post-Doc salary and consumable costs commencing 2017

R&D tax concession

- FY2016 $951,434
- FY2017 $503,671

Patents

SCV Cell Substrate for manufacturing:

- Viral Vector Manufacturing. Inventor: Paul Howley and Liang Liu. International Application Number: PCT/AU2014/050330 (International publication number: WO 2015/061858)

- *National phase examinations: AU, NZ, CA, CN, EP, IL, JP, MY, KR, RU, ZA, US, IN, HK*
- *Granted: SG*

SCV Peanut Allergy Vaccine:

- Immune Modulation. Inventor: Paul Howley. International Application Number: PCT/AU2014/000286 (International Publication Number: WO 2014/138824A1)

- *National phase examinations: AU, US, EP, RU, ZA, CN, KR, IL, MY, JP, CA, HK*
- *Granted: NZ, SG*

SCV dual Zika/Chikungunya vaccine:

- Viral Vaccines. Inventor: Paul Howley. International Application Number: PCT/AU2017/050879

Board

Maurice O'Shannassy

» Non-Executive Chairman

Maurice spent 25 years in the financial services industry in Australia and overseas. He held a number of CEO and CIO roles around the world for BlackRock and its antecedents prior to becoming CEO of BlackRock Australia. He currently holds a number of directorships in a variety of industries and not for profit organisations.

Paul Howley PhD

» CEO, Chief Scientist, Board Director, Co-Founder and Inventor

Paul's scientific background is in the field of molecular virology, specialising in viral vector systems and vaccinology. Paul is the inventor of the Sementis SCV platform vaccine delivery technology and of a number of vaccines in development. He directs and manages the vaccine development programs for Sementis, utilising his extensive knowledge, experience and networks in the areas of antigen design and discovery, proof of concept studies in animal models, GLP preclinical and toxicology studies, process development and cGMP manufacturing, regulatory affairs and first in man studies concerning live viral vectored vaccines.

Peter Wulff MSc

» Non-Executive Director

Peter has over 30 years experience in the biotech and pharma industry, especially vaccines and patents. Peter co-founded Bavarian Nordic, a biotechnology company listed on the Copenhagen Stock Exchange, developing vaccines for infectious diseases and cancer. He served as president and CEO from 1994 until the company had secured a large supply contract with the U.S. government for its MVA smallpox vaccine, Immvamune, in 2007. Peter has participated in several private placements, two IPOs, and a number of follow-on offerings. He also has extensive experience with investor relations and government relations in Europe, Asia, and North America. Peter later co-founded Sentinext Therapeutics (Malaysia) in 2009 to develop vaccines against EV71 and dengue, as well as other infectious diseases. He is currently an Independent Consultant to the Biotech industry and sits on the Advisory Board of the Veterinary Institute at the Danish Technical University. Peter is a qualified European Patent Attorney.

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