

Sementis AGM

November 2018

CEO

Presentation

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There are many risks for Sementis, many of which involve factors that cannot be controlled by board of Sementis. Sementis cannot provide any assurance that any known or unknown risks will not adversely affect its business or financial position in the future.

Management Team

Dr Paul Howley: *Co-founder, Inventor of SCV technology, CEO and Chief Scientific Officer*

Scientific background in the field of molecular virology & vaccinology. Inventor of the SCV vaccine delivery technology and of a number of vaccines in development.

Peter Wulff: *Board Director, VP, Business Development & IPR*

Ex CEO of Bavarian Nordic, brings to Sementis business development experience and expertise in the Biotech and vaccine industry.

Maurice O'Shannassy: *Non-executive Chairman*

25yrs experience in the financial services industry. Currently holds a number of Directorships in a variety of industries and not for profit organizations.

Mei Cockerall: *Financial Controller*

CPA. Previous experience in Biotech: Virax Holdings Ltd.

Board of Directors

Maurice O'Shannassy: *Non-executive Chairman*

25yrs experience in the financial services industry. Currently holds a number of Directorships in a variety of industries and not for profit organizations.

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Ex CEO of Bavarian Nordic, brings to Sementis business development experience and expertise in the Biotech and vaccine industry.

Dr Glen Burgess, MB, BS, FRACS: *Non-Executive Director*

Otolaryngologist , Head and Neck surgeon. Principal of Southern ENT, and Director of Monash Health, Snoring and Sleep Apnoea Clinic. Lecturer (adj) at Monash University Dpt of Surgery.

Michael Hickinbotham, BEc, LLB(Hons): *Non-Executive Director*

Managing Director of the Hickinbotham Group – the largest property development group in South Australia.

Corporate Structure

Shares on Issue: 956 million

Number of shareholders: 57

Shareholdings:

1st Major Share Holder – 45%

2nd Major Share Holder – 27%

3rd major Share Holder – 7%

4th & 5th Major Share Holder – 5% & 5%

Debt Obligations: None (no loans or Convertible Notes on issue)

Infrastructure: None (no rents or leases)

In-licensing: ThermoFisher CHO cell line

- one-off single license covers Infectious diseases and therapeutics
 - No licensing maintenance fees
 - No royalty out-reach

2018 Achievements

SCV-dual chikungunya/Zika virus vaccine (SCV1002)

- Preclinical proof-of-concept studies completed
- Results published in Peer Review Journal: Prow NA, Liu L, Nakayama E, Cooper TH, Yan K, Eldi P, Hazlewood JE, Tang B, Le TT, Setoh YX, Khromykh AA, Hobson-Peters J, Diener KR, Howley PM, Hayball JD, and Suhrbier A (2018) A vaccinia-based single vector construct multi-pathogen vaccine protects against both Zika and chikungunya viruses. Nat Comms. DOI: 10.1038/s41467-018-03662-6
 - Single shot vaccination of mice was able to elicit a robust, balanced and durable CHIKV-specific antibody response and provide protection against viremia, acute arthritis and persistence of viral RNA following CHIKV challenge.
 - Single shot vaccination of IFNAR-/- mice was able to elicit a robust, anti ZIKV-specific antibody response and provide protection against viremia and lethal challenge. Furthermore, a significant anti-CHIKV immune response was also generate.
 - Single shot vaccination of IFNAR-/- mice was able to afford protection against viraemia and detrimental fetal outcomes in a preclinical model of Zika pregnancy.
 - Single shot vaccination of mice was able to protect against viraemia and testicular damage in a preclinical model of Zika.
 - Single shot vaccination of mice that had a prior infection with chikungunya were still able to raise anti-ZIKV antibodies and were not compromised by pre-existing anti-CHIKV immunity.
 - Single shot vaccination of mice that were previously vaccinated with SCV-vector only, still had the ability to raise anti-ZIKV and anti-CHIKV antibody responses and were NOT affected by prior VACV infection. This suggested that anti-vector immunity does not affect the efficacy of SCV vaccination.
 - Single shot vaccination of mice that were previously vaccinated with SCV-CHIK still had the ability to raise significant anti-ZIKV responses and boosting anti-CHIKV responses.
 - Single shot vaccination of IRF3/7^{-/-} mice protected them against a lethal challenge from Ross River Virus – protection was afforded by cross-reactive vaccine induced CHIKV immune responses

2018 Achievements

SCV1002 vaccine testing in Non-Human-Primates

- Study funded by National Institute of Allergies and Infectious Diseases (NIAID) in USA
- Study carried out by Southern Research in USA
- Study results:
 - Single shot vaccination protected monkeys from Zika virus infection
 - Single shot vaccination stimulated antibodies to chikungunya antibodies as well as to Zika virus
 - Studies results to be published soon

SCV1002 GMP Manufacturing at CSIRO

- Objective: produce a clinical batch of SCV1002 ready for first-in-man clinical trial
- CSIRO will manufacture the following:
 - Cell Substrate Master Cell Bank (MCB) → biosafety testing by Sartorius, UK
 - Cell substrate Working Cell Bank (WCB) → biosafety testing Eurofin, Australia
 - SCV1002 Master Seed vaccine (MSV) → biosafety testing by Sartorius, UK
 - SCV1002 Working Seed Vaccine (WSV) → biosafety testing by Sartorius, UK
 - SCV1002 Clinical Batch → biosafety testing by Sartorius, UK

Biosafety Testings

Biosafety Test	MCB	WCB	MSV	WSV	Clinical Batch
Bacteria/Fungi	✓				
Mycoplasma	✓				
Adventitious Agents: In vitro	↻				
Adventitious Agents: In Vivo	↻				
Retroviruses: EM	START				
Retroviruses: Infectivity	START				
Retroviruses: Reverse transcriptase	START				
CHO-Specific Viruses: MVM	✓				
CHO-Specific Viruses: Vesivirus	✓				
Mouse Specific Viruses:	START				
Human Specific Viruses:					
General Safety					
CHO-DNA					
CHO-proteins					
Endotoxin					

2018 Achievements

Peanut Hypoallergy vaccine preclinical proof-of-concept:

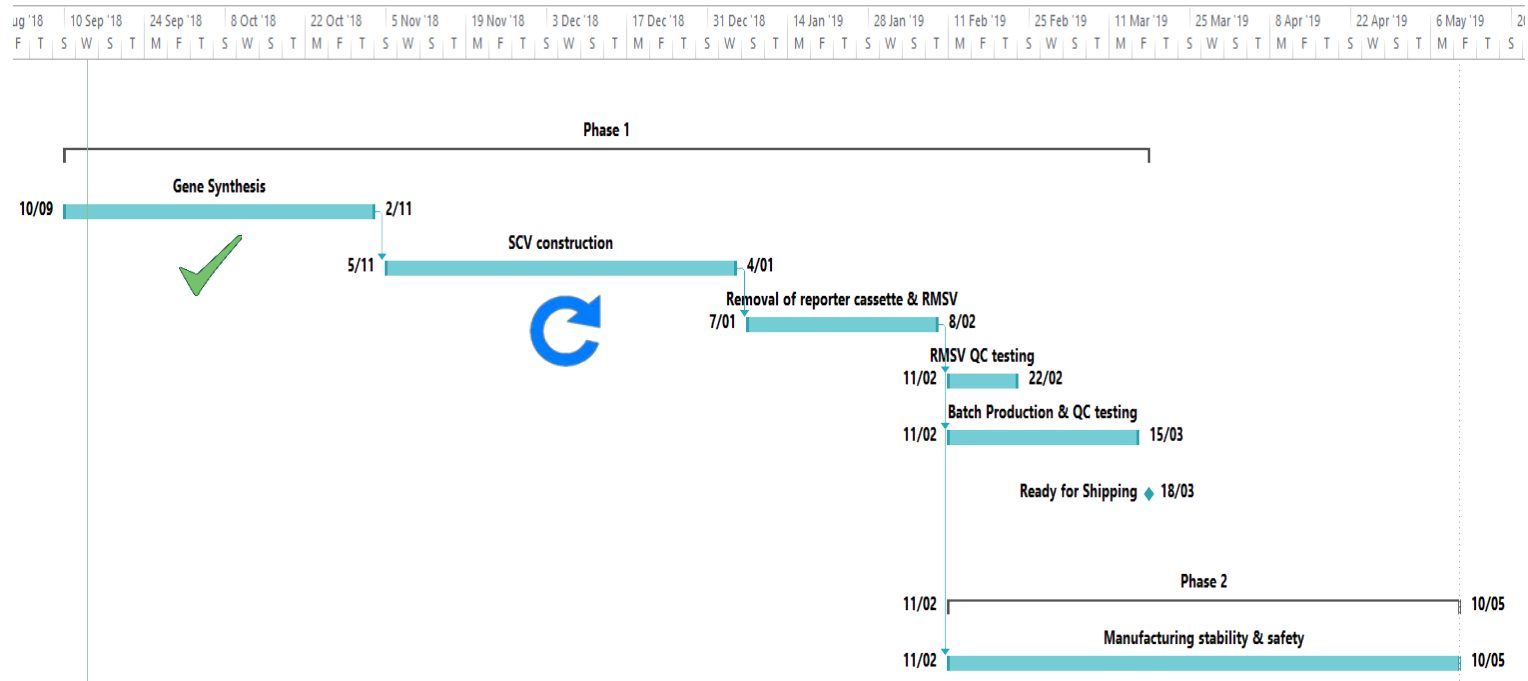
- **Human Ex vivo studies (test-tube vaccination studies) using blood donated by peanut allergic individuals:**
 - Vaccination of Antigen Presenting Cells followed by mixing with total T-cell population (Th2 biased population) and then exposing to peanut protein stimulation the production of peanut-specific Th1 T-cells and the reduction of peanut-specific Th2 T-cells
 - Vaccination of Antigen Presenting Cells obtained from peanut allergic individual “flicks the switch” from peanut-specific Th2 to peanut-specific Th1 immune environment
 - The essential ingredient for initiating desensitization against peanut allergy
- **Safety studies in mice on-going:**
 - Testing for vaccine induced anaphylactic reactions in sensitized mice
 - Testing for vaccine induced Th1 pathology in peanut sensitized mice after intensive feeding with peanuts

Business Opportunities

Technology Evaluation Agreement with undisclosed Big Pharma:

Big Pharmaceutical Company Evaluating Sementis' SCV Technology

- Sementis to construct a test vaccine
- Sementis to carry out stability experiments
- BigPharma – vaccinology experiments in mice
- BigPharma – Monkey Vaccination study to test protection against target disease causing agent
- 18 Month evaluation study (started September 2018)
- Next Step – partnership agreement

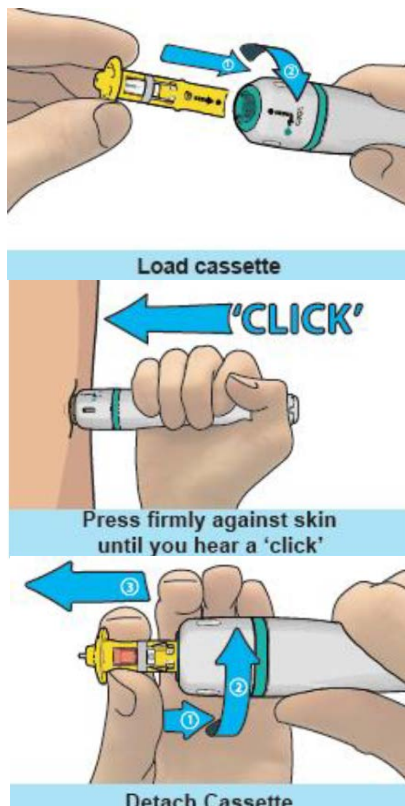


Business Opportunities

Technology Evaluation Agreement with Enesi Pharma:

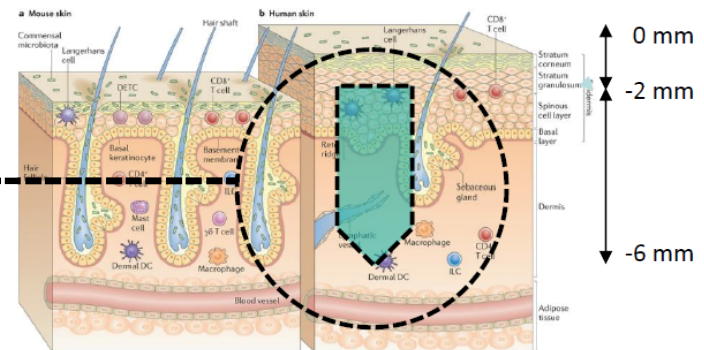
Sementis Evaluating Enesi Pharma Implavax Technology

- Implavax Technology – Needle-free thermo-stable vaccine delivery technology
- Sementis to carry out immunogenicity studies in mice with respect to infectious disease vaccines and allergy vaccine
- Enesi – to carry out vaccine stability studies



Universal Vaccine Implant (UVI)

- unit solid dose
- needle free, syringe free
- stored safely inside cassette until delivery
- eliminates need for point-of care reconstitution with diluent
- eliminates needle-stick-injury and sharps disposal challenge
- unit dose delivery assured – each time every time
- enhanced stability
- reduces / eliminates cold chain



Nature Reviews | Immunology

Business Opps

InProTher – HIV vaccine development

- Danish Company with HIV vaccine development background
- Evaluation only agreement (MTA) in place
- Sementis to construct SCV vaccine with InProTher proprietary HIV antigen
- InProTher to test vaccine efficacy in HIV preclinical models

BreakImmune – cancer vaccine development

- Joint Venture between InProTher (Denmark), Sirion (Germany) & Sementis
- Funding source: Novo Ventures
- Sementis will have two positions on the board of directors consisting of six
- InProTher – proprietary anti-cancer antigens & anti-cancer preclinical proof-of-concept capabilities
- Sirion – Adenovirus vector technology
- Sementis – SCV vector technology
- Note: Heads-of-Agreement still being negotiated and drafted

ALK (Denmark)

- Interest in Sementis' SCV platform vector for the House Dust Mite immunotherapy project - Exploratory status

Coalition of Emergency Preparedness Innovations (CEPI)

- Possible source of funding of an expanded SCV1002 clinical trial to test the safety and effectiveness of low dose, medium dose and high dose single shot vaccination strategy

Intellectual Property

The Company has filed the following:

Peanut Allergy vaccine antigen design

PCT filing March 2014

International Application Number: PCT/AU2014/000286

International Publication Number: WO 2014/138824A1

National phase examinations: AU, US, EU, ZA, CN, KR, IL, MY, JP, CA, HK,

Granted: NZ, SG, RU

SCV Production Cell Line

PCT filing November 2014

International Application Number: PCT/AU2014/050330

International Publication Number: WO 2015/061858

National phase examinations: AU, NZ, US, CN, KR, IL, MY, JP, CA, HK, IN

Granted: SG, ZA, RU, EU

Chikungunya & Zika virus multivalent Vaccine

PCT filing August 2017

International Application Number: PCT/AU2017/050879

National phase examinations: Feb 2019

Outlook for 2019 and beyond

To Test the Safety and Immunogenicity of the SCV system in Human

- Small Open label Phase Clinical Trial using SCV-CHIK/ZIKA (SCV1002) vaccine
 - Objectives:
 - In 10 healthy volunteers:
 - Single shot vaccination with “MVA dose”
 - Safety (site reaction and blood chemistry and organ functions)
 - Immunogenicity using pre-vaccination status as bench mark:
 - Antibody and T-cell responses to:
 - Chikungunya
 - Zika Virus
 - Ross River Virus
 - Passive Protection against challenge (passively transfer human serum into mice and then challenge with Chikungunya/Zika virus/Ross River Virus)

Outlook for 2019 and beyond

Planned Work in 2019:

- Produce the GMP clinical batch of SCV-CHIK/ZIKA (SCV1002) vaccine at CSIRO-Manufacturing Melbourne
- Biosafety testing at Sartorius in UK
- Toxicology Study at Tretra-Q (Queensland)
- Write Technical Document that includes CMC, Toxicology, Investigator Brochure and Clinical Trial Protocol
- File CTN application for licence to do clinical trial in Australia (TGA)
- Perform clinical Trial at Q-Pharm, QLD

Possible funding from CEPI (Chikungunya vaccine development)

- Start manufacturing of SCV-Peanut Hypoallergy Vaccine (CSIRO)

Outlook for 2020 and beyond

Double Blinded Placebo Controlled Phase 1/2a Peanut Hypoallergy vaccination study in Peanut allergic individuals

- Objective:
 - Vaccinate peanut allergic volunteers
 - Monitor immune status with respect to peanut-specific Th1 immune response (akin to previous Ex Vivo studies)
 - Challenge with escalating doses of peanut
- Trial Design:
 - Treatments groups:
 - Vaccine
 - Placebo (SCV vector only)
 - Treatment group size: 30 volunteers (total 60 volunteers)
 - Follow up period: 12 months

Laboratories and collaborations

University of South Australia (UniSA)

Scientific work carried out in the Experimental Therapeutic Laboratories (ETL) headed and run by Assoc. Prof. John Hayball

Lab staff:

- 3 PhD scientists (Salaries: 50% Sementis/50% Grants)
- 2 Research assistants (Salaries: 100% Sementis)

UniSA/ETL ensures:

- Laboratory facilities to accommodate scientist and access to service facilities, eg, animal house, sequencing, pathology
- OH&S compliant (Assoc. Prof. Hayball's responsibility)
- HR management of staff (employment contracts, monthly salary payments etc)
- OGTR compliant (Assoc. Prof. Hayball's responsibility)

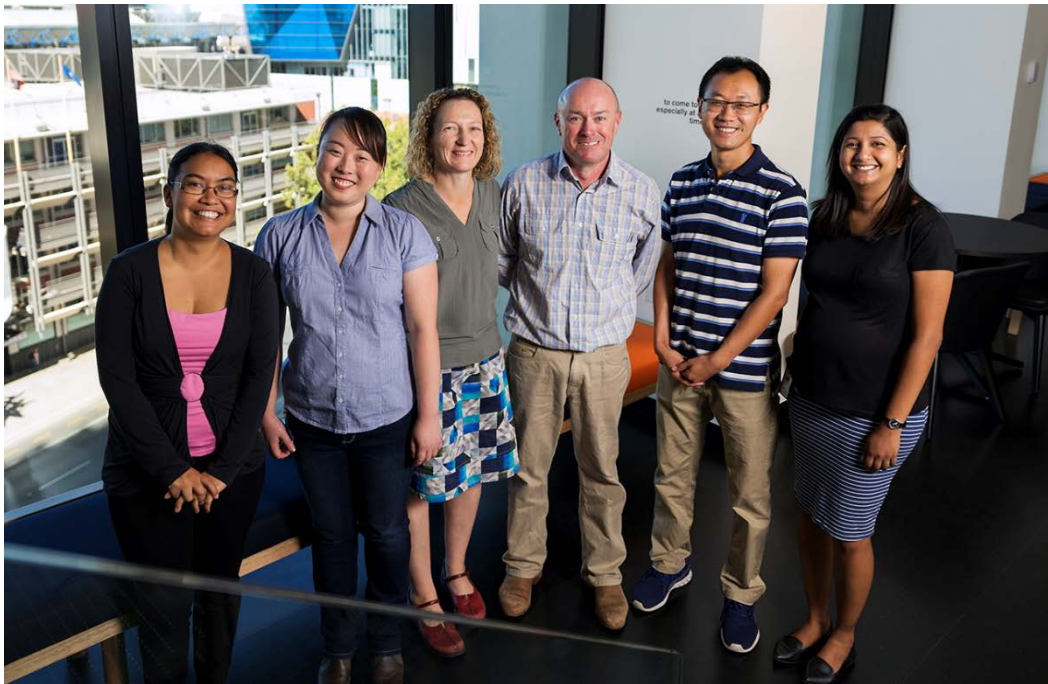
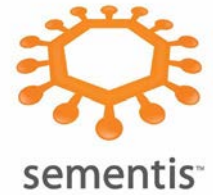
Note:

- Staff are official employees of UniSA but contracted to work on Sementis projects only
- Sementis manages and directs the scientific work through Paul Howley (UniSA Adjunct Senior Research Fellow)

New Laboratories at University of South Australia (UniSA)



New Laboratories at University of South Australia (UniSA)



Collaborations



Queensland Institute of Medical Research Berghofer (QIMR-B):

Prof Andreas Suhrbier

- 1 PhD scientist (salary: Queensland Government; Consumables: Sementis)

Zika virus and chikungunya vaccination studies in mice

- Biosafety Level 3 laboratories (Chikungunya is a BSL3 organism)
- Stocks of multiple strains of Chikungunya
- Stocks of multiple Zika virus strains
- Inventors of the chikungunya and CZS animal models – accepted world wide for testing vaccines and antivirals

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RESEARCH ARTICLE
Host-Microbe Biology



Chikungunya Virus Arthritis in Adult Wild-Type Mice^{†‡}

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Fontenay-aux-Roses, France³; Department of Pathology, University of Texas Medical Branch, Galveston,
Texas⁴; and Griffith Medical Research College, Griffith University, Brisbane, Australia⁵

Received 12 December 2009/Accepted 25 May 2010

Chikungunya virus is a mosquito-borne arthrogenic alphavirus that has recently reemerged to produce the largest epidemic ever documented for this virus. Here we describe a new adult wild-type mouse model of chikungunya virus arthritis, which recapitulates the self-limiting arthritis, tenosynovitis, and myositis seen in humans. Rheumatic disease was associated with a prolific infiltrate of monocytes, macrophages, and NK cells and the production of monocyte chemoattractant protein 1 (MCP-1), tumor necrosis factor alpha (TNF- α), and gamma interferon (IFN- γ). Infection with a virus isolate from the recent Reunion Island epidemic induced

De Novo Generation and Characterization of New Zika Virus Isolate Using Sequence Data from a Microcephaly Case

Yin Xiang Setoh,^a Natalie A. Prow,^b Nias Peng,^a Leon E. Hugo,^c Gregor Devine,^c
Jessamine E. Hazlewood,^b Andreas Suhrbier,^b Alexander A. Khromykh^a

Australian Infectious Diseases Research Centre, School of Chemistry and Molecular Biosciences, University of Queensland, St. Lucia, Queensland, Australia^a; Inflammation Biology Group, QIMR Berghofer Medical Research Institute, Brisbane, Queensland, Australia^b; Mosquito Control Group, QIMR Berghofer Medical Research Institute, Brisbane, Queensland, Australia^c

ABSTRACT Zika virus (ZIKV) has recently emerged and is the etiological agent of congenital Zika syndrome (CZS), a spectrum of congenital abnormalities arising from neural tissue infections in utero. Herein, we describe the *de novo* generation of a new ZIKV isolate, ZIKV_{Natal}, using a modified circular polymerase extension reaction protocol and sequence data obtained from a ZIKV-infected fetus with microcephaly. ZIKV_{Natal} thus has no laboratory passage history and is unequivocally associated with CZS. ZIKV_{Natal} could be used to establish a fetal brain infection model for CZS.

Received 27 April 2017 Accepted 2 May 2017 Published 17 May 2017

Citation Setoh YX, Prow NA, Peng N, Hugo LE, Devine G, Hazlewood JE, Suhrbier A, Khromykh AA. 2017. De novo generation and characterization of new Zika virus isolate using sequence data from a microcephaly case.