

# Sementis AGM November 2015

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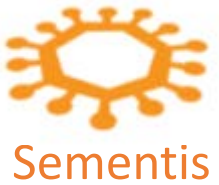
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# Management team

**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.

**Dr Jane Ryan: *CEO Elect and business development Consultant***

Has international experience in the pharma and biotech Industry. Managed R & D programs. Employed in key roles in business development and alliance management.

**Dr Paul Howley: *Co-founder, Inventor of SCV technology, Interim-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.

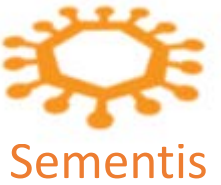
**Dr Thomas Quirk: *Non-executive Director***

Nuclear physicist and has been a Fellow of three Oxford Colleges. He has extensive experience in the biotech industry (including startups) and Venture Capital.

**Mei Cockerall: *Financial Controller***

CPA. Previous experience in Biotech: Virax Holdings Ltd.

# 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

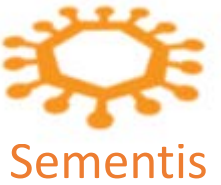
Sementis pays a yearly contract fee of \$1.7M to cover the the following:

- Salaries for 9 scientist
- Laboratory consumables and animal housing and maintenance costs in UniSA animal house
- Overheads (30%)

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

Prof Andreas Suhrbier - contract to do chikungunya challenge studies to test efficacy of Sementis' Chikungunya vaccine

# Sementis vaccine pipeline



- **Current focus**

- Peanut allergy vaccine SCV204 (11 allergen vaccine) and SCV209 (4 major allergen vaccine)
- Chikungunya/small pox SCV305

- **Future focus**

- Cat allergy

- **Explore collaborations for contract manufacture**

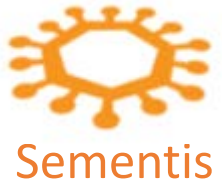


Sementis

# Recent progress

# Intellectual property

- **Peanut Allergy vaccine antigen design PCT filing March 2014**  
National phase examinations: Au, NZ, US, EU, RU, ZA, CN, KR, IL, MY, JP, CA
- **SCV Production Cell Line PCT filing Nov 2014**  
National phase examinations: Au



PATENT COOPERATION TREATY			
From the RECEIVING OFFICE		31 MAR 2014	
<b>To:</b>  DAVIES COLLISON CAVE 1 NICHOLSON STREET MELBOURNE VICTORIA 3000 AUSTRALIA		<b>PCT</b>  NOTIFICATION OF THE INTERNATIONAL APPLICATION NUMBER AND OF THE INTERNATIONAL FILING DATE  (PCT Rule 20.2(c))	
		Date of Mailing 26 March 2014 (day/month/year)	
Applicant's or agent's file reference 35215185		IMPORTANT NOTIFICATION	
International Application No. PCT/AU2014/000286	International Filing Date (day/month/year) 17 March 2014	Priority Date (day/month/year) 15 March 2013	
Applicant SEMENTIS LIMITED			
Title of the invention IMMUNE MODULATION			
1. The applicant is hereby notified that the international application has been accorded the international application number and the international filing date indicated above.  2. The applicant is further notified that the record copy of the international application: <div style="margin-left: 20px;"> <input checked="" type="checkbox"/> was transmitted to the International Bureau on 26 March 2014  <input type="checkbox"/> has not yet been transmitted to the International Bureau for the reason indicated below and a copy of this notification has been sent to the International Bureau*:  <div style="margin-left: 40px;"> <input type="checkbox"/> because the necessary national security clearance has not yet been obtained.  <input type="checkbox"/> because (reason to be specified):               </div> </div>			
* The International Bureau monitors the transmittal of the record copy by the Receiving Office and will notify the applicant (with Form PCT/IB/301) of its receipt. Should the record copy not have been received by the expiration of 14 months from the priority date, the International Bureau will notify the applicant (Rule 22.1(c)).			
Name and mailing address of the receiving Office AUSTRALIAN PATENT OFFICE IP Australia PO Box 200 Woden, ACT 2606 E-mail address: pct@ipaustalia.gov.au		Authorised Officer PCT Administration Officer  Telephone No +61-2-6222-3626	



# External funding and awards

## Sept 2014

Awarded the Department of Industry Entrepreneur's Infrastructure "Researchers in Business" grant – funds a salary position at UniSA for 1 year

## Nov 2015

Awarded the Department of Industry Entrepreneur's Infrastructure "Research Connections" grant – funds a salary position at UniSA for 1 year

## Submissions:

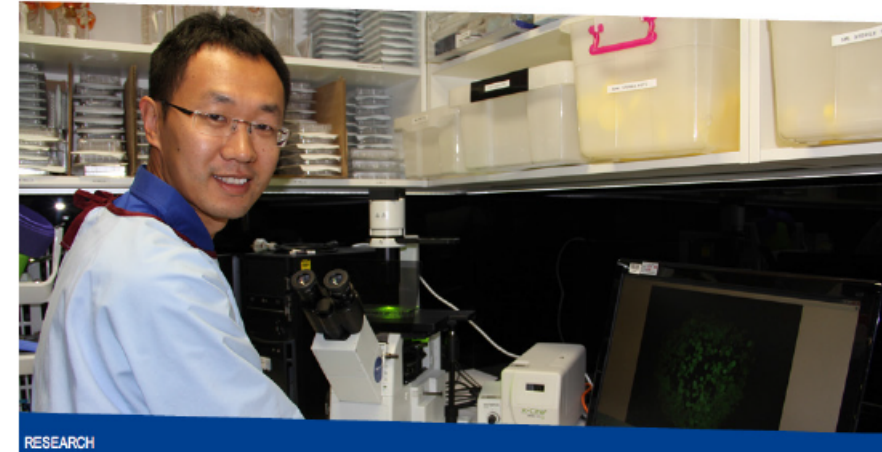
- Nov 2015: ARC-LINKAGE with UniSA – 1 salary for 3 years
- Oct 2015: Advance Queensland Research Fellowship with QIMR – 1 salary for 3 years



### Chikungunya vaccine edges closer.

[Back to story index](#)

by Kelly Stone



RESEARCH  
Research Fellow and Research Connections grant recipient Dr Liang Liu

UniSA's Experimental Therapeutics Laboratory is set for an exciting year ahead in 2016, as it edges closer to developing a protective vaccine against the mosquito-borne Chikungunya virus.

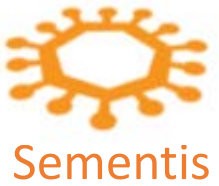
In a collaborative research partnership with Melbourne-based biotechnology company Sementis Ltd, the lab is progressing work on vaccines of the future, with Chikungunya 'first cab off the rank' as outbreaks of the virus rise worldwide.

While Chikungunya hasn't yet made it to Australia, Experimental Therapeutics Laboratory head Associate Professor John Hayball said it's only a matter of time and developing a vaccine for Chikungunya is an international health priority.

"Chikungunya is a mosquito-borne infectious disease causing debilitating symptoms and death in severe cases," he said.

"In addition to the acute onset of the virus, Chikungunya often has long-term effects including arthritis. As well as being preventative, the vaccine we're working on may also be able to counter some of these long-term chronic effects associated with infection."

# Tax refund on research



Thursday, 13 October 2015

## Announcement

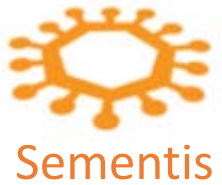
The company is pleased to announce that it has received from the ATO a refund of **\$851,681** from the R&D Tax Incentive scheme.

## R&D Tax Incentive Scheme

The Research and Development (R&D) tax incentive provides a tax offset for eligible R&D activities and is targeted toward R&D that benefits Australia.

It is administered jointly by AusIndustry (on behalf of Innovation Australia) and the Australian Taxation Office (ATO). Companies register their eligible R&D activities with AusIndustry and claim the tax offset in their company tax return through the ATO.

# Peanut hypoallergy vaccine development



## Peanut hypoallergy antigen design proof of concept

Vaccination of mice produced a Th1 response upon peanut protein challenge



## Peanut hypoallergy Candidate Vaccines

Candidate vaccines constructed

- Ongoing testing in a mouse therapeutic desensitizing study
- Ongoing testing in human ex vivo immunogenicity testing

# Chikungunya vaccine development

## CHIKV antigen design proof of concept

Vaccination of mice gave full protection against challenging with virulent CHIKV

Protection from disease ✓

Protection from virus multiplication ✓



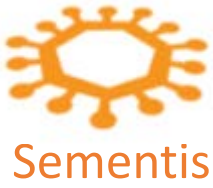
## CHIKV Candidate Vaccine

Vaccination of mice gave full protection against challenging with virulent CHIKV

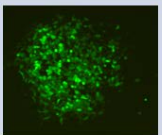

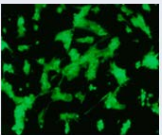
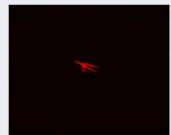
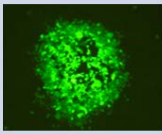
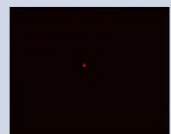
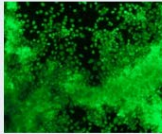
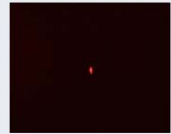
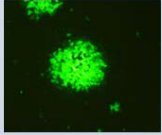

Protection from virus multiplication ✓

Protection from disease ✓

# SCV does not multiply in human and mammalian cells lines

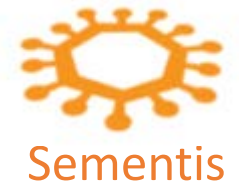


Cell line	Virus Multiplication	
	Vaccinia	SCV
Chinese hamster ovary cell line (CHO)	No	No
SCV-CHO-Rescue cell line	Yes	Yes
Baby hamster kidney cell line clone 21 (BHK21)	Yes	No
African Green Monkey kidney cell line (Vero)	Yes	No
Human bone cell line (143B)	Yes	No
Human lung cell line (MRC-5)	Yes	No
Human Kidney cell line (HEK-293)	Yes	No
Human skin epidermis cell line (A431)	Yes	No
Human cervical cells (HeLa)	Yes	No

	Vaccinia	SCV
Human Bone Cells		
Human Lung Cells		
Human Kidney Cells		
Human Skin Cells		
Human Cervical Cells		

The results above are from infectivity studies showing virus spread from a single cell infection to neighbouring cells. SCV was able to infect a single cells as shown by one point of red red fluorescence but unable to spread its infection to the neighbouring cells with in the same manor as vaccinia shown by the spread of green fluorescence in the table of photographs. The only cell line that SCV was able to multiply in was the genetically engineered SCV-CHO rescue cell line used as cell substrate for virus production. The overall conclusion is that the attenuated SCV virus vector is **TOTALLY** attenuated in all cell lines tested except for the rescue cell line used for SCV production.

# SCV does not disseminate in severely immune deficient (SCID) mice



## Detection of virus in the organs of SCID (immune deficient) mice post infection

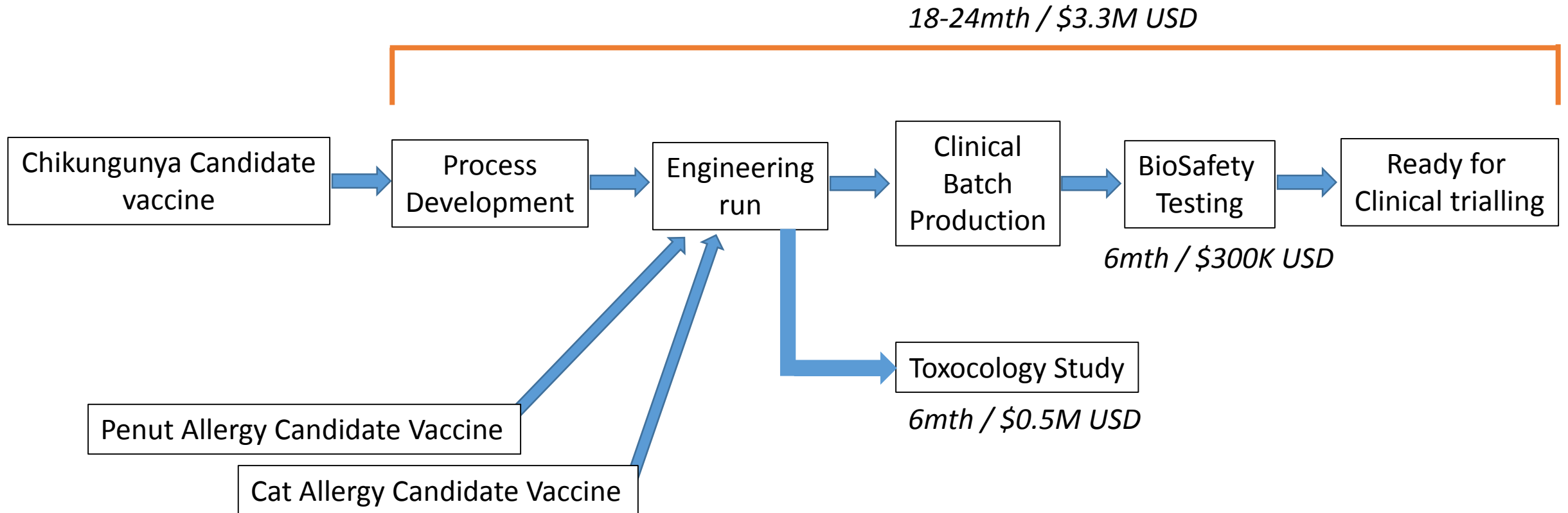
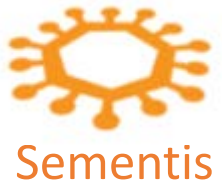
		Day 1	Day 2	Day 3	Day 5	Day 9	Day 15	Day 21	Day 100
Lung	VACV-COP	✓	✓	✓	✓	✓	✓	✓	
	SCV104	✗	✗	✗	✗	✗	✗	✗	✗
Kidney	VACV-COP	✓	✓	✓	✓	✓	✓	✓	
	SCV104	✗	✗	✗	✗	✗	✗	✗	✗
Spleen	VACV-COP	✓	✓	✓	✓	✓	✓	✓	
	SCV104	✗	✗	✗	✗	✗	✗	✗	✗
Ovaries	VACV-COP	✓	✓	✓	✓	✓	✓	✓	
	SCV104	✗	✗	✗	✗	✗	✗	✗	✗

All mice of the VACV-COP group either died or were euthanized by day 21 post infection

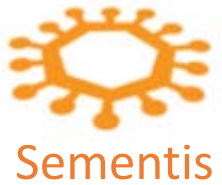


- Develop SCV platform and manufacturing capability through government funded initiatives
  - Emerging diseases
    - Chikungunya/small pox vaccine
- Grow pipeline in high value diseases with significant unmet medical need
  - Allergies
    - Lead peanut allergy: 2 candidate vaccines are being studied
    - Work on cat allergy has commenced
- License SCV platform for application in non-core therapeutic areas
  - Oncology
  - Immunomodulation
  - Infectious diseases

# Manufacturing development

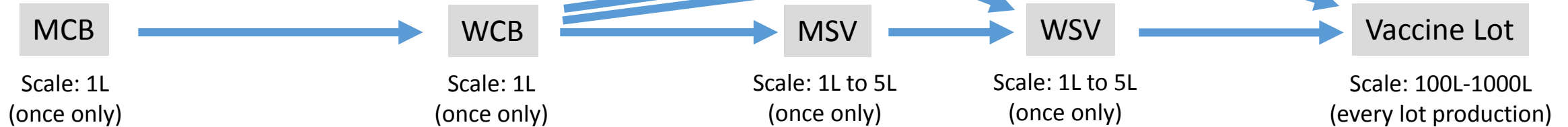


# GMP manufacturing overview:



Cell banking and testing (once for all products)

Vaccine banking  
and testing (once per vaccine product)



## Testing Regime (once only):

### 1. Identity and Purity

1. Morphology
2. biochemical (eg isoenzymes)
3. immunological (eg histocompatibility)
4. cytogenetic markers
5. nucleic acid finger printing
6. Karyotype (diploid cell lines)
7. Life span (diploid cell lines)

### 2. Extraneous Agents

1. Bacterial and fungal contamination
2. Mycoplasmas
3. Retroviruses

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### 1. Identity and Purity

1. Morphology
2. biochemical (eg isoenzymes)
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6. Karyotype (diploid cell lines)
7. Life span (diploid cell lines)

### 2. Extraneous Agents

1. Bacterial and fungal contamination
2. Mycoplasmas
3. Tests in cell culture
4. Co-cultivation
5. Tests in animals and eggs

## Testing Regime (once only):

1. Test for identification
2. Potency

## Testing Regime (once only):

1. Test for identification
2. Potency
3. Extraneous agents
  1. Bacterial and fungi sterility
  2. Mycoplasmas
  3. Mycobacteria
  4. In vitro testing of AvA
  5. In vivo testing of AvA
  6. Retroviruses
4. Neurovirulence
5. Toxicity

## Testing Regime (every batch):

1. Test for identification
2. Potency
3. Extraneous agents
  1. Bacterial and fungi sterility
  2. Mycoplasmas
  3. Mycobacteria
  4. In vitro testing of AvA
  5. In vivo testing of AvA
  6. Retroviruses
4. Neurovirulence
5. Toxicity
6. Stability

## Cell line control:

1. Identity
2. Extraneous agents (as above)

# Summary ongoing activities

- Complete negotiations of due diligence activities for the technology from a contract manufacturing organization. If successful, will develop production methods for Chikungunya and smallpox vaccines
- Manufacture Chikungunya and smallpox vaccines for initiation of toxicology studies
- Complete testing of properties of peanut allergy vaccine in mice
- Complete *ex vivo* testing of peanut allergy vaccine in human cells as a proof of concept