



DEVELOPING COMMERCIAL OUTCOMES

CEO AGM 2023 Presentation

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FY2023 Highlights



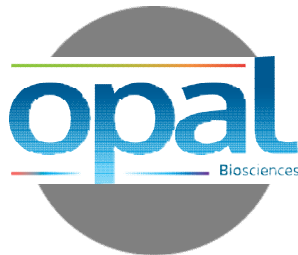
Income from royalties,
milestone and
consulting fee
payments totalling
\$419,108
(2022:\$403,184)



Changchun BCBT
Biotech Co further
extension of licenced
territories; Serum
Institute of India
launch quadrivalent
liquid LAIV



Board
consideration of
sale of LAIV
technology;
process
commenced



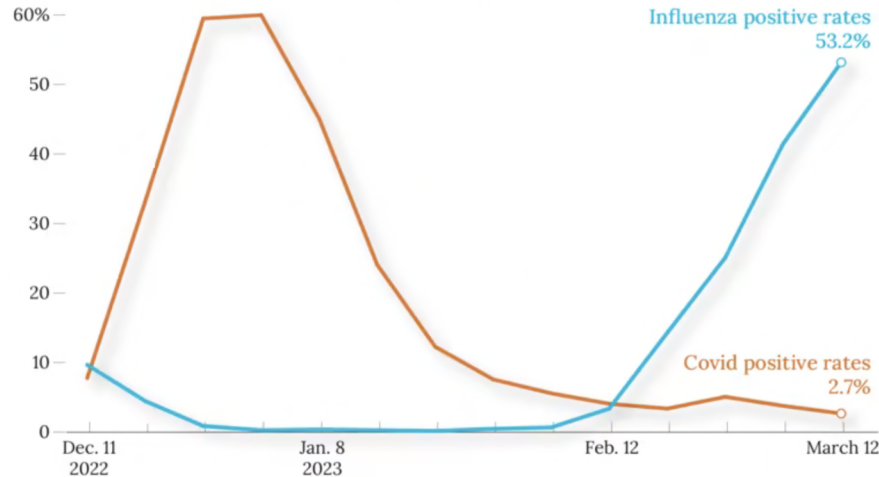
\$5m grant award to
establish Australian
small-scale
manufacturing
facility for clinical
trial and precision
medicine supplies

Seasonal influenza - China

China emerges from COVID, but flu epidemic concerns grow

Schools hit as symptomatic students stay home despite spring semester start

Just as China's Covid Epidemic Fades, Flu Cases Surge



Note: The rates were recorded by hospitals.
Source: Chinese Center for Disease Control and Prevention

Caixin

ZHAO JINZHAO, HUA ANG, WANG BOWEN, QI ZHANNING and WANG XINTONG, Caixin

March 22, 2023 12:39 JST

China says a surge in respiratory illnesses is caused by flu and other known pathogens

China's health ministry says a surge in respiratory illnesses across the country that has drawn the attention of the World Health Organization is caused by the flu and other known pathogens and not by a novel virus

By The Associated Press
November 26, 2023, 11:14 PM



FILE - Commuters wearing face masks as they wait at an intersection in the central business district during the morning rush hour in Beijing, Friday, May 26, 2023. A surge in respiratory illnesses across China that has drawn the attention of the World Health Organization is caused by the flu and other known pathogens and not by a novel virus, the country's health ministry said Sunday. (AP Photo/Mark Schiefelbein, File)

The Associated Press

Avian influenza - China



NEWS TOPICS & PROJECTS PODCASTS NEWSLETTERS ABOUT



China reports fatal H5N6 avian flu case

News brief | September 28, 2023

[Lisa Schmirring](#)

Topics: [Avian Influenza \(Bird Flu\)](#)



SHARE

China has reported a fatal H5N6 avian flu infection in a 68-year-old man from Chongqing, the country's fourth largest city, Hong Kong's Centre for Health Protection (CHP) said in a **statement** today.

The man's symptoms began on August 5, and he was hospitalized 5 days later. He died on August 20. An investigation revealed that he had been exposed to live domestic poultry before he got sick.

China has now reported six H5N6 cases this year. The **last case** was reported in the middle of August, in a woman from Sichuan province.

H5N6 is known to circulate in poultry in some Asian countries, and the first human case was reported in 2014. Of 88 global cases, 87 have been reported from China. Laos is the only other country that has reported a human H5N6 case. Infections involving the strain are often severe or fatal.



Juhan Sonin / Flickr cc



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Disease Outbreak News

Avian Influenza A(H3N8) - China

11 April 2023

Description of the Situation

Situation at a glance

On 27 March 2023, the National Health Commission of the People's Republic of China notified WHO of one confirmed case of human infection with an avian influenza A(H3N8) virus. This is the third reported case of human infection with an avian influenza A(H3N8) virus; all three cases have been reported from China.



--- Mucosal Immunity + Humoral Immunity + Cellular Immunity ---

INFLUENZA VACCINE, LIVE, NASAL, FREEZE-DRIED

Good Safety: 【Free of Inactivator, Split Agent and Preservative】

Indicated for Age Groups from 3 Years-17 Years



Seasonal influenza - India



SERUM INSTITUTE OF INDIA PVT. LTD.

Cyrus Poonawalla Group

NASOVAC-S4

Influenza Vaccine (Human, Live Attenuated) I.P.
Seasonal, Quadrivalent (Liquid) Intranasal

INDICATION

Indicated in individuals above 2 years of age.

ROUTE OF ADMINISTRATION

For administration by intranasal spray.

Video of Administration Process of Nasovac-S4

DOSAGE

A single intranasal dose of 0.5 ml is administered as 0.25 ml per nostril.

PRESENTATION:

1 dose vial (0.5 ml) Intranasal





Mylab and Ekincare to promote Serum Institute's nasal flu vaccine among corporates

Updated - November 27, 2023 at 04:39 PM. | Mumbai

Ekincare is a corporate health benefits platform and its collaboration with Mylab will enable businesses to incorporate NASOVAC-S4 into their employee wellness programs

thehindubusinessline.com/news/national/mylab-and-ekincare-to-promote-serum-institutes-nasal-flu-vaccine-among-corporates/article67579438.ece



Search



India gets first nasal vaccine against influenza: What is it & why it's important



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World's largest vaccine manufacturer Serum Institute of India and Pfizer's BioCrucis Solutions have launched the first nasal flu vaccine in the country. It has raised hopes that millions of people who are vulnerable to seasonal influenza can now get better-protected.

youtube.com/watch?app=desktop&v=kEGnEQoPaEA



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An Australian company focused on growing Australia's vaccine and pharmaceutical development and manufacturing capability

FY23 Highlights



\$250,000 raised from option exercise
\$162,431 and **\$87,569** shortfall placement



Company strategy implementation: to establish Australian small-scale manufacturing facility for clinical trial supplies



Share purchase agreement to acquire Formulytica Pty Ltd



Three grant applications lodged to support new strategy (partners Formulytica Pty Ltd; University of Western Australia)



\$5m grant awarded from WA Investment Attraction Fund



The pandemic has
highlighted **major**
manufacturing
gaps and reliance
on imports

Opal Biosciences Ltd ("Opal") is an Australian public company focused on growing Australia's pharmaceutical manufacturing capability.

- **Opal has signed an agreement to acquire Formulytica Pty Ltd** ("Formulytica"), a revenue-generating Melbourne-based product development company (non-cash, share issue acquisition)
- **Opal has been awarded a \$5 million WA government grant** towards building a facility in Perth with Formulytica.

The new facility will manufacture injectable products for clinical trial and personalised medicine treatment e.g. cancer vaccines.

This will extend Formulytica's current business and provide a new fee-for-service business for local, national and international clients.

Opal's acquisition of Formulytica will

- trigger the \$5m WA grant to add a new manufacturing facility in Perth, and
- build a merged business to meet increasing demand for onshore pharmaceutical and vaccine development and manufacturing
 - to include **personalised medicine** and **clinical trial** material.

\$5m from the Western Australian Investment Attraction Fund

Grant awarded to Opal Biosciences Ltd to assist establishment of a small scale pharmaceutical manufacturing facility in Perth for sterile injectable liquids. The grant requires Opal to contribute matching funds over the 5 year grant period.



Investment Attraction Fund



Grant applications

Perth manufacturing site; WA visits

- 
- **Western Australian Investment Attraction Fund** EOI submitted (May 2022)
 - Full application submitted (Oct 2022)
 - **Funding agreement signed (July 2023) for \$5m**
 - **Medical Research Future Fund (MRFF): 2023 National Critical Research Infrastructure** grant for \$5m:
 - Grant application finalized and submitted 31 Jul 2023 (*Outcome awaited*)
 - **CRC-P** (Round 15) grant application for \$3m:
 - Grant application finalized and submitted 14 Sep 2023 (*Outcome awaited*)



Formulytica's Current Melbourne-based capability



- **Existing revenue-generating** (\$2m+) Melbourne-based fee-for service business with local and international clients; and royalty-generating having commercialized own in-house innovative technologies
- **US FDA regulatory standard level** focus and quality systems
- Injectable drug development capabilities including
 - formulation development of new small molecule drugs,
 - reformulation of generic drugs,
 - development of targeted drug delivery systems for biomolecules including proteins, peptides, DNA, siRNA, and mRNA, and
 - formulation and development of a wide range of complex sterile injectables.





Formulytica's Current Melbourne-based capability

- a CRDMO[#] with own products/technologies



Formulation development

chemistry experts for development of topicals and injectables



Analytical

formula analysis with a focus on monitoring drug stability and formulation physico-chemical properties.



GMP manufacturing and technical transfer

transfer from laboratory to GMP manufacturing. Optimising manufacturing processes to reduce costs for companies



Specialist training and problem solving

world class training and solutions for clients



Regulatory

Chemistry and manufacturing controls (CMC) for USA (IND, ANDA and NDA) and Australia (TGA, AUSTR and AUSTRAL)



Formulytica's Partners have included

Singapore Research Institutes

4 projects funded by grants and direct investment – injectable ophthalmic products

Will lead to 2 spin out companies

Technology based on liposomes and nanoparticles - patent applied

US mid size pharma

4 projects to develop dermatology treatments for atopic dermatoses

Technology based on aerosol foam

Australia personal care companies

- i) 16 products developed and launched
- ii) Tan removal product - new technology - patent applied

Mid-sized pharma

Rheology training

Products successfully developed

Aerosol	Anaesthetic spray
Foams	Topical
	Rectal
	Otic
Topical	Creams
	Lotions
	Gels
	Ointments
Injectable	Ophthalmic
	Intravenous and intramuscular delivery
	Veterinary
Liposome technologies	Small molecule API's
	Liposome development
	Clinical GMP supply
Oral	Liquid
	Nasal and throat capsules



Formulytica a product successes

- developed by Formulytica staff & launched



Bondi Sands
Tan eraser
2017 (patent app)



Skinstitut
Micellar water
2018



Connetics
Ketoconazole Foam
Anti-fungal
2006



GSK/Stiefel
Tazarotene Foam
Acne
2012



Connetics for JJ
Minoxidil Foam
Hair growth
2007



Brands RMJ
Magnesium spray
2017



**Connetics/Stiefel
for Novartis**
Anti-fungal
2004



Stiefel
Betamethasone Foam
Psoriasis
1999



Stiefel
Clobetasol Foam
Psoriasis
2007



Stiefel
Calcipotriene
Foam
Psoriasis
2012



**Webster's Single Dose
Vaccine Technology** 1997

**Plus other foam products and
30+ personal care products**

Perth focus

Small-scale cGMP quality manufacture and fill/finish of vaccines and sterile injectables for research and clinical trial (including formulation development); it will focus on small scale production including for individual patient treatment.

Synergies

Address current growth in clients
Accommodate existing contract growth
Extend Contract services for existing clients
Service West coast and Southeast Asia
Provide integrated onshore capability for companies locally and overseas to manufacture injectables for clinical trial in Australia; facilitating access to the RD tax incentive.



The facility will accelerate development of, and patient access to, new treatments.



Successful products developed in the facility can be transitioned to a larger scale facility for manufacture for larger trials and commercial production.

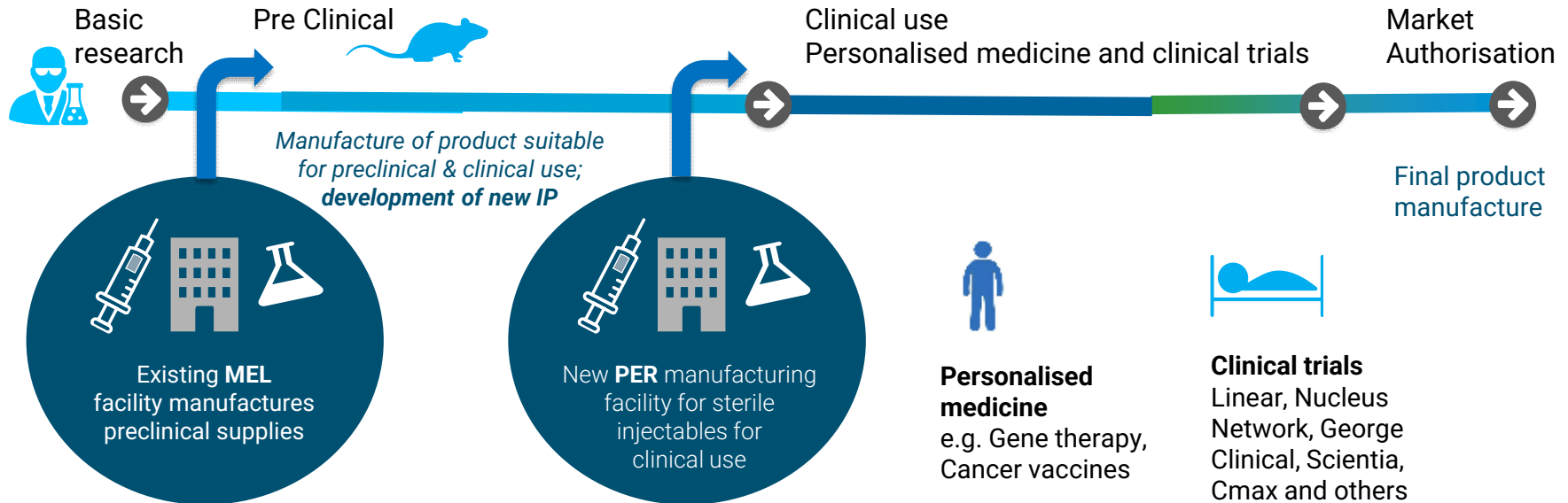
Planned Perth sterile manufacturing facility

– to supply Australian and overseas clients

Opal-Formulytica will manufacture materials for personalised medicine and clinical trials and develop its own new intellectual property
- for local and overseas clients

Drugs need extensive testing before permission to start human studies

The drug development pathway





Opal-Formulytica Products & services overview: for national and overseas clients

Manufacture of sterile injectable drug products

- Bulk formulation and aseptic fill and finish
 - Solutions
 - Specialty formulations
 - Liposomes
 - Lipid Nanoparticles

Capacity/scale

- Small-scale, flexible manufacturing facility
 - Up to 5L bulk product
 - Personalised medicine (sterile injectable)
 - Phase I (non-GMP) initially
 - Phase II (GMP) after TGA licence (~18-24 months after up and running)

Other services

- Formulation development
 - Small or large molecule, liposomes, nanoparticles
- Analytical method development and validation
- Stability Testing
- Storage and shipping of clinical trial supply drug product



Investment opportunity



June 23

Merger
announced

July 23

WA govt
grant \$5m
announced

August 23

Additional \$5m
grant application
lodged

Cap raising
opened

March 2024

**Cap raising closes
and transaction
completed**

**WA grant
commences
Apr 2024**

Opal and Formulytica:

- Perth operations commence
- Innovative product development
- Formulytica continues under existing trade name
 - Fee-for service business
 - New product development
 - New drug delivery technology development
- Personalised medicine development commence



Opal Biosciences Limited is seeking to raise
AUD\$2.5 million
to acquire Formulytica Pty Ltd and **access**
the \$5m WA grant

Summary of the offer

Share issue price: AU\$0.25 with one free attaching Option exercisable at AU\$0.25 expiring 10 October 2025

No. of Shares on issue pre-Acquisition: 26,419,838

Post-Acquisition & Post-Issue of Offer securities^f :
57,362,392

Full diluted post-Issue of Offer securities :
67,362,392

Opens: 1 September 2023
Closes: 31 March 2024

Offer open only to sophisticated and professional investors in Australia and certain wholesale investors in Hong Kong and New Zealand. For Information Memorandum and application form see www.opalbiosciences.com

^f Assumes \$2.5m raised from Issue and full \$750k debt conversion to shares as completion of Formulytica acquisition.



Outlook for FY24

LAIV

Pursue discussions re outlicence

Opal Biosciences Ltd (subsidiary)

Continued execution of plan to **establish small scale manufacturing capability for sterile liquid products including vaccines.**

- Two grant application results (due in next few months)
- Completion of capital raise (Information Memorandum to raise up to \$2.5m open to sophisticated investors)
 - Completion of Formulytica Pty Ltd acquisition
 - Access to grant and commencement of Formulytica's extension into Perth
 - Continuation of existing Melbourne-based business



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Thank you for your attendance