



AGM 2023

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30th November 2023

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



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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.



Opal-Formulytica will support Australian **R&D medicine** development and commercialisation onshore by addressing **need for sterile injectables for personalised medicine** and **clinical trials**

- a market gap exists for “small batch” manufacture
- onshore manufacture may allow companies to access to R&D tax benefit

\$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*)

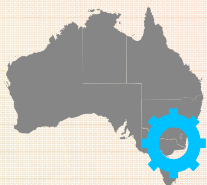


Formulytica's Current Melbourne-based capability



- **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
AUSTL)



Formulytica's Melbourne-based team

Highly Experienced Scientists

Richard Buchta PhD MBA *CEO managing director:* 26 yrs in R&D & formulation of topical, injectable & vaccine formulations & analytical method development, BD & marketing; developed 22 products launched in Aus/US & 12 patents

Michael Andrews Luke PhD *Dep Managing Director Innovation & Biologics Director:* 20 years in R&D & formulation of topical & injectable biologics & cosmetics with a focus on product & technology innovation

Billie Roughan PhD *Formulation Director:* 16 yrs in development of drug delivery formulations including scale-up & clinical trial supply

Rose Ye PhD *Analytical Director:* 20 yrs in R&D in pharmaceutical industry focused on analytical methods development, CMC & stability, and responsible for analytical development of over 60 products

Development Team *12 scientists:* Experienced in CMC development for FDA ready products; skilled in developing innovative formulations & drug delivery technologies



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
Oral	Clinical GMP supply
	Liquid
	Nasal and throat capsules



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



Formulytica a product successes

- developed by Formulytica staff &
launched



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.

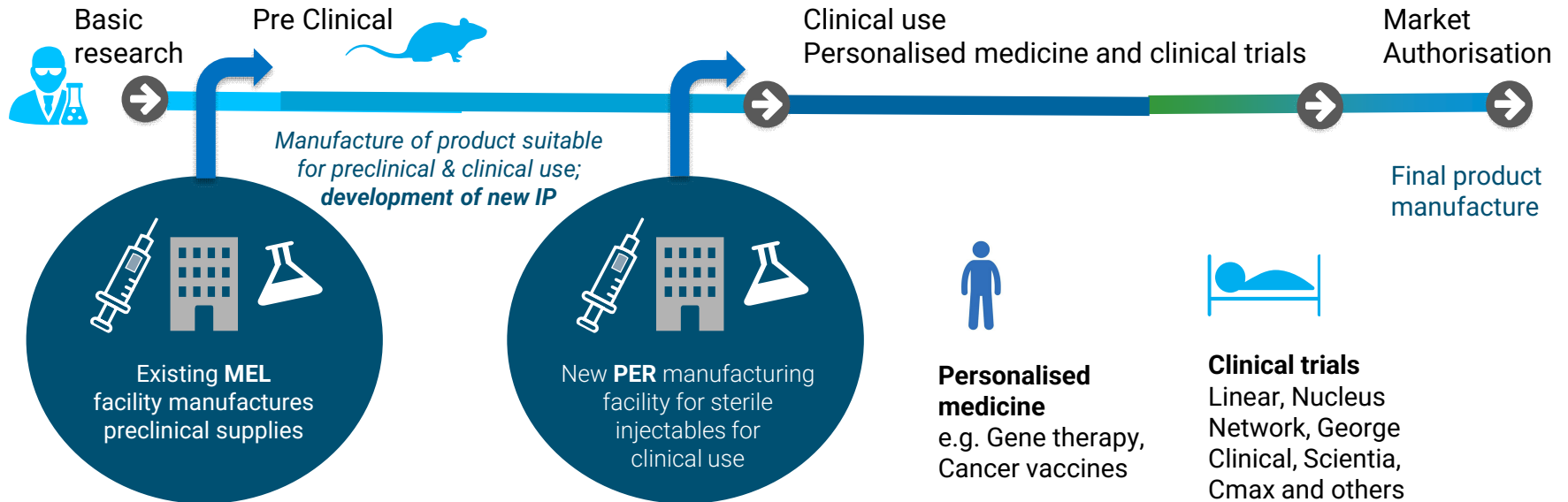
Planned Perth sterile manufacturing facility

– 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



Client focus

Assisting those transitioning from research stage to clinical trials *including personalised medicines* (Australian and overseas-based)

- Start-up companies
- University spin outs
- Universities
- Medical Research Institutes
- Established biotech/pharmaceutical companies



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:

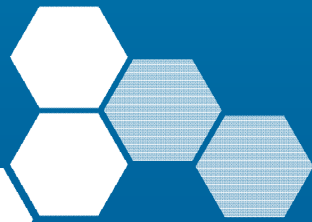
- Perth operations commence
- Innovative product development
- Formulytica continues under existing trade name
 - Fee-for service business
 - New product development
 - New drug delivery technology development
- Personalised medicine development commence



Board Management

opal
Biosciences

F O
R M ulytica[™]



Board of Directors post-Acquisition

Ken Windle Chairman	Former senior international positions at GSK including Head of Global Commercialisation.
Julie Phillips Managing director	Multinational pharma background in regulatory affairs, health economics and clinical trials
Damien Hannes Non-executive director	Finance, operations, sales and management experience in Asia & Australia
Peter Cox Non-executive director	Foundation investor and director at Formulytica with over 20 years' experience as the finance function leader with Ensign Laboratories Pty Ltd a custom and contract manufacturing chemistry business.
Dr Richard Buchta Non-executive director	Industry experience incl GSK and Stiefel developing numerous vaccines, injectables and topicals (including aerosols and foams).



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

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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