



Laboratory to clinical trial: bridging the gap in
**Australian R&D medicine
manufacturing |**

Opal Biosciences Ltd – Information Memorandum 2023

Investor Presentation 2023






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

Opal Biosciences Ltd is an Australian public company focused on growing Australia's pharmaceutical manufacturing capability. Its plan is to acquire Formulytica Pty Ltd and build new manufacturing facility.

- Agreement to acquire Formulytica Pty Ltd has been signed. Formulytica is a revenue-generating Melbourne-based product development company
- \$5 million WA government grant awarded to build a manufacturing facility in Perth for injectable products for clinical trial and personalised medicine treatment e.g. cancer vaccines.

Opal's plan extends Formulytica's existing Melbourne business and provides a new fee-for-service Perth business for local, national and international clients in the fast-growing market areas of personalised medicine and clinical trial material manufacture.

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.



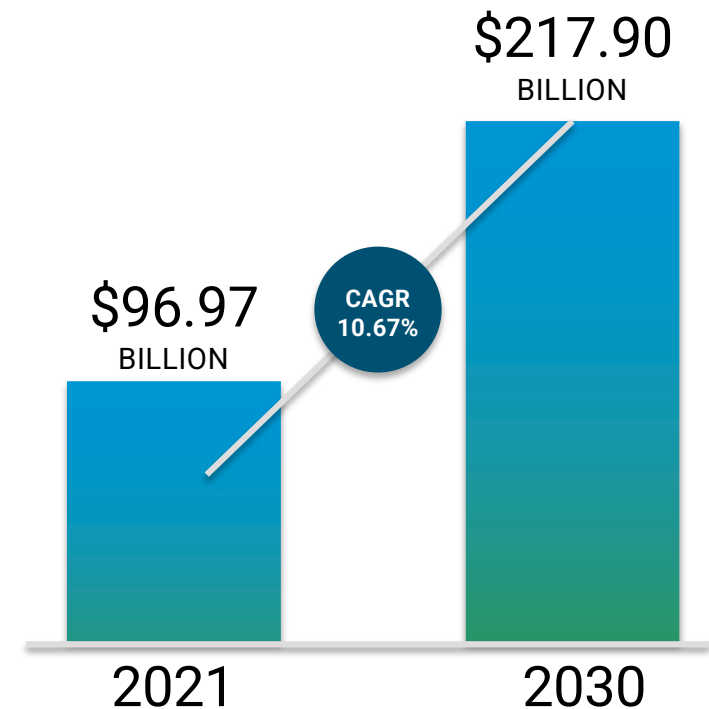
The Opal-Formulytica merged business will support Australian **R&D medicine** development and commercialisation onshore by addressing **need for sterile injectables for personalised medicine and clinical trials**

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



What is Personalised Medicine?

It is tailor-made prevention and treatment strategies for individuals or groups so patients receive the specific therapies that work best for them



Global Personalized Medicine Market Size By Product (Personalized Medicine Therapeutics, Personalized Medicine Diagnostics), Verified Market Research report, Sep 2022



nature medicine

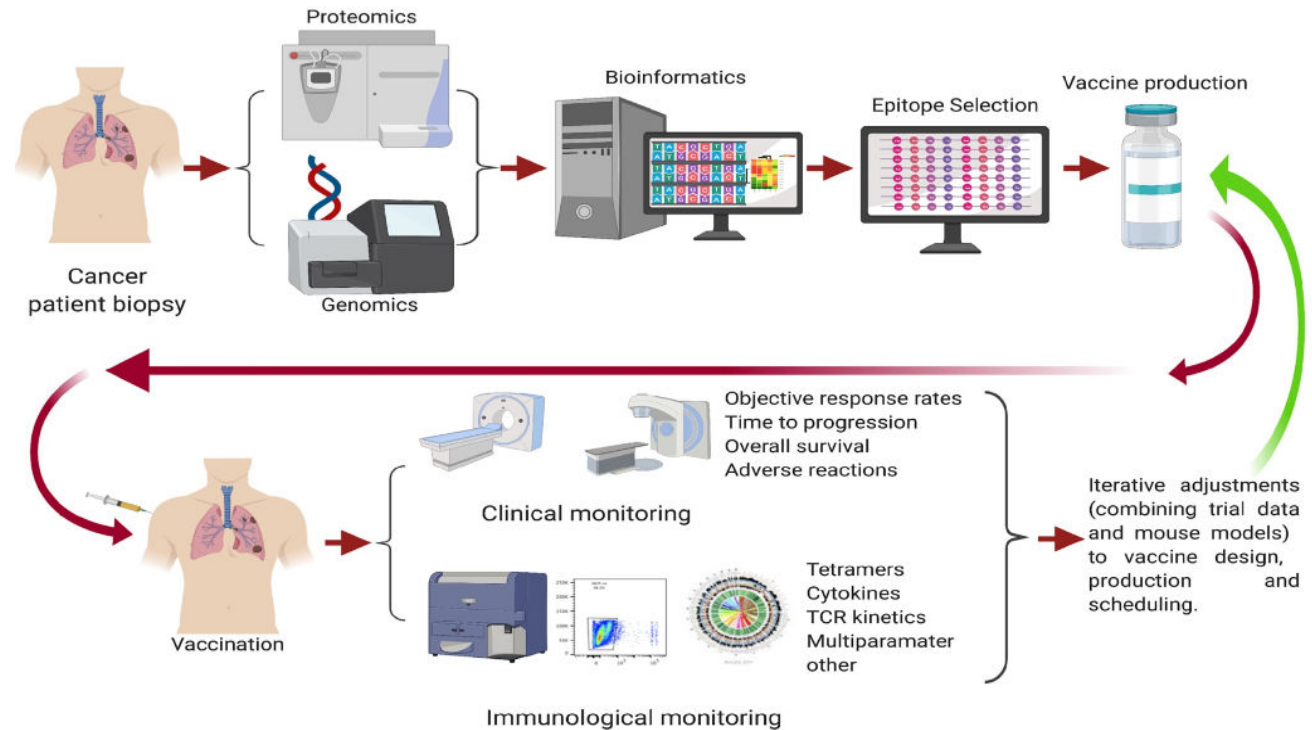
Perspective

<https://doi.org/10.1038/s41591-022-02160-z>

The next generation of evidence-based medicine






“In the era of individualized genomic medicine, N-of-1 trials are emerging as a tool to study potentially fatal rare diseases. The N-of-1 trial is a single-patient clinical trial using the individual person as a unit of investigation to evaluate the efficacy and/or adverse events of different interventions through objective data-driven criteria”

Personalised Medicine is revolutionising medicine



Cancer vaccine example: Using a patient's own tumour tissue to design a vaccine customised for an individual patient

Clinical trials are growing in Australia and require materials for administration to patients. **A market need exists.**

Metric	2015*	2019**	CAGR (2015–19)
 Expenditure	\$1.1 billion	\$1.4 billion	5%
 Employment	6,900 employees	8,000 employees	4%
 Patient participation	Not reported	95,000	N/A
 Number of trials started	c.1,360	c.1,880	7%
 Share of global industry sponsored trials	c.5%	c.5%	Nil

Note: * As calculated in *Clinical Trials in Australia* (2017) report; ** As calculated in this report



The global Clinical Trials Market size was **USD 54.24 billion in 2022.**

The market is expected to **grow from USD 57.76 billion in 2023 to USD 92.45 billion by 2030**, exhibiting a CAGR of 6.9% during the forecast period.

Fortune Business Insights Report, 31 Mar 2023, Clinical Trials Market Size, Share and COVID-19 Impact Analysis, By Phase (Phase I, Phase II, Phase III, and Phase IV), By Application (Oncology, CNS disorder, Cardiology, Infectious Disease, Metabolic Disorder, Renal/Nephrology, and Others,) and Regional Forecast, 2023 to 2030.

“Australian private equity firm Crescent Capital Partners has put its clinical research business Nucleus Network on the block, with expectations of a \$600 million-plus payday.” AFR, 30/6/2021

The Blackstone logo, featuring the word "Blackstone" in a white serif font on a black rectangular background.

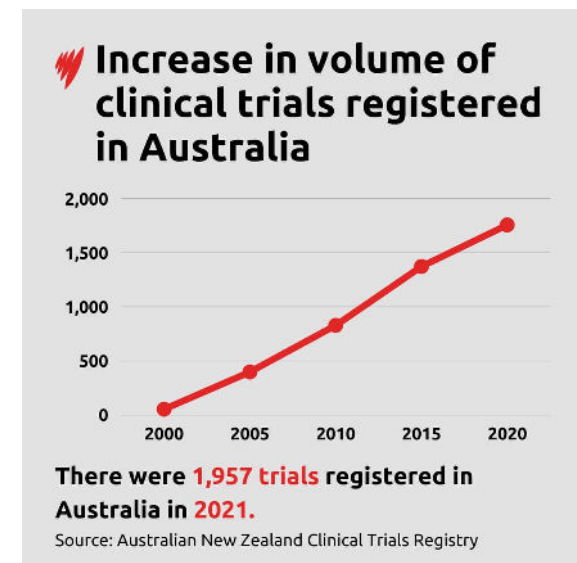
Blackstone to Acquire Nucleus Network, Australia's Largest Phase One Clinical Trials Specialist

29 October 2021

“...Australia is a globally leading destination for clinical trials supported by the country's open regulatory regime, strong talent pool, and distinguished research and healthcare facilities. Phase one trial volumes in Australia are expected to grow significantly, driven by the increasing demand from offshore biotech companies to conduct speedy and reliable trials...”

Ref: blackstone.com/news/press/blackstone-to-acquire-nucleus-network-australias-largest-phase-one-clinical-trials-specialist-2/

Australia's clinical trials are growing



“From 2006 to 2020, the number of early phase studies being conducted in Australia has **more than tripled** and in the last five years, the proportion of early phase studies has **increased from 27% in 2016 to 40% in 2020.**”

<https://www.anzctr.org.au/docs/ClinicalTrialsInAustraliaUPDATE2006-2020.pdf>

More than 15%[#] of Phase I clinical trials in Australia use research-stage injectable products

based on 43 of 256 Phase I trials in Australia as at 2 Aug 2023 per ANZCTR

The Australian Government driving support for both clinical trials and manufacturing

Boost clinical trials in Australia

Clinical Trial Determination

AusIndustry released the [R&DTI Determination for Clinical Trials](#) to simplify the registration of R&D activities and Advance and Overseas Finding applications for the biotechnology sector. Broadly, if the clinical trials satisfy the criteria set out in the Determination, those activities are eligible core R&D activities under the R&DTI. The goal of the Determination is to reduce the compliance and administrative burden of registering R&D activities that fall under this Determination, as well as providing certainty to claimants.

<https://business.gov.au/grants-and-programs/research-and-development-tax-incentive/assess-if-your-randd-activities-are-eligible/clinical-trials-determination-guide>

1 April 2022

Onshore manufacturing

The Hon Ed Husic MP

Minister for Industry and Science

A Future Made in Australia: Deepening Australia's Economic Complexity

Address to the American Chamber of Commerce Australia
23 August 2023

"Growth, jobs and the flexibility to respond to economic shocks will come from making more things in Australia."

Opal awarded \$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



Opal's Experienced Leadership team

Kenneth Windle BPharm MPS *Chairman:* Ken Windle worked 30 yrs with Glaxo/Glaxo Wellcome (now gsk) in international senior executive management positions.

Damien Hannes *Non-Executive Director:* over 25 years of finance, operations, sales and management experience in Asia & Australia.

Julie Phillips BPharm MSc MBA *Managing Director:* strong background in the biotech/pharmaceutical industry; product development; senior management roles; Chair R&D Incentive Committee (fed govt); non-executive director, MTPConnect; Council member of University of Newcastle.

Phil Leslie *Project Manager:* ex- Head of Manufacturing, GSK. 29yrs in senior roles including in UK and NZ; ran GSK's sterile manufacturing stream; led the introduction of the first commercial vaccine in blow-fill-seal technology at Boronia; received Victorian government 'Manufacturing Excellence in Victoria' award.



Formulytica's Experienced 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 Melbourne-based business to be acquired by Opal and extended to Perth, WA

- **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)

contract research development and manufacturing organisation




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
Injectable	Ointments
	Ophthalmic
	Intravenous and intramuscular delivery
Liposome technologies	Veterinary
	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 product successes

- developed by Formulytica staff &
launched



New Perth sterile manufacturing facility

– will service Australian and overseas clients

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.

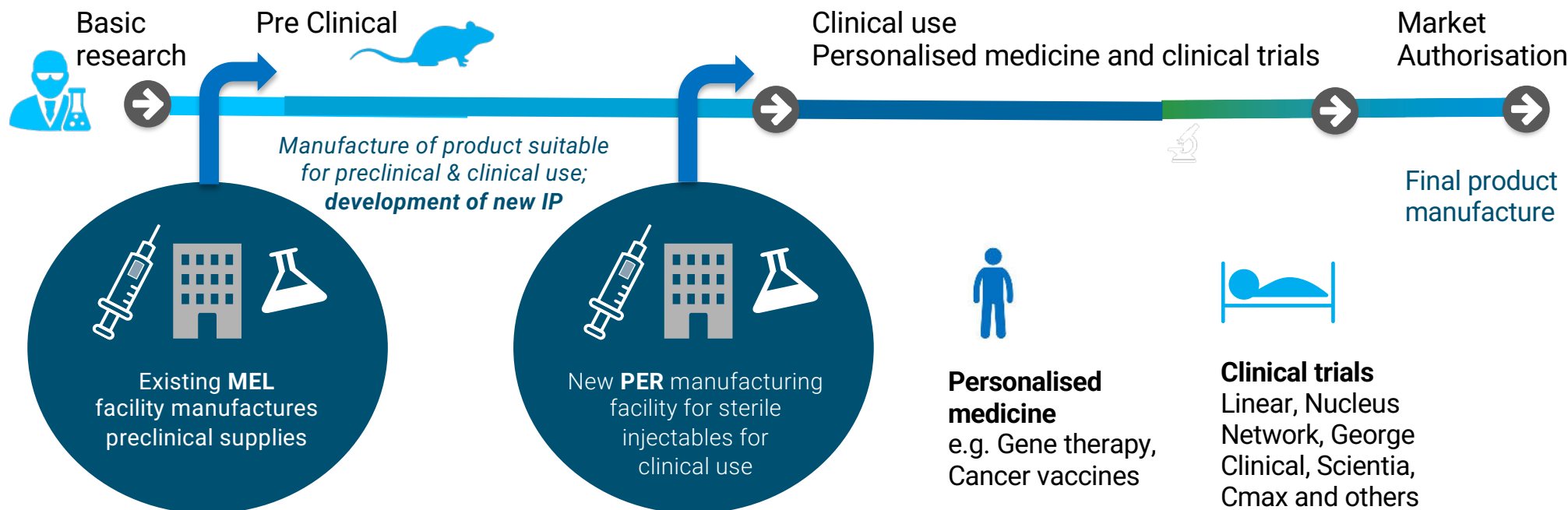


Successful products developed in the facility can be transitioned to a larger scale facility for manufacture for larger trials and commercial production.

The merged Opal-Formulytica will manufacture materials for personalised medicine and clinical trials and develop its own intellectual property

Drugs need extensive testing before starting human studies and need high quality materials

The typical drug development pathway and where Opal-Formulytica services fit in





Opal-Formulytica Products & services overview: for national & 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



Opal-Formulytica 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



Personalised Medicine

Examples include

- Personalised mRNA vaccines for patient-specific cancer targeting (partnership with University of Western Australia)
- Gene delivery for genetic disorders

Opal-Formulytica: increases sovereign capability

GMP-compliant manufacturing of injectables (including vaccines)

Formulation and development of pharmaceuticals

- Sites in Perth and Melbourne site servicing national/international clients
- Products for clinical trial (or individual patient use)
- Data e.g. stability and formulation, provided for CMC section of IND dossier



Grow client base
and projects



Additional capabilities incl
Vaccine formulation and
manufacture



Strategic partnerships in up and down
stream product development
capability



Grow existing inhouse
technology development
and commercialization



Investment opportunity





Board Management

opal
Bioscience

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.



For further information contact:

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