



Opal Biosciences Limited | ABN 97 605 631 963

2023 INFORMATION MEMORANDUM

For the capital raising of \$2.5m through the issue of 10,000,000 new Shares at \$0.25 (25 cents) per Share together with one (1) free attaching Option for every one (1) new Share having an exercise price of \$0.25 (25 cents) and expiring 10 October 2025.

This Information Memorandum is issued by Opal Biosciences Ltd ACN 605 631 963.

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2023

INFORMATION MEMORANDUM

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Important notices

Information Memorandum

This Information Memorandum ("**IM**") is dated 1 September 2023 ("**IM Date**").

This information Memorandum has been prepared by Opal Biosciences Limited ACN 605 631 963 ("**Opal**") for the purpose of providing certain financial and business information to potential investors on a private and confidential basis for use solely in connection with their consideration of investing in 10,000,000 new fully paid ordinary shares ("**New Shares**") in Opal at an issue price of \$0.25 (25 cents) per share to raise approximately \$2.5m (the "**Offer**"). Opal will also issue 1 Option for every 1 New Share subscribed to applicants whose valid application forms together with all application money are received on or prior to the close of the Offer.

The Offer of New Shares made pursuant to this IM is only available to investors to whom an offer can be made without the need for a disclosure document to be provided under the *Corporations Act 2001* (Cth) ("**Corporations Act**"). The IM is not a prospectus or product disclosure document under the Corporations Act and has not been lodged with ASIC. By retaining this IM, you represent that you are not an investor to whom disclosure is required to be made under the Corporations Act. Accordingly, the IM may not be copied or reproduced, in whole or part, for any purposes other than that for which it is intended and none of its contents may be divulged to third parties without the prior written consent of Opal.

The Offer of New Shares in Opal is being made in Australia only and has not been lodged with any regulatory authority outside Australia. This IM does not constitute an offer of shares in any jurisdiction in which, or to any person to whom, it would be unlawful to make such offer or invitation. It is the responsibility of overseas applicants to ensure compliance with all laws of the country in which they reside in relation to any application made for New Shares in Opal.

This IM does not purport to be all inclusive or contain all of the information which its recipients may require in order to make an informed assessment of whether to invest in Opal. Accordingly, this IM does not take into account the investment objectives, financial situation and particular needs of the individual investor. Before making an investment in Opal, the investor, or prospective investor, should consider whether such an investment is appropriate to their particular investment needs, objectives and financial circumstances and consult a financial, tax or legal adviser if necessary.

This IM contains forward looking statements. Statements about Opal's future operations, projections and forecasts are based on assumptions about future events and management actions which may not necessarily take place and are subject to uncertainties which may be outside the control of Opal. Opal makes no guarantees, representations or warranties regarding whether projections or forecasts will be achieved or whether they represent the most likely outcomes.

Opal and each of its agents, directors, officers and employees:

- a. does not warrant or represent the origin, validity, accuracy, completeness or reliability of, or accept any responsibility for errors or omissions in this IM;
- b. disclaims and excludes all liability for all claims of whatever nature that may arise in any way from or in connection with the provision of this IM and any inaccuracy or incompleteness, or any reliance by any person on it; and
- c. does not, by this IM, provide any recommendation, service or advice.

Important information for New Zealand investors

This document has not been registered, filed with or approved by any New Zealand regulatory authority under the Financial Markets Conduct Act 2013 (**FMC Act**). The New Shares may only be offered or sold in New Zealand (or allotted with a view to being offered for sale in New Zealand) to a person who is a wholesale investor within the meaning given to that term under Part 1 of Schedule 1 of the FMC Act.

Important information for Hong Kong investors

WARNING: The contents of this document have not been reviewed by any Hong Kong regulatory authority. You are advised to exercise caution in relation to the Offer. If you are in doubt about any contents of this document, you should obtain independent professional advice.

Definitions and abbreviations

Some words and expressions used in this IM have defined meanings, which are explained in the Glossary at the end of this IM.

All references to time in the IM are references to Melbourne (AEST) time.



Executive Summary

1 Executive Summary

This IM relates to an offer of approximately 10,000,000 new ordinary shares ("**New Shares**") in Opal Biosciences Ltd ACN 605 631 963 ("**Opal**") at a price of \$0.25 each ("**Issue Price**") to raise approximately \$2,500,000 (the "**Offer**"). Opal will also issue 1 Option for every 1 New Share subscribed to applicants whose valid application forms together with all application money are received on or prior to the close of the Offer.

The Offer is being made as a prerequisite to Opal's acquisition of Formulytica Pty Ltd ACN 605 865 825 ("**FLT**").

- The proceeds from the Offer will be used to complement the \$5 million grant awarded to Opal by the Western Australian (WA) State government through its Investment Attraction Fund.
- The grant will be used to assist Opal to establish a facility in Perth to manufacture sterile liquid pharmaceutical products suitable for:
 - personalised medicine e.g. patient-specific cancer vaccines, and
 - clinical trial supplies (i.e. the drug material administered to patients in clinical trials to test new medicines).
- This addition will expand FLT's existing Melbourne-based pharmaceutical development business.
- The merged companies will fill a growing need in the Australian pharmaceutical market for services to assist those transitioning from research stage to clinical trial development.
- The business will increase the inhouse intellectual property portfolio developed by FLT through partnerships with academic and medical research institutes.
- The expertise of FLT's scientists combined with Opal's commercial expertise will promote the revenue growth of the merged business.

FLT is a revenue-generating pharmaceutical development company which currently specialises in the formulation and development of topical, oral, ophthalmic and injectable products. FLT generates revenue from its fee-for-service business and also from royalties from licences to its innovative technology. Formulytica was formed in response to a global market demand from companies wanting to outsource their topical and injectable formulation development projects. FLT services companies who lack the internal resources, time or the skill-set to develop new formulations and prepare market-ready products.

Opal's proposed acquisition of FLT (the "**Acquisition**") represents a unique opportunity to grow a new, merged business designed to meet the significantly increased requirement for onshore manufacturing in Australia. This need has is driven by growth in clinical trials and the evolving market for personalised medicines.

Opal's new business will service overseas and local biotechnology and pharmaceutical companies wishing to conduct clinical trials in Australia and formulate product for clinical and nonclinical studies.

The new business will target the significant opportunity for preparation of personalised medicine and clinical trial supplies.

As consideration for acquiring all of the issued share capital in FLT, Opal will issue 16,109,657 Shares to FLT's existing shareholders. Following completion of the Acquisition and Offer, and assuming \$2.5 million is raised and the outstanding debt to be satisfied by the issue of Shares is \$750,000 (see Section 6.3), FLT's shareholders will hold approximately 40.84% of Shares in Opal (34.78% on a fully diluted basis).



How to apply

2 How to apply

2.1 Description of the Offer

This IM relates to the offer of approximately 10,000,000 new ordinary shares ("New Shares") at a price of \$0.25 each ("Issue Price") to raise approximately \$2,500,000 (the "Offer").

Opal will also issue 1 Option for every 1 New Share subscribed to applicants whose valid application forms together with all application money are received on or prior to the close of the Offer.

Each Option will have an exercise price of twenty-five cents (\$0.25) and expiry date of 10 October 2025. Each option will entitle the holder, upon exercise, to one fully paid ordinary Share in the issued capital of Opal. The full terms of the options are set out in section 6.

2.2 Applications

The Offer opens for Applications on 1 September 2023 ("**Open Date**").

Applications for New Shares must be made using the Application Form accompanying this IM. Payment of the New Shares must be made in full at the Issue Price, being \$0.25 per New Share.

Completed Application Forms and Application Money must reach Opal no later than 5pm (Melbourne time) on 29 September 2023 ("**Closing Date**"), subject to the Board extending the Closing Date.

2.3 Who can apply

The Offer is open to any person with a registered address in Australia who is a "professional investor" or "sophisticated investor" within the meaning of sections 708(8) or 708(11) of the Corporations Act and to wholesale investors in Hong Kong and New Zealand to whom the Offer can be made without the need for registration of an offer document (an "**Applicant**").

2.4 Allotment and Application Money

It is expected that allotment of the New Shares will take place as soon as practicable after the Closing Date. However, if the Closing Date is extended, the date for allotment may also be extended. The allocation of New Shares under the Offer will be determined at the absolute discretion of the Board.

Application Money will be held in trust for Applicants until allotment of the New Shares. Application Money will be held in a separate subscription account until allotment. This account will be established and kept by Opal in trust for each Applicant. Any interest earned on the Application Money will be for the benefit of Opal and will be retained by Opal, irrespective of whether allotment takes place, and each Applicant waives the right to claim any interest.

Where the number of New Shares allotted is less than the number applied for, the surplus money will be returned by cheque or EFT as soon as practicable after the Closing Date. Where no allotment is made, the amount tendered on application will be returned in full by cheque as soon as practicable after the Closing Date. Interest will not be paid on money refunded.

2.5 Important Dates

Offer opens	1 September 2023
Offer closes	29 September 2023
Issue date and despatch of share certificates to New Shares and Options	10 October 2023

2.6 Enquiries

All enquiries in relation to this IM should be directed to melanie.leydin@vistra.com.au.

If you are unclear in relation to any matter or are uncertain as to whether the Offer or New Shares are a suitable investment for you, you should seek professional guidance from your stockbroker, solicitor, accountant, financial adviser or other independent professional adviser before deciding whether to invest.



Opal's business

3 Opal Biosciences Ltd's business

Opal Biosciences Ltd ("Opal") is a public company registered in Victoria. Opal is a subsidiary of BioDiem Ltd ACN 096 845 993, which has an intranasal influenza vaccine technology licensed to the World Health Organisation, BioDiem Ltd receives royalties from the vaccine which is marketed in India (Nasovac-S®) and China (Defluvac®). Formulytica Pty Ltd is a private company based in Mulgrave, Victoria (see section 4).

3.1 Overview of the current and proposed Opal business

Opal's strategic focus is to grow Australia's vaccine and pharmaceutical manufacturing capability. Opal announced its proposed merger with FLT in June 2023. In July 2023 Opal announced it was awarded a \$5 million grant by the Western Australian (WA) government through its Innovation Attraction Fund (IAF). A funding agreement has been signed with the WA government which includes a schedule of payments over a five year period. The grant requires Opal to contribute matching funds to access the full government funding over the 5 year grant period.

The IAF grant will assist the merged Opal-FLT business to establish a pharmaceutical manufacturing facility in Perth for:

- research stage products for testing in preclinical and early stage (Phase I/IIa) clinical studies and
- precision medicine treatments e.g. individually tailored cancer vaccines.

The market size for Phase I clinical trial supply of research-stage sterile injectables for trials conducted in Australia each year is approximately \$12 million¹. As at 2 August 2023, more than 15% of clinical trials registered on the Australian and New Zealand clinical trial registry (ANZCTR) were Phase I studies using research-stage injectable products². The compound annual growth rate (CAGR) of the global market for clinical trials is estimated at 6.9%³ driven by the rising number of clinical trials globally and the increasing prevalence of chronic diseases heightening the demand for the development of efficient therapeutics. From 2006 to 2020 the number of early phase studies being conducted in Australia more than tripled, and between 2016 and 2020 the proportion of early phase studies increased from 27% to 40%⁴. (see section 3.2.1).

The personalised medicine market is emerging with the personalised medicine therapeutics segment projected to have the fastest CAGR of an estimated 10.7%⁵. (see section 3.2.2)

¹ Based on number of Phase I clinical trials registered in ANZCTR as at 2 Aug 2023 and requiring research-stage sterile injectables, using in-house costing.

² ANZCTR results as at 2 Aug 2023 showing 256 Phase I studies with 43 using research-stage sterile injectables.

³ 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*.

⁴ www.anzctr.org.au/docs/ClinicalTrialsInAustraliaUPDATE2006-2020.pdf

⁵ Grandview Research Report, 2023, *Personalised Medicine Market Size, Shares and Trends Analysis Report by Product, (Personalised Medicine Therapeutics, Personalised Medical Care, Personalised Nutrition and Wellness), by Region, and Segment Forecasts, 2023 to 2030*.

In addition to penetration of these growing markets, the Opal-FLT business will provide services for preclinical product manufacture, contract formulation development, analytical method development and validation to augment the existing revenue-generating Melbourne-based business with its strong CMC⁶ capabilities (see Fig 1).

Once established, the new Perth-based arm of the Opal-FLT business will provide flexible and high speed turnaround manufacture of sterile injectable products at small scale e.g. personalised products for individual patients and early stage clinical trials. The facility's capability for quick turnaround will allow high throughput of a number of manufacturing campaigns, such as multiple small batches of personalised medicines including vaccines. There is a gap in the Australian market for this contract manufacturing capability.

It is expected that revenue will grow through expansion of the existing Melbourne fee-for-service business (formulation development, analytical chemistry, stability testing for topical, oral, ophthalmic and injectable products) to include small scale sterile injectable products as described. In addition, the novel technology development opportunities will increase and will expand the existing commercialised royalty-producing technology portfolio.

The new capability to be established in Perth will boost assistance to those groups transitioning from research stage to clinical trials and will include both Australian and overseas based clients. In particular start up companies, university spin outs, university groups, medical research institutes and established biotech and pharmaceutical companies will benefit from this expansion. The Opal-FLT existing network and client base includes companies and organisations across the full spectrum of pharmaceutical product research, preclinical and clinical development, manufacture and commercialisation. The network includes service providers in regulatory affairs, clinical research, pharmacoeconomics, international marketing and promotion.

In July 2023 in partnership with the University of Western Australia (Professor Archa Fox, Prof Jenette Creaney, Prof Bruce Robinson and Assoc Prof Alec Redwood), Opal and FLT submitted an application to the Medical Research Future Funds (MRFF) National Critical Research Infrastructure grant program requesting \$5m. This application proposes development of personalised medicines for cancer vaccines in the manufacturing facility to be established in Perth. The outcome of this grant application is expected in early 2024.

On successful completion of this capital raising the merger with FLT will be effective and access to the \$5m WA IAF grant will commence.

⁶ Chemistry, Manufacturing and Quality Controls (an essential part of regulatory compliance) (see Fig 2)

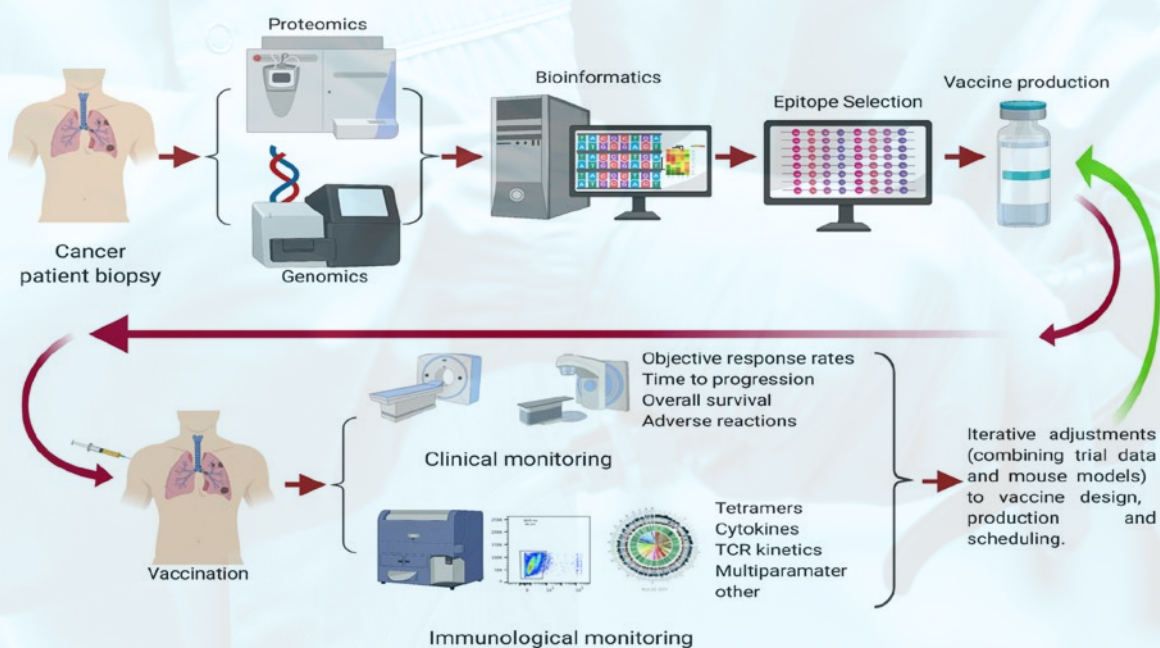
\$5m from the Western Australian Investment Attraction Fund

Grant awarded for establishment of
small scale sterile liquid pharmaceutical
manufacturing facility in Perth



Personalised Medicine is revolutionizing medicine

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



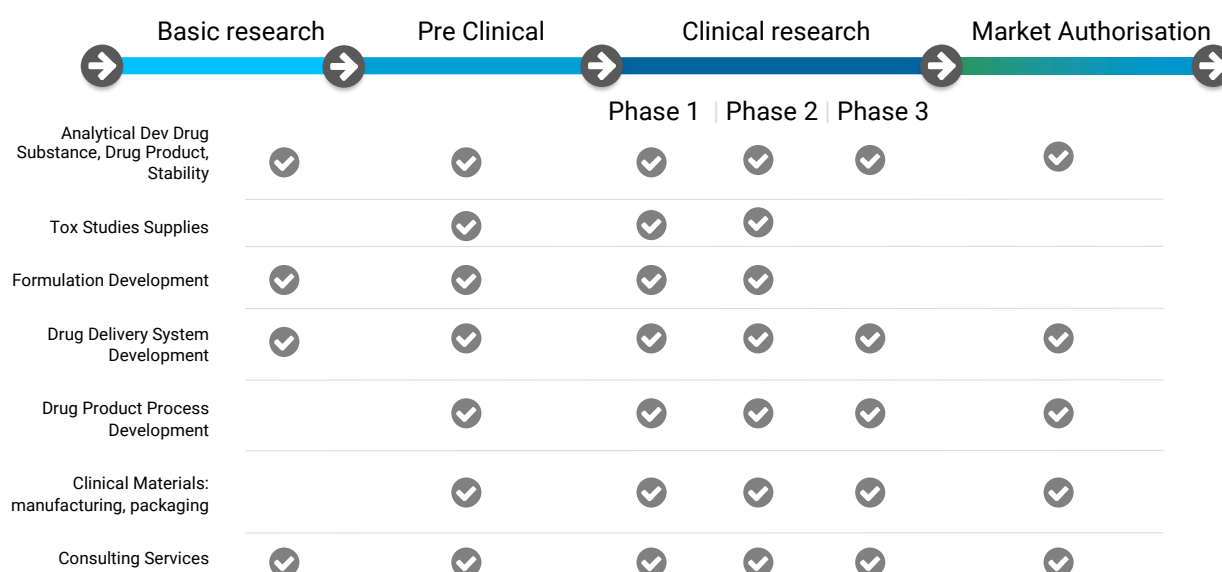


Fig 1 (above): The importance of CMC Services across drug development

Overview of the industry

The Australian biotechnology and pharmaceutical industry is knowledge-based, and technology-intensive. It plays a critical role in research and development of new medicines aimed to extend life or improve its quality. It does this through partnerships with local and international universities, researchers and other biotechnology companies targeting unmet clinical need. The pharmaceutical industry has a global network, allowing access, sometimes transnational, to the resources and capabilities needed in the often highly sophisticated development needs of a innovative new medicine.

To be approved for widespread use, a new medicine must undergo a series of tests which can take many years. The final stages of testing include studies in humans to verify the right dosage and to measure efficacy and detect any side effects. These studies or clinical trials are staged carefully to minimise harm to trial participants. Clinical trials can provide patients with early access to new and potentially life-saving medicines.⁷ There are many reasons for overseas and local companies to conduct clinical trials in Australia: our world-class medical system of medical professionals and healthcare structure, a rigorous, sophisticated and efficient regulatory review system, access to the R&D Tax Incentive program, high ethical standards and a well-tuned clinical trial infrastructure.

There are three main drivers for growth in the Australian new medicine or therapeutic product development area providing the opportunity to grow the Opal-FLT business: clinical trials, personalised medicine and onshore manufacturing focus. These drivers support the basis for the proposed Opal FLT merger with the successful \$5m WA grant to address the current gap in manufacturing capability in Australia.

⁷ <https://www.medicinesaustralia.com.au/policy/clinical-trials/>

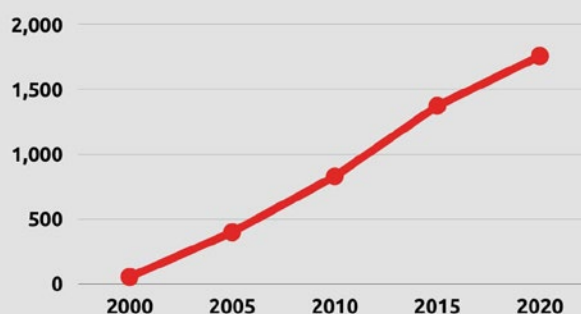


Australia's clinical trials are growing

LATEST UPDATE OF THE
**CLINICAL TRIALS
LANDSCAPE IN
AUSTRALIA** (2006-2020)



Increase in volume of clinical trials registered in Australia



There were **1,957 trials** registered in
Australia in **2021**.

Source: Australian New Zealand Clinical Trials Registry

"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-sage injectable products

based on 43 of 256 Phase I trials in Australia as at 5 August 2023 per ANZCTR

3.2.1 Clinical trials

Australia is a growing and highly attractive jurisdiction to conduct clinical trials. On 1 April 2022 the federal government's new R&D Tax Incentive determination for clinical trials came into effect. This determination means clinical trials automatically qualify for the Australian R&D tax incentive giving companies certainty about their eligibility for the tax incentive. The incentive will grow the ecosystem significantly by attracting even more overseas clinical trials.

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.

The global clinical trials market size was estimated to be more than US\$54 billion in 2022 and expected to grow to more than \$92 billion by 2030 with a CAGR of 6.9%⁸.

The Australian government has invested in facilities and training, and promotion of Australia's capability to conduct clinical trials.⁹ According to the Australian and New Zealand clinical trial registry (ANZCTR) report¹⁰ from 2006 to 2020 the number of early phase studies being conducted in Australia more than tripled and in the five years 2016-2020 the proportion of early phase studies increased from 27% to 40%. The report found that compared to other countries clinical trial activity in Australia was higher than in France, Germany, the UK and USA. The MTP Connect Report on Australia's Clinical Trials Sector¹¹ in 2021 showed 1880 clinical trials started in Australia in 2019 with more than 95,000 Australians participating.

⁸ <https://www.globenewswire.com/news-release/2023/03/31/2638483/0/en/Clinical-Trials-Market-Size-Expected-to-Reach-USD-92-45-billion-at-a-CAGR-of-6-9-by-2030.html>

⁹ australianclinicaltrials.gov.au/why-conduct-clinical-trial-Australia

¹⁰ <https://www.anzctr.org.au/docs/ClinicalTrialsInAustraliaUPDATE2006-2020.pdf>

¹¹ https://www.mtpconnect.org.au/images/MTPConnect_Australia%27s%20Clinical%20Trials%20Sector%20report%202021.pdf

The report estimates that clinical trials contributed approximately \$1.4 billion to the Australian economy through direct expenditure or investment in 2019 which is up 6.5% per annum from \$1.1 billion in 2015. The expenditure on industry sponsored clinical trials increased from 4.8% per annum since 2015 to approximately \$1.1 billion in 2019. This growth in its economic value is explained predominantly by the growth in the number of industry sponsored trials during the period. Non-industry organisations such as universities hospitals and MRI 's also conduct clinical trials. Expenditure by non-industry groups was estimated at \$288 million in 2019 up from \$165 million in 2015. This expenditure came from government grants and the MRFF as well as philanthropic sources, other government sources and grants, etc.

3.2.2 Personalised (precision) medicine

Personalised (precision) medicine is an emerging approach to disease treatment and prevention which is gaining significant traction within clinical medicine. The global market is predicted to reach ~US\$140b by 2028 growing at a CAGR¹² of 11.5% 2021-2030¹³. Australia is investing significantly in genomic medicine including through the Genomics Australia initiative and the Precision Oncology Screening Platform Enabling Clinical Trials initiative, known as PROSPeCT which was launched on 27 July 2023 and represents a \$185 million investment¹⁴.

In cancer, precision medicine uses genetic and molecular profiling to guide and select the best treatment for an individual patient. mRNA cancer vaccines are examples of precision, or personalised medicine, where genetic profiles (mutations) of an individual patient's tumour can be used in vaccine design to train the immune system to target the cancer. "Off the shelf" mRNA cancer vaccines are also under investigation for broader patient application¹⁵. The mRNA approach offers many potential advantages over peptide-based approaches, such as high potency, safe administration, rapid development times and cost-effective large-scale manufacturing¹⁶.

The successful development of a precision medicine product requires a range of highly specialised and trained personnel with an understanding of the stringent regulatory and quality requirements demanded by the regulators. Often the GMP standards required for precision manufacturing can be critically important - the products can have limited shelf life, strict temperature requirements, sensitivity to contamination and necessitate close involvement of the patient for sample collection and distribution. This sets it apart from standard pharmaceutical production where well established, increasingly automated, techniques are used to produce large batch quantities of drug. For precision medicine products, trained clean room staff are required and the small batches generally will have many manual manufacturing and QC requirements.

¹² Compound Annual Growth Rate

¹³ Report, *Precision Medicine Market Size to Hit US\$140.69 BN by 2028*, BioSpace, 11 Mar 2022.

¹⁴ <https://www.omico.com.au/news/185-million-investment-to-fast-track-treatments-for-rare-and-untreatable-cancers/>

¹⁵ Unlocking the potential of vaccines built on messenger RNA, *Nature* 574, S10-S12 (2019)

¹⁶ Miao et al. *mRNA vaccine for cancer immunotherapy*, *Molecular Cancer* (2021) 20:41

3.2.3 Onshore manufacturing focus

The COVID-19 pandemic raised the awareness of Australia's exposures to gaps in manufacturing ability and risks from supply chain disruption. Initiatives to encourage manufacturing have been offered by state and federal governments. Federal initiatives included the \$1.3 billion Modern Manufacturing Initiative¹⁷, the Victorian government's \$60 million Manufacturing and Industry Development Fund and more recently the \$15 billion National Reconstruction Fund¹⁸. Manufacturing to the quality standards required for personalised usage and clinical trial success is complex, capital intensive and requires adequate documentation to support eventual product approval. This is particularly the case with injectables and even more so with vaccines. As a result, there is both domestic and international demand for contract manufacturers who have the necessary skills and facilities (including fill/finish) to provide these services to clinical researchers, companies and others approaching the clinical usage or trial phase of product development.



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.

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

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

The Hon Ed Husic MP | Minister for Industry and Science

23 August 2023 | Address to the American Chamber of Commerce Australia

¹⁷ <https://www.industry.gov.au/news/modern-manufacturing-initiative-and-national-manufacturing-priorities-announced>
¹⁸ <https://www.minister.industry.gov.au/ministers/husic/media-releases/national-reconstruction-fund-board-announced>

Blackstone

29 October 2021

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

"...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..."

Currently in Australia, the capabilities and infrastructure for small scale sterile liquid injectable and vaccine manufacturing and fill/finish are scarce. In some cases, for individual patient scale or very small scale trials, hospitals are used for manufacturing, requiring upskilling and implementation of QA systems and QC processes. These constraints frequently preclude this approach. Meanwhile, existing contract manufacturers prefer higher volume batch production for profitability due to the cost and complexity of requirements for cGMP manufacture of sterile injectables, even if for investigational use¹⁹.

Australian researchers and companies commonly rely on overseas manufacturers to produce their clinical trial materials. The consequences are delays, risk and expense: lead times can be uncertain and long, and costs high due to demand, exchange rates and shipping.

¹⁹ PICS guide to good manufacturing practise for medicinal products annexes – see Annex 13 <https://www.tga.gov.au/sites/default/files/gmp-guide-annexes.pdf>

3.3 Opportunities for diversification

Opal has identified a commercial opportunity to acquire FLT. Details of the proposed Acquisition are set out in Section 3.7 of this IM.

In addition, Opal is exploring other potential commercial opportunities for diversification. Opal's ability to identify, progress and realise any opportunities will depend on a number of factors, including the availability of funding from investors, government grants and other sources; the development and continuation of government policies supportive of the biotechnology and pharmaceutical industry in Australia; and the maintenance of a robust and respected regulatory system in Australia.

3.4 Capital structure

The details of the ownership of Shares and Options as at the IM Date is:

Shares issued as at the IM Date	26,419,838
Number of New Shares to be issued under the Offer	10,000,000
Maximum Number of Shares to be issued to satisfy outstanding debt (see Section 6.3)	4,832,897
Number of Shares issued to FLT shareholders as consideration for the Acquisition	16,109,657
Total Shares	57,362,392
Options on issue as at the IM Date	10,000,000
Number of Options to be issued under the Offer	10,000,000
Total Options	
Full diluted post-Issue of Offer securities	67,362,392

The Company's Top 10 Shareholders are:

The Company's Top 10 Shareholders are:		
BIODIEM LIMITED	55%	14,610,234
PJT HOLDINGS PTY LTD <ATF THE PJT TRUST>	8%	2,225,000
SUBTECH INTERNATIONAL PTY LTD <SUPER FUND A/C>	4%	1,065,001
INVIA CUSTODIANS PTY LTD <SNOWBALL SUPER FUND (1) A/C>	4%	925,851
HENRY KENNETH WINDLE	3%	791,065
DR. PETER MICHAEL MILNE CHOMLEY	3%	698,522
AG & E JENZEN PTY LTD NO2 SUPERANNUATION FUND	3%	666,666
S & D MAHNKEN <ATF THREE FISH TRUST>	2%	550,000
DR DAVID KWOK PO LI	2%	500,000
D A HANNES	2%	500,000
CARDINAL STRATEGIES INC.	2%	500,000
LESLIE FAMILY PTY LTD	2%	400,000
REGINALD JAMES CHANDLER	1%	310,000
JKL DEVELOPERS PTY LTD <PHTCFT A/C>	1%	260,000
LIU CHEE MING	1%	250,000
MAXVALUE INVESTMENTS LIMITED	1%	250,000
OTHERS	7%	1,917,499
	100%	26,419,838

3.5 Opal's current Board of Directors and Management team

3.5.1 Board of Directors

Kenneth Windle *Chairman, BPharm, DipEc, MPS* : Ken Windle worked 30 years with Glaxo/ Glaxo Wellcome (now gsk) in International positions including Member of the Group's Executive Committee. This career included Head of Global Commercialisation based in London, CEO of subsidiaries in UK, Australia, and Regional President Asia Pacific. He was Chairman and CEO of Advent Pharmaceuticals Pty Ltd which he co-founded in 2001 and sold in 2018. He was Director of Aus Bio Ltd, Chairman of their R&D Committee, Deputy Chair of Acrux, and NED of NZ Pharmaceuticals. He served 8 years as a Member of Innovation Australia which included Chairman of the Board's COMET and P3 Committees, member of IIF Committee, and PISG Working Group. He was Chairman of the working group in Victorian Govt's. Biotechnology Strategic Development Plan. Graduating from Otago University in Pharmacy and pharmacology, he further studied Economics at Massey University, and completed the Executive Programme at London Business School. Mr Windle has previously served as Consultant to the (Australian) Prime Minister's Science Council on Industry Development, Director of the (Singapore) Economic Development Board EDB, and (Singapore's) Committee on Competitiveness. He was for 2 three-year terms Chairman of the APMA (now Medicines Australia), a member

of the Pharmaceuticals Industry Advisory Committee, a member of Pharmaceuticals Industry Action Agenda (PIAAG), member of the Pharmaceuticals Industry Strategy Group (PISG), and has been twice a winner of the Governor of Victoria's Export Prize.

Julie Phillips *Managing Director, BPharm, MSc, MBA, MPS, MAICD*: Ms Julie Phillips is a strong advocate for the Australian biotech and pharmaceutical industry. With more than 25 years experience as the CEO /Director of start-up biotechnology companies following a background in pharmaceutical multinationals. As CEO of Biodiem Ltd she negotiated the LAIV influenza vaccine licence to the World Health Organisation, and commercial licences to the Serum Institute of India and Changchun BCHT Biotechnology Ltd (China); and many Australian and international research agreements including with the US Centers of Disease Control and Prevention (CDC). Julie is CEO of BioDiem Ltd (a royalty-receiving company, Opal's parent company). She is Chairman of Industry Innovation and Science Australia's R&D Incentives Committee, until Feb 2020 was Chairman of AusBiotech Ltd, the peak biotechnology industry association in Australia, and is currently a non-executive director of the Medtech and Pharma Growth Centre, MTP Connect. Julie is a member of the University of Newcastle's Council, and the steering committee of the Australian Antimicrobial Resistance Network.

Damien Hannes *Non-Executive Director*: Mr. Hannes has over 25 years of finance, operations, sales and management experience. He has most recently served over 15 years as a managing director and a member of the operating committee, among other senior management positions, for Credit Suisse's listed derivatives business in equities, commodities and fixed income in its Asia and Pacific region. From 1986 to 1993, Mr. Hannes was a director for Fay Richwhite Australia, a New Zealand merchant bank. Prior to his tenure with Fay Richwhite, Mr. Hannes was the director of operations and chief financial officer of Donaldson, Lufkin & Jenrette Futures Ltd, a US investment bank. He has successfully raised capital and developed and managed mining, commodities trading and manufacturing businesses in the global market. He holds a Bachelor of Business degree (NSW University of Technology) and completed the Institute of Chartered Accounts Professional Year before being seconded into the commercial sector. From 2009 to 2019 Mr Hannes was a non-executive director of Sundance Energy Australia Ltd (ASX) and Sundance Energy Inc (NASDAQ) after a re-domicile to the US. Mr Hannes was Chairman of the remuneration committee and a member of the audit committee in his time on the board at Sundance Energy. Mr Hannes has held various other Directorships in other private businesses in a capacity as Chairman and as a non executive Director. Mr Hannes is Chairman of BioDiem Ltd, Opal's largest shareholder.

[See section 3.8 for the proposed Opal board membership after the acquisition of FLT.](#)

3.5.2 Company secretary

Melanie Leydin: Managing Director, Australia, Vistra

Melanie Leydin has over 25 years' experience in accounting and corporate secretarial functions including extensive experience in relation to public responsibilities including the ASX and ASIC.

Melanie was the founder and Managing Director of Leydin Freyer (LF), a corporate governance, accounting and company secretarial services firm for 21 years. LF was acquired by Vistra in late 2021.

Melanie holds a Bachelor of Business (Accounting and Corporate Law) from Swinburne University. A member of the Institute of Chartered Accountants and Fellow of the Governance Institute of Australia. A registered Company Auditor.

3.6 Formulytica Pty Ltd

Formulytica Pty Ltd ACN 605 865 825 ("FLT") is a product development business established in 2015 and based on the premises of Ensign Laboratories Pty Ltd in Mulgrave, Victoria. FLT was founded in 2015 and has 12 employees, all of whom are scientists.

FLT has a US FDA regulatory standard level focus and quality systems. It has two business segments:

- Fee-for-service contract services providing expert pharmaceutical formulation development and analytical method development and validation services to clients globally. FLT provides end-to-end support for topical therapeutic product R&D and production (human and veterinary), and personal care products. Its expertise focuses on topical, injectable, (incl. ophthalmic), and oral applications. The customer base includes local and overseas companies and organisations for development projects including preparation for clinical trial supply. FLT also has some personal care product clients.

FLT's client base has included local and overseas-based startup companies and university spinouts, universities and medical research institutes, and established biotech/ pharmaceutical companies. Examples of clients include:

- Singapore research institutes - four projects
- US mid-size pharmaceutical companies - four projects
- Australian pharmaceutical and biotechnology companies, also personal care – more than 16 products developed and launched

FLT's Injectable drug development capabilities include:

- 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.
- Innovative products (patent-protected and royalty earning): FLT-owned products and licensed novel delivery and formulation technology. Between the members of FLT's team, they have developed 20+ pharmaceutical products launched in US, EU and Australian markets.
 - FLT currently has three patent applications in prosecution.

Investment is required to scale-up to meet the growing demand for its services. Opal's \$5 million WA government grant will assist Opal and FLT to establish a manufacturing facility in Perth focusing on personalised medicine and clinical trial ready materials.

Its focus will be on the formulation development and manufacture (including fill/finish)²⁰ of sterile pharmaceutical injectables for

- Australian companies and researchers to accelerate development of their discoveries, and
- international clients who wish to conduct their clinical trials in Australia and have product made here.

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

A research program for personalised mRNA vaccines for patient-specific cancers is the subject of an MRFF (Medical Research Future Fund) grant application with the University of WA as a partner.

3.7 Overview of the Acquisition

Opal's expertise in full product development (from discovery stage to clinical trials, market access and marketing), reputation and contacts in the pharmaceutical and biotechnology industries will assist FLT hone its growth strategy and implementation, facilitate its promotion and provide a structure for raising the investment required. In return, FLT will provide Opal with a revenue-generating business, and the skills and capability of its R&D staff in its current Melbourne based laboratory and also to grow its Perth based facility. Both companies will promote development of future products where the merged entity owns the intellectual property rights. This will include discovery projects in the antimicrobial area. There is significant opportunity in the Australian marketplace to grow manufacturing capability. The gaps associated with the COVID-19 pandemic have highlighted the need for broader-based onshore manufacturing.

Opal and FLT have executed a share purchase agreement whereby subject to a condition precedent²¹, Opal would acquire all of the shares in FLT. The consideration for the Acquisition of shares in FLT will be the issue of 16,109,657 Shares in Opal. FLT would be a wholly owned subsidiary of Opal. Following completion of the Acquisition and Offer, and assuming the entire \$2.5 million is raised and the outstanding debt to be satisfied by the issue of Shares is no more than \$750,000 (see Section 6.3), FLT's shareholders will hold approximately 40.84% of Shares in Opal (34.78% on a fully diluted basis). The merged entity would commence the program to establish the Perth facility through access to the \$5 million WA grant.

²⁰ Fill means to fill the vials or syringes. Finish includes labeling, packaging and quality inspection before the drug product leaves the manufacturer.

²¹ \$2m capital raise



Products and activities: for current local 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

The aim of the merged entity is to grow existing Melbourne-based FLT services and add new sterile manufacturing capability in the Perth facility, achieved by:

- establishing a manufacturing facility in Perth for personalised medicine and sterile injectable pharmaceuticals for clinical trials (small scale and sterile manufacture [up to 50kg batch size]);
- broadening FLT's customer base (locally and internationally);
- promoting its formulation expertise including in topical products especially aerosol foams (where FLT is a world leader), aerosols, liposomes and injectables;
- increasing throughput by extending and deepening the range of work undertaken across the full product development cycle in the discovery, preclinical and clinical areas;
- extending product development areas e.g. assay development, preclinical/clinical trial supplies;
- increasing revenue from royalties through innovative in-house product development and product candidates (with ability to access R&D tax incentive); and
- position the company for acquisition/ASX-listing.

3.8 Opal Board membership post-Acquisition

Following the Acquisition, the composition of Opal's Board will change and will comprise:

Ken Windle – Chairman;

Julie Phillips – Managing Director;

Richard Buchta – Executive Director;*

Damien Hannes – Non-Executive Director; and

Peter Cox – Non-Executive Director.*

**Appointed as Director following the Acquisition*

Richard Buchta will join the Board as an Executive Director

Richard Buchta PhD, Managing Director: Richard Buchta, Director and Managing Director of Formulytica, is a PhD qualified scientist with 30 plus years' experience in biotechnology, pharma and personal care industries. Richards previous employers in include, GSK, Stiefel, Connetics, Wyeth, AstraZeneca and Arthur Websters. His experience in the industry covers R&D of new products, manufacturing, regulatory and marketing. He worked on and led teams that developed over 30 products that reached market in US, Australia and Europe, in particular vaccine range under a patented technology brand SingVac and numerous topical products (eg. Rogaineä) incorporating aerosol foam technology. He is co-inventor on 15 patents and author of 40 publications. Richard's consulting services are sought widely. He is also a senior lecturer at University of Melbourne in the Master of Biotechnology course.

Peter Cox will join the Board as a Non-Executive Director.

Peter Cox B. Com (Melb) CA, is a Director of Formulytica Pty Ltd and has been involved since the company was formed as both a director and a shareholder. Peter is also a shareholder in and the Finance Director of Ensign Laboratories Pty Ltd a role he has held for more than 20 years. Peter is highly experienced in the management and control of manufacturing businesses and has overseen the growth of Ensign's contract manufacturing business to 400+ full time equivalent employees. Ensign is a custom and contract manufacturing chemist based in Melbourne specializing in therapeutic liquid products for local and export markets. Ensign is recognized for its leading quality systems and modern manufacturing technologies.

Other Key Executives:

Michael Andrews Luke PhD, *Innovation & Biologics Director*

Michael completed a PhD in cell biology at the University of Melbourne, and has 20 years' experience leading innovative projects in the biotechnology, pharmaceuticals, and cosmetics industries. Michael is currently Innovation and Biologics Director at Formulytica, and his previous employers include Aesop, Arana Therapeutics, GlaxoSmithKline, and Immunexus. Through his career he has developed a number of skin care products that were successfully launched on the market, and has developed several topical and injectable drug formulations that have entered clinical trials. He has been a key inventor on a number of patent applications involving new drug discovery and delivery technologies, including formulations to enable the transport of large molecule drugs (biologics) through the skin and the gut, an engineered bispecific antibody technology for enhancing cancer therapy, and a nanoparticle-based delivery system for siRNA therapeutics.

Philip Leslie – *Project Lead*: Ex-GSK Head of Manufacturing, Boronia, Australia (Vic) for 29 years in senior management roles. Philip ran the Sterile manufacturing stream operating eight filling lines 24 hours per day 6 days/week and led the introduction of the first commercial vaccine in blow-fill-seal technology at Boronia and was recognised by the Victorian government for his contribution to 'Manufacturing Excellence in Victoria'. Philip has also worked at pharmaceutical plants in the UK and NZ.



Details of the Offer

4 Details of the Offer

4.1 Overview of the Offer

This IM relates to the offer of approximately 10,000,000 new ordinary shares ("New Shares") at a price of \$0.25 each ("Issue Price") to raise approximately \$2,500,000 (the "Offer").

The total number of Shares on issue at completion of the Offer is expected to be 57,362,392 (including 16,109,657 Shares issued to FLT's shareholders as consideration for the Acquisition) and all Shares will rank equally with each other. On a fully diluted basis the number of Shares on issue will be 67,362,392. The New Shares offered under this IM will represent approximately 17.43% of the Shares on issue on completion of the Offer.

A summary of the rights attaching to the Shares (including the New Shares) and Options are set out in Section 6.1.

4.2 Proposed use of funds

Funds raised from the issue of New Shares will be used to complement the \$5m WA grant funding to establish fee-for-service sterile pharmaceutical manufacturing facility in Perth, to fund the transaction costs associated with the Acquisition, and the expansion of FLT's contract manufacturing and innovative businesses, and to provide Opal with working capital to continue the development and operation of the merged company's business. Specifically, the proceeds from the issue of New Shares under the Offer will be used as follows:

Use of proceeds	\$ Amount	% of proceeds
Transaction costs associated with the Acquisition	20,000	0.8%
Proposed sterile/GMP facility construction and fit-out	2,105,000	88.2%
General working capital	350,000	10%
Costs of the Offer	25,000	1.0%
Total	2,500,000	100%

4.3 Underwriting

The Offer is not underwritten.

4.4 Minimum Subscription

The minimum subscription amount is \$2,000,000 ("**Minimum Subscription**"). If the Minimum Subscription amount is not reached, any Application Money received by Opal will be returned in full (without interest) to Applicants.





Risk factors

5 Risk factors

Investors should carefully consider the risks in this Section 5, in light of their personal circumstances (including financial and taxation issues) and obtain professional investment advice from their accountant, lawyer or other professional adviser before deciding whether to invest in Opal.

There are a number of risks and uncertainties that could potentially impact upon the future operating and financial performance of Opal, its investment returns and the value of the New Shares. These risks are both specific to Opal and also relate to the general business and economic climate. Following the Acquisition, the risks and uncertainties may affect the merged Opal -FLT business. References to Opal and its business should be read as including references to FLT and its business following the Acquisition.

Opal has taken steps to put in place safeguards, appropriate governance, and compliance and risk management frameworks to mitigate risks, but it cannot guarantee that these safeguards and systems will be effective. There are risks that are outside the control of Opal and its Board, and cannot be mitigated.

Opal distinguishes between different types of risk and takes an integrated approach toward managing them. Each of these risks described below could, if it eventuates, have a material impact on Opal's operating and financial performance.

These risk factors are not exhaustive. There may be additional risks and uncertainties, of which the Company is unaware, or that it considers to be immaterial, but which may become important factors that adversely affect Opal's business, financial position and operational results. There can be no guarantee that Opal will achieve its stated objectives or that any forward looking statements or forecasts will eventuate.

Before deciding whether or not to accept an Offer, investors should carefully consider these risk factors. If in any doubt, investors should seek advice from their stockbroker, accountant, financial planner or other professional adviser before deciding to accept an Offer.

None of Opal, the Directors, or any person associated with Opal guarantee the performance or future performance of Opal, the performance of any investment into Opal, the payment of dividends or any value of any Shares.

Set out below are some general risk factors applicable to Opal. Section 5.3 elaborates on specific risks relating to Opal's business.

5.1 General Risks

5.1.1 Market conditions and illiquidity

Opal is currently not listed on any stock exchange and therefore there is no open market on which its Shares are traded. As a result, New Shares issued on acceptance of the Offer may be illiquid.

If Opal becomes listed on a stock exchange, the market price for its Shares can rise and fall subject to varied and unpredictable influences on the market for securities generally and pharmaceutical securities in particular. Neither Opal nor the Directors warrant the future performance of Opal or any return on an investment in New Shares.

5.1.2 Dependence on general economic conditions

The performance of Opal may be influenced by the general condition of the Australian economy and industry activity in Australia. Changes in interest rates, employment rates, inflation, consumer spending and government policy may affect sales and operating profits. Changes in economic conditions may result in customers changing spending patterns or their level of consumption, which may have an adverse impact upon Opal's operating and financial performance.

5.1.3 Legislative and regulatory changes

Changes in relevant taxes (including GST), legal and administrative regimes and government policies may adversely affect the financial performance of Opal. Any change to the corporate tax rate will impact on shareholder returns both in terms of profits that Opal is able to distribute as dividends and the level of franking credits available to frank future dividends. Any change to the current rates of income tax applying to individuals and trusts will similarly impact on shareholder returns. Any material adverse changes in government policies or legislation of any countries in which Opal operates or may operate in may affect the viability and profitability of Opal.

5.2 Shareholder dilution

In the future, Opal may elect to issue Shares or engage in capital raisings to fund further acquisitions or other activities, for working capital purposes or for other opportunities that Opal may decide to pursue. While Opal will be subject to the applicable constraints of the Corporations Act, Shareholders at the time may be diluted as a result of such issue of Shares and subsequent capital raisings.

5.3 Specific Risks

5.3.1 Contractual and completion risk

Opal intends to acquire 100% of the issued share capital in FLT subject to the fulfillment of certain conditions specified in the Share Purchase Agreement. Opal has agreed to issue 16,109,657 Shares as consideration. The ability of Opal to achieve its stated objectives will depend on the performance by the parties of their obligations under the Share Purchase Agreement. If any party defaults in the performance of their obligations, it may be necessary for Opal to approach a court to seek a legal remedy which can be costly.

Moreover, there is a further risk that if the conditions specified in the Share Purchase Agreement are not satisfied or waived, or any of the counterparties do not comply with their obligations, completion of the Acquisition may be deferred or not occur. Failure to complete the Acquisition would adversely impact Opal's level of operations.

5.3.2 Acquisition due diligence risk

Opal and its advisers have performed certain pre-Acquisition due diligence on FLT. While Opal has obtained certain warranties from FLT under the Share Purchase Agreement, there is a risk that the due diligence conducted has not identified issues that would have been material to the decision by Opal to acquire FLT. A material adverse issue which was not identified prior to Opal's acquisition of FLT could have an adverse impact on the financial performance or operations of the relevant businesses and may have a material adverse effect on Opal.

5.3.3 Consideration Shares

Under the Share Purchase Agreement, Opal will issue 16,109,657 Shares to FLT's existing Shareholders. Some of those Shareholders may not intend to continue to hold their Shares and may wish to sell them. There is a risk that this may adversely impact on the price of and demand for Shares following completion of the Offer and the Acquisition.

5.3.4 Force majeure events

Events may occur within or outside Australia that could impact upon the Australian economy, the operations of Opal and the value of the New Shares. The events include but are not limited to acts of terrorism, an outbreak of international hostilities, fires, floods, earthquakes, labour strikes, civil wars, natural disasters, outbreaks of disease (including COVID-19) or other natural or man-made events or occurrences that can have an adverse effect on the demand for Opal's products and its ability to conduct business.

In relation to COVID-19, further prolonged periods of social distancing, quarantines, travel restrictions, work stoppages, health authority actions, lockdowns and other related measures within Australia and internationally may directly and indirectly impact a number of aspects of Opal's business.

The Board is monitoring the situation and has considered the impact of COVID-19 on Opal's business and financial performance.

Opal has implemented operational procedures to mitigate the impact to its business of a pandemic or significant community health risk, specifically arising from the impact of COVID-19.

However, the situation is continually evolving, and the consequences are therefore inevitably uncertain.

5.3.5 Key personnel risk

Opal relies on its ability to continue to attract, train, retain and motivate highly skilled and qualified employees in order to run its business. There can be no guarantee that key personnel will remain committed to Opal. Employees are free to leave Opal at will, subject to termination notice requirements, without (other than in the case of certain executives) being subject to lock-in or restraint of trade conditions. Opal is dependent on the principal members of its scientific and management team, the loss of whose services could materially and adversely affect Opal and might impede the achievements of its research and development objectives. Because of the specialised nature of Opal's business, Opal's ability to maintain its program effectively will depend in part on its ability to attract and retain qualified research personnel either within Opal or via its contracted activities. There can be no assurance that Opal will be able to retain sufficient qualified personnel on a timely basis, retain its key scientific and management personnel or maintain its relationships with its collaborators. The failure to retain such personnel and develop such expertise could materially adversely affect Opal's prospects for success. The ability of Opal to maintain and develop the competence and skills of its key responsible managers is affected by its size. Extensive ongoing training opportunities are not feasible for small biotechnology companies such as Opal.

5.3.6 Competitive threats

Opal operates in a competitive market and its financial performance or operating margins could be adversely affected if the actions of competitors or potential competitors become more effective, or if new competitors enter the market, and Opal is unable to counter these actions. The biotechnology and medical technology industries are characterised by rapid and continuous technology innovation. Opal faces high competition as new and existing companies enter the market and advances in research and new technologies become available. Opal's technology, services and expertise may be rendered obsolete or uneconomical by technological advances or entirely different approaches developed by Opal or one or more of its competitors. Opal's success will depend on strategic partnering and the extent to which these partners are interested in pursuing licensing and further development of Opal's research outputs. The number of Opal's potential strategic partners is diminishing as the current trend towards consolidation continues. Accordingly, Opal expects that an increasingly small number of partners will account for a substantial portion of our licensing and partnering opportunities with third parties.

5.3.7 Operating costs

Opal's ability to maintain a relatively low cost operating structure is not guaranteed and there is no assurance that the current estimated ratio of expenses to revenue can be maintained.

5.3.8 Intellectual property

Any adverse impact on Opal's ability to compete due to the inability to obtain, maintain and enforce intellectual property protection for its products could harm Opal's business.

If a third party asserts that Opal is infringing its intellectual property, Opal could be subjected to costly and time-consuming litigation or expensive licence fees, and its business might be harmed.

Obtaining, securing and maintaining rights to technology and patents are an integral part of securing potential product value in Opal's activities. Competition in retaining and sustaining protection of technology and the complex nature of technologies can lead to patent disputes. Opal's success depends, in part, on its ability to obtain patents, maintain trade secret protection and operate without infringing the proprietary rights of third parties. Additionally, success may depend on Opal enforcing and defending its intellectual property against third-party challengers. Because the patent positions of biotechnology and pharmaceutical companies can be highly uncertain and frequently involve complex legal and factual questions, neither the breadth of claims allowed in biotechnology and pharmaceutical patents nor their enforceability can be predicted. There can be no assurance that any patents which Opal may own, access or control will afford Opal commercially significant protection of its technology or its products or have commercial application, or that access to these patents will mean that Opal will be free to commercialise its technology.

5.3.9 Reliance on government grants and policies

Opal operates its business in the highly regulated pharmaceutical industry. In order to grow its business and generate profit, Opal relies on government policies that support its R&D initiatives (whether through regulations or the availability of government grants). Moreover, it is essential to Opal's business that Australia's regulation of the pharmaceutical industry is relatively stable and not subject to unforeseen change. This not only assists Opal with its compliance obligations, but also advertises to prospective clients that Australia is an attractive jurisdiction in which to invest in pharmaceutical manufacturing and clinical trial services. If the Australian government were to significantly reduce the availability of R&D incentives to Australian pharmaceutical companies, or introduce onerous regulations that inhibit the operation of Opal's business, the Company's financial and operational performance would suffer.

Opal has been awarded a \$5m grant from the WA government and a funding agreement has been executed. The conditions of the grant are that Opal must match the funding provided by the WA government over the five year period of the grant to secure the full funding. If Opal cannot provide the matching funding, Opal will not be able to access the full amount of the grant and this may adversely impact Opal's ability to establish the proposed facility in Perth.

5.3.10 Accounting changes

Changes in financial accounting standards or practices may cause adverse, unexpected financial reporting fluctuations and affect Opal's financial performance. Opal's financial performance could be negatively impacted by changes in, or changes in the interpretation or application (by the courts, government agencies or otherwise) of, tax or other laws or regulations in Australia or elsewhere.

5.3.11 Failure to retain existing clients and attract new clients

Following the Acquisition, the growth of Opal's business will depend in part on the number of its clients, especially its key clients. There is a risk that clients may terminate their contracts with Opal or choose not to renew those contracts. There is also a risk of losing key clients to other providers. Failure to maintain customer relationships or renew agreements could result in Opal's revenues declining or plateauing. The loss of key clients to competitors could adversely affect the business and its operating results. Opal intends to continue FLT's strategy of continually developing relationships and gaining clients in Australia and in the international industry. This will be a key focus of the new, merged entity.

5.3.12 Uncertainty of research: Project Risks

Following the Acquisition, the success of any novel technologies developed by Opal will be dependent in part on the quality of the research it undertakes, its results and its acceptance in the market. There are risks related to the successful research and development of any technology and ensuing commercialisation. Product development involves lengthy processes and is subject to evaluations by external groups such as the United States Food and Drug Administration ("**FDA**") and Australian Therapeutic Goods Administration ("**TGA**"). There is a risk inherent in activities of this nature that obtaining approvals may be affected by factors outside the control of Opal and its partners, including but not only that government agencies may not process applications in a timely manner or that their activities may be interrupted or delayed due to government policy changes or funding not being available.

Additionally, new products must also find acceptance in a competitive marketplace. Market acceptance will depend on many factors, including convincing potential customers and alliance partners that Opal's product is more attractive than other alternative products and the ability to manufacture products in sufficient quantities with acceptable quality at an acceptable cost. Because of these and other factors, our products may not gain market acceptance and this may adversely affect Opal's ability to profitably commercialise its research. In order to continue Opal's research and development of its projects and investments, Opal may from time to time enter into new business initiatives. Such arrangements will expose Opal to risks commonly associated with such ventures including amongst others assimilation of the new operations and personnel into Opal. There can be no assurance that any potential venture will not have a material adverse effect on Opal's business, financial conditions and operations. Opal has also applied for a \$5m MRFF grant for the Perth facility establishment and the development

of a cancer mRNA vaccine with University of Western Australia as a partner. If successful, this would supplement the proposed Perth development however its success is not included in the merged business planning

5.3.13 Commercialisation

The commercialisation of technology developed by Opal could require the licensing of technology to or from other entities. Opal cannot give an assurance that such licences will be obtained or, if obtainable, will be on commercially acceptable terms. Furthermore there is always the risk that licensing arrangements, once negotiated, could be terminated for reasons that may be beyond Opal's control. Commercialisation may also depend on obtaining and/or maintaining government approvals for production, marketing and sales. Opal and its partners are dependent on government agencies having funding for their functions, and being able to perform their roles without undue delay. A delay in an application being processed may result in a product not being able to be marketed or distributed, or to obtain or maximise sales, in a particular market.

5.3.14 International agreements

Opal has and will have contractual relations with parties that are domiciled in foreign jurisdictions. There is scope for change in the areas of contract law, property and in particular intellectual property in developing foreign jurisdictions which is outside Opal's control. Where possible, Opal will seek to have contracts that are entered into with foreign entities governed by the laws of Western jurisdictions such as Australia, the United States of America or European countries in order to attempt to minimise any risks in this regard.

5.3.15 Funding requirements

Operating costs and net losses and negative cash flow from Company operations may increase for the foreseeable future, due primarily to increases in expenses for establishing the new business in Perth including fit-out and purchase of equipment prior to revenue generation in the new facility. The time required for Opal to reach or sustain profitability is highly uncertain and Opal may not be able to achieve or maintain profitability. Also, if Opal does achieve profitability, the level of any profitability cannot be predicted and may vary significantly. Opal may need additional funds in the future to continue to develop and fund its business. If, and to the extent that, Opal's capital resources are insufficient to meet future capital requirements, Opal may have to raise additional funds to continue the development of its technology. Opal may not be able to raise funds on favourable terms or at all. Opal's current operating plan could change as a result of many factors and Opal may require additional funding sooner than anticipated.

Opal's requirements for additional capital may be substantial and will depend on many factors, some of which are beyond Opal's control, including:

- slower than anticipated progress in research;
- requirement to undertake additional research;
- competing technological and market developments;
- the cost of protection of patent and other intellectual property rights;
- progress with commercialisation.

Technology development is inherently high risk and the above risks are not exhaustive. Other risks may become evident with further development of the technology and commercial relationships. Opal can give no assurance that all of Opal's objectives can be satisfactorily achieved.

5.3.16 Foreign currency and exchange rate fluctuations

Revenue and expenditure of Opal may be domiciled in currencies other than Australian dollars and as such expose Opal to foreign exchange movements, which may have a positive or negative influence on the Australian dollar equivalent of such revenue and expenditure. Opal will appropriately monitor and assess such risks and may from time to time implement measures, such as foreign exchange currency hedging, to assist managing these risks. However the implementation of such measures may not eliminate all such risks and the measures themselves may expose Opal to related risks.

5.3.17 Future performance of business activities

The value of Opal's business activities is subject to the various and unpredictable influences of the market it operates in and the economy in general. Accordingly, adverse economic and market conditions may be experienced by Opal which are outside of its control and may have an adverse effect on Opal.

5.3.18 COVID-19 impact

In March 2020, the World Health Organization declared the outbreak of a novel coronavirus (COVID-19) as a pandemic, which continues to spread globally as well as in Australia. The spread of COVID-19 has caused significant volatility in Australian and international markets. Opal has measures in place to enable its employees to work remotely if required. As the circumstances continue to evolve, there may be disruptions to the future work timelines if employees, consultants or their respective families are personally impacted by COVID-19 or if travel and other operational restrictions are imposed.

5.3.19 Contract manufacturing operations

Following the Acquisition, Opal intends to continue to offer and expand Formulytica's contract manufacturing services to clients in the pharmaceutical and biotechnology industries, including targeting preclinical and clinical trial materials for a range of pharmaceutical products and, increasingly, injectables and precision medicine treatments. There is a risk that clients may be dissatisfied with Opal's services or the results of the preclinical or clinical trials and either refuse to pay Opal or damage Opal's reputation. Further, there is a risk that unexpected circumstances may cause preclinical or clinical trials to go over the client's cost estimate. While Opal ensures that its services are conducted diligently and professionally, it cannot completely control how clients will receive the work product.

5.3.20 Legal proceedings

Legal action arises from time to time in the normal business activities of Opal. Litigation can arise from commercial disputes between Opal and its business partners, clients, suppliers, employees, financiers and other third parties and government bodies for alleged or actual failures to adhere to government regulations. Litigation is costly and time consuming and consumes board and management time and resources. It creates reputational risk, brand damage and potential liabilities for Opal, its directors, officers and employees. Some of this litigation may, depending on its nature, have a material adverse impact on the financial and operational performance and financial position of the Opal.

5.3.21 Environment

Following the Acquisition, Opal is subject to environmental laws and regulations, particularly pertaining to the handling and disposal of poisons. Opal could incur material costs in order to comply with those laws and regulations, or as a consequence of a breach of those laws and regulations. These costs may have a material adverse impact on the operating and financial performance of the new, merged entity. In addition, changes to environmental laws and regulations may have a material adverse impact on the operating and financial performance of Opal.

The above list of risk factors should not be taken as exhaustive of the risks faced by Opal or by investors in Opal. The above factors, and others not specifically referred to above, may in the future materially affect the financial performance of Opal and the value of New Shares offered under this IM.

Therefore, the New Shares to be issued pursuant to this IM carry no guarantee with respect to the payment of dividends, returns of capital or the market or other value of the New Shares. Potential investors should consider that the investment in Opal is speculative and should consult their professional advisors before deciding whether to apply for New Shares in Opal.



Additional information

6 Additional information

6.1 Rights and liabilities attached to New Shares

New Shares issued under the Offer will rank equally with all existing Shares in the Company.

The rights and liabilities attaching to the ownership of the New Shares arise from a combination of the Constitution, statute and general law.

A summary of the significant rights, liabilities and obligations attaching to the New Shares are set out below. This summary is not exhaustive nor does it constitute a definitive statement of the rights and liabilities of Shareholders.

Voting at a general meeting

Subject to the Constitution and the rights or restrictions on voting which may attach to any class of Shares, each Shareholder present at a general meeting (whether in person, by proxy, representative or attorney) has one vote on a show of hands and, on a poll, one vote for each Share held by the Shareholder.

Dividends

The power to declare dividends, including the timing for payment and quantum of those dividends, is vested in the Directors. Interest is not payable by Opal in respect of any dividend or other distribution.

Transfer of Shares

Shares may be transferred by a proper transfer effected in accordance with the Constitution. Subject to compliance with the Constitution, Shares may be transferred by a written instrument of transfer in any usual or common form or by any other form as the Directors so determine.

Issue of further Shares

The Directors are vested with the power to allot, issue, cancel or otherwise dispose of Shares to any persons, on any terms and conditions, at the issue price and at those times as the Directors think fit.

Variation of class rights

At present, the Company's only class of shares on issue are the Shares. If there are different classes of shares, the rights attached to any class may, unless their terms of issue state otherwise, be varied or cancelled with the written consent of the holders of not less than 75% of the issued shares of that class or the sanction of a special resolution passed at a separate general meeting of the holders of the shares of that class.

Calls on unpaid amounts

Directors may, upon at least 30 business days' notice, make calls on Shareholders for all monies unpaid on Shares which are not monies made payable by the conditions of allotment at fixed times. Shareholders must pay the amount of every call made on it at the times and places appointed by the Directors. Any sum not paid on or before the date for payment stipulated by the Directors shall bear interest at any rates as the Directors may determine.

Joint tenants

Two or more persons registered as the holders of any Share are deemed to hold that Share as joint tenants with benefits of survivorship.

Share buy-backs

Opal may, in accordance with the Corporations Act, buy back its own Shares.

6.2 Rights and liabilities attached to Options

Rights attaching to the Options offered under this IM are as follows:

- Each option entitles the holder to acquire one ordinary fully paid share in the capital of the company
- The Options are exercisable at any time prior to 5:00 PM Melbourne Victoria time on 10 October 2025 ("the Expiry Date") by completing an Option exercise form and delivering it together with payment for the number of Shares in respect of which the Options are exercised to the registered office of the Company or such other address as the Company specifies. Any Option that has not been exercised prior to the Expiry Date automatically lapses.
- The exercise price of the Options is twenty-five cents (\$0.25) per Option payable in full on exercise.
- The Options will not give any right to participate in dividends. Shares issued pursuant to the exercise of Options will participate in dividends declared after the date of issue of the Shares.
- There are no participation rights or entitlements inherent in the Options. Option holders are not entitled to participate in new new issues of securities offered to shareholders without first exercising the Options. The Company will send notices to Option holders at least five days prior to the record date applying to offers of securities made to shareholders during the currency of the Options.
- In the event of a reconstruction in brackets including consolidation, subdivision, reduction or return close brackets of the issue capital of the company prior to the expiry date, the number of options or the exercise price of the options or both shall be reconstructed.

Shares issued upon the exercise of Options will be fully paid ordinary Shares and will have the same voting and other rights as the existing Shares of the Company.

6.3 Repayment of debt on completion of Acquisition

On completion of the Acquisition, FLT will have no more than \$750,000 in outstanding debt. If the Minimum Subscription is obtained, the debt will be satisfied by the issue of Shares in Opal. The number of Shares to be issued will be determined by dividing the amount of the debt by \$0.1552.

6.4 Taxation

Investors should be aware that there may be taxation implications of investing in New Shares under the Offer.

Any advice given to investors by Opal, including the information contained in this document, is general information only and does not take into account any investor's personal objectives, financial situation and needs.

Opal recommends that investors obtain their own independent advice on tax and any other matters relevant to the Offer.

6.5 Privacy

If you complete an Application, you will provide personal information to the Company. The Company will collect, hold and use your personal information in order to assess your Application, service your needs as an investor, provide facilities and services that you request and carry out appropriate administration.

Information contained in the Company's register of members is also used to facilitate dividend payments and corporate communications (including the Company's financial results, annual reports and other information that the Company may wish to communicate to its shareholders) and compliance by the Company with legal and regulatory requirements.

If you become a Shareholder, the Corporations Act requires the Company to include information about you (including your name, address and details of the shares held) in its public register of members. The information contained in the Company's register of members remains in the register even after you cease to be a Shareholder.

By submitting an Application, you are agreeing that the Company may use the information provided by you on an Application for the purposes set out in this privacy disclosure statement and may disclose it for those purposes to the Company's Related Bodies Corporate, agents, contractors and third party service providers, including mailing houses and professional advisers, and to regulatory authorities.

If you do not provide the information required on the Application, the Company may not be able to process or accept the Application or administer your shareholding appropriately. You have a right to gain access to the information that the Company and the share registry hold about you, subject to certain exemptions under law.

6.6 Electronic IM

This IM is available in electronic form via <http://opalbiosciences.com/>. Applicants using the Application Form must be a “professional” or “sophisticated” investor within the meaning of sections 708(8) or 708(11) of the Corporations Act with a registered address in Australia or a wholesale investor in Hong Kong or New Zealand to whom the Offer can be made without the need for registration of an offer document. Persons who receive an electronic version of this IM should ensure they download and read the entire IM.

6.7 Governing law

This IM and the contracts that arise from the acceptance of Applications under this IM are governed by the laws applicable in Victoria, Australia and each Applicant under this IM submits to the exclusive jurisdiction of the courts of Victoria, Australia.

Kenneth Windle

Dated: 1 September 2023

Ken Windle

Chairman

Opal Biosciences Ltd



Glossary

7 Glossary

The following is a glossary of the terms used in this IM:

Term	Definition
\$ dollars or cents	means Australian currency, unless otherwise indicated.
Acquisition	means the proposed acquisition of 100% of the issued share capital in FLT.
AEST	means Australian Eastern Standard Time.
Applicant	means a person who submits an Application, who is a person with a registered address in Australia and who is a “sophisticated” or “professional” investor within the meaning of section 708(8) or 708(11) of the Corporations Act or a person who is a wholesale investor in Hong Kong or New Zealand to whom the Offer can be made without the need for registration of an offer document.
Application	means an application to acquire New Shares pursuant to the Offer.
Application Form	means the application form included in or accompanying this IM relating to the Offer.
Application Money	means the amount of money accompanying an Application Form submitted by an Applicant.
ASIC	means Australian Securities & Investments Commission.
ASX	means ASX Limited ACN 008 624 691 or the financial market operated by ASX Limited, as the context requires.
Board	means the Board of Directors of the Company, from time to time.
CAGR	means compound annual growth rate.
Closing Date	means the date on which the Offer closes, being 29 September 2023.
Company	means Opal Biosciences Ltd ACN 605 631 963.
Constitution	means the constitution of the Company (as amended from time to time).
Corporations Act	means the <i>Corporations Act 2001</i> (Cth).
COVID-19	means the outbreak of the novel coronavirus disease.
Directors	means the directors of the Company, from time to time.
FDA	means the U.S. Food & Drug Administration.
FLT	means Formulytica Pty Ltd ACN 605 865 825.
Glossary	means this glossary of terms used in the IM.
GLP	means Good Laboratory Practice
IM	means this Information Memorandum.
IM Date	means the date of this IM, being 1 September 2023.
Issue Price	means \$0.25 (25 cents) per New Share.

Term	Definition
Minimum Subscription	means the minimum amount which must be raised under the Offer, being \$2,000,000.
New Shares	means the new Shares to be issued by the Company under the Offer.
Offer	means the offer of 10,000,000 New Shares at an issue price of \$0.25 to prospective Applicants pursuant to this IM to raise approximately \$2.5 million.
Opal	means Opal Biosciences Ltd ACN 605 631 963.
Open Date	means the date on which the Offer opens, being 1 September 2023.
Option	means an Option issued by the Company an exercisable at \$0.25.
Optionholder	means the registered holder of an Option.
Share	means a fully paid ordinary share in the Company.
Shareholder	means the registered holder of a Share.
Share Purchase Agreement	means the share purchase agreement between the Company and each of FLT's shareholders under which the Company acquires 100% of the issued share capital in FLT in exchange for issuing 16,109,657 Shares to FLT's existing shareholders.
TGA	means the Therapeutic Goods Administration.

