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Proposed acquisition of specialist formulation company Formulytica

Melbourne, 21 June 2023: Opal Biosciences Limited (“Opal”) is pleased to announce its proposed merger with specialist company, Formulytica Pty Ltd (“Formulytica”). Opal and Formulytica have partnered to establish a new sterile pharmaceutical development and manufacturing facility. The new facility will be focused on small scale product manufacture of sterile liquid products for clinical trial and personalised medicine treatment.

The objective of the new merged business will be to serve the needs of local and overseas groups who need manufacture of research stage products for testing in preclinical and early stage (Phase I/IIa) clinical studies and for some precision medicine treatment development e.g. individually tailored cancer vaccines.

Formulytica is recognised internationally for its strengths in formulation development (topical applications and injectables). Formulytica will continue to operate its fee-for-service business under its own internationally recognised brand. It will service local and international clients and in addition continue to gain royalties from its own in-house innovative technologies, some of which have already been outlicensed and commercialised.

Opal’s Managing Director, Julie Phillips said, “Australia is a growing and highly attractive jurisdiction to conduct clinical trials. On 1 April 2022 the new R&D Tax Incentive determination¹ for clinical trials came into effect. This determination means clinical trials are automatically eligible for the R&D tax incentive. This will grow the ecosystem significantly by attracting even more overseas clinical trials. However, currently in Australia, the necessary capabilities and infrastructure for small scale sterile liquid injectable and vaccine manufacturing and fill/finish are scarce. Our plan will transform and grow Opal.”

Formulytica’s Dr Richard Buchta said “We welcome this opportunity to join with Opal and both our companies recognise the enormous opportunity the current environment for conduct of clinical trials in Australia presents to grow our business further. Australian companies would prefer to have more of their formulation and development work conducted onshore for their preclinical and clinical trials”.

The transaction will be effective on the completion of a capital raising. Opal will then acquire all the shares of Formulytica to form a wholly-owned subsidiary and any existing debt within Formulytica will be converted to equity. Formulytica’s Peter Cox and Dr Richard Buchta will then join the Opal board. The details of the capital raising will be announced shortly.

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¹ <https://business.gov.au/news/r-and-d-tax-incentive-determination-for-clinical-trials>

Further information

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About Opal Biosciences Ltd (www.opalbiosciences.com)

Opal's focus in partnership with Formulytica Pty Ltd is to grow Australian pharmaceutical manufacturing capability. Opal's parent company, BioDiem Ltd (biodiem.com) is a public company which has successfully commercialized a live attenuated influenza virus vaccine technology, now licenced to the World Health Organisation, Serum Institute of India and Changchun BCHO Biotechnology Ltd, with products marketed in India and China.

About Formulytica Pty Ltd (www.formulytica.com)

Formulytica was formed in response to a global market demand from companies wanting to outsource their topical and injectable formulation development projects and acts as an outsourced innovation and development laboratory, servicing companies who lack the internal resources, time or skill-set to develop new formulations and prepare market-ready products. With its US FDA regulatory standard level focus and quality systems Formulytica's scientists help bring innovative and regulated products to market and problem-solve formulation issues for their clients.

Formulytica's injectable drug development capabilities include the formulation development of new small molecule drugs, reformulation of generic drugs, and 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 team of highly qualified scientists have been working in product development for the Australian, US and EU markets for over 20 years.