

BIODIEM LTD ABN 20 096 845 993 Level 4 100 Albert Rd, South Melbourne, Victoria, 3205

Phone: +61 3 9692 7240 Fax: +61 3 9077 9233 Web: www.biodiem.com

2022-23 Pre-Budget Submission 28 January 2022

Vaccine Manufacture in Australia

This submission is written to encourage the federal government to make an allocation in the forthcoming budget to secure and maintain an existing operating manufacturing site for vaccine manufacture in Australia, to prevent its loss.

There are very few sites currently in Australia for any form of commercial human vaccine development and manufacture. Over the past 10 years we have looked to develop and manufacture different vaccine technologies here¹, and to our knowledge there are currently only two sites that can manufacture vaccines to cGMP standard at population scale: CSL and GSK (Boronia, Vic). For example, the recent federal "Approach to Market" result showed no applicants could manufacture mRNA vaccines onshore end-to-end.

GSK announced closure of its Boronia, Victoria plant by the end of 2022². It currently manufactures and exports a vaccine and other pharmaceutical products. GSK's announcement in February 2021 of the site being on the market caught us and many others by surprise. This 16ha pharmaceutical manufacturing site with its experienced and skilled workforce, and potential for bulk-filling of pandemic and other vaccines, is immensely valuable and has had millions of Australian taxpayer dollars invested in it.

The site has since been sold to the property developer, Charter Hall. GSK is leasing it back and operating it for the period until they exit the site fully, in 2023. A window of time during 2022 therefore exists to invest in the transition of the site to a multi-tenanted precinct to maintain its pharmaceutical manufacture infrastructure, workforce and function following GSK's departure.

Through our subsidiary company Opal Biosciences Ltd we have promoted the value of the site as a life sciences precinct with an industrial manufacturing focus. We see such a multitenanted precinct offering key advantaged, one being that it will serve as a focal point for companies and universities to collaborate and develop products.

By capitalising on the site's existing infrastructure and trained workforce such a brown field precinct would:

- preserve and extend the site's existing extensive pharmaceutical manufacturing capabilities (including vaccine manufacture)
- retain the skilled workforce (~300 employed on the site)
- provide access to medical researchers/universities to facilitate industry input into research commercialisation (quality standards, analytical and microbiology lab support, regulatory and commercialisation input, etc)
- provide internships, training and other opportunities for work-integrated learning.

¹ Live attenuated influenza vaccine (intranasal) – now licenced to WHO and manufactured overseas; SAVINE scrambled antigen vaccine technology (abandoned due to no access to local development facilities).

 $^{^2\} https://au.gsk.com/en-au/media/press-releases/2020/following-decision-announced-in-july-gsk-confirms-boronia-manufacturing-site-to-close-at-end-of-2022/$

The site also has current and specific key attributes related to national security:

Blow fill seal (BFS) of bulk vaccine (population scale). The site is a centre of excellence for BFS³ with ~10 filling lines. Subject to the necessary TGA licences and approvals, Boronia would be able to "fill and finish" any vaccine type including mRNA e.g. imported bulk COVID-variant vaccines. This gives Australia flexibility in future vaccine choice and for local manufactured product. "Fill and finish" capability and capacity are commonly rate-limiting for vaccine production globally. Bulk vaccine could be made locally or imported to fill and finish at the Boronia site.

But why does Australia need Boronia when there are other initiatives around Australia?

Australia needs more capabilities in pharmaceutical/vaccine development and manufacture

For Australia to seize the opportunity to grow a more globally competitive life sciences industry and maintain more of its tax-payer funded IP onshore, we must address the current gaps. These include product development (including preclinical) and manufacturing capabilities to allow companies to see their pathway to full product commercialisation onshore right through to final product manufacture and export. Existing initiatives are not sufficient. Boronia is an existing operating facility with a workforce, and with a short start-up lead time.

2. Improving University-Industry Collaboration

In July 2021 CBRE Research released an Asia-Pacific report (attached) A NEW ERA OF LIFE SCIENCES GROWTH - Opportunities for Occupiers and Investors⁴. The report states that Australia is emerging as a world-leading life sciences hub. MonashUniversity's Pharmacy and Pharmacology disciplines rank 2nd only to Oxford University (per QS World Rankings 2020). Unfortunately Australia's ranking in university-industry collaboration is low i.e. 39th in the Global Innovation Index 2020 (https://www.globalinnovationindex.org/analysis-indicator).

The biotech precinct vision for Boronia will in part address this. Beyond the plan for using the existing highly specialised infrastructure for high value pharmaceutical manufacturing (sterile pharmaceuticals and vaccines), the vision is to create a venue for universities and industry to collaborate within a commercial setting. The leap from academic work to commercial vaccine development requires experienced industry input. This in turn will promote high value job creation and GDP growth through commercialisation of Australia's world class medical research. This idea has wide support by universities and the industry.

3. <u>Increasing Australia's export diversity</u>

According to the Harvard Atlas of Economic Complexity⁵ Australia ranks 86th out of 133 in the Economic Complexity Index dropping 6 places from a decade ago. Australia has the tools to improve this ranking once some barriers to more complex high value product development, manufacture and export are addressed.

The GSK Boronia site offers an opportunity to secure an existing operating much-needed manufacturing infrastructure to address gaps in Australia's current needs and to accelerate

³ https://www.invest.vic.gov.au/resources/case-studies-search/case-studies/glaxosmithkline

⁴ https://apacresearch.cbre.com/en/research-and-reports/asia-pacific-life-sciences-major-report

⁵ https://atlas.cid.harvard.edu/countries/14

local full product development and commercialisation and provide a facility to allow final product manufacture "at scale" and export. A modest investment from the federal government will have both immediate and long term benefits in many areas.

Yours sincerely,

Julie Phillips

CEO