ISSN 1443-850X

BIOSHARES
Australia's Independent Biotech Investment Resource, est.1999

1 May 2023
Edition 937

	Bioshares Portfolio
Year 1 (May '01 - May '02)	21.2%
Year 2 (May '02 - May '03)	-9.4%
Year 3 (May '03 - May '04)	70.6%
Year 4 (May '04 - May '05)	-16.3%
Year 5 (May '05 - May '06)	77.8%
Year 6 (May '06 - May '07)	17.4%
Year 7 (May '07 - May '08)	-35.8%
Year 8 (May '08 - May '09)	-7.4%
Year 9 (May '09 - May '10)	50.2%
Year 10 (May '10 - May'11)	45.4%
Year 11 (May '11 - May '12)	-18.0%
Year 12 (May '12 - May '13)	3.1%
Year 13 (May '13 - May '14)	26.6%
Year 14 (May '14 - May '15)	23.0%
Year 15 (May '15 - May '16)	33.0%
Year 16 (May '16 - May '17)	16.8%
Year 17 (May '17 - May '18)	-7.1%
Year 18 (May '18 - May '19)	-2.3%
Year 19 (May '19 - May '20)	39.5%
Year 20 (May '20 - May '21)	86.8%
Year 21 (May '21 - May '22)	-15.6%
Year 22 (May '22 - Dec '22)	-2.2%
Year 23 (CY2023)	-10.0%
Cumulative Gain	1411%
Av. Annual gain (22 yrs)	18.1%

Companies covered: IMC, PXS, TLX

2023 Top Six Picks: -0.1%

Bioshares is published by Blake Industry & Market Analysis Pty Ltd. ACN 085 334 292
PO Box 447
Flinders Lane Vic 8009
AFS Licence No. 258032

Mark Pachacz - Editor/Analyst
Email: mark[at]bioshares.com.au
Ph: 0403 850 425

Edition Number 937 (1 May 2023)

Extract from Bioshares –

Immuron – Sales Start to Rebound Strongly

Immuron's (IMC: $0.078) business was severely impacted by the pandemic, with its lead product, Travelan, sold to prevent traveller's diarrhea. Sales fell from $2.7 million in FY2020 to just $166,000 in FY2021.

However, there are some very clear signs that the rout is behind the company, with a strong recent rebounding in sales, and a depth of clinical programs which are based on the core gut technology that underpins the business.

Immuron has the capability to develop polyclonal antibodies (which are broader acting than monoclonal antibodies produced in fermentation vessels) that can target a range of virus and bacteria subunits in the gut.

These antibodies are produced in cows that have been vaccinated to produce the polyclonal antibodies which are collected from the colostrum when they are breeding. It's a proven process that supports the technology behind the established Travelan product.

The appealing feature of these bovine produced antibodies is that a) they are not de-graded in the gut when taken orally, and b) being antibodies they are not absorbed into the blood stream, which makes the development pathway considerably less complicated from a regulatory standpoint.

Sales Rebound

Sales for the company's two products, Travelan and Protectyn, have now started to rebound. Protectyn is effectively the same product as Travelan, containing hyperimmune bovine colostrum active against LPS (lipopolysaccharide) found on harmful bacteria such as E.coli. The cows are immunised with 14 different strains of E.coli.

Sales reached an all-time peak of $2.7 million in FY2020, however plummeted during the pandemic, and now show signs of rebounding. In the current financial year up to 14 April, the company announced that sales have reached $2.1 million, including $0.32 million in the first two weeks of this month. The company generates a 70% gross margin on its products.

Continued over

The issue for Immuron from the pandemic has not only been the almost cessation of international travel, but also supply chain delays for its tablet packaging material which has interrupted manufacturing of its products. This has now been addressed with an alternative supplier contracted.

Two thirds of the company's sales are generated in Australia through pharmacies with one third mainly in the US through the group Passport Health. Passport Health provides travel medicines in the US through its network of clinics. The company expects to start selling into Canadian pharmacies next year. It expects to increase its marketing spend on Travelan to aggressively grow sales.

In the UK, the company intends to sell the Travelan product through Ateria Health, which sells the product Juvia for the treatment of irritable bowel syndrome. Last year Immuron invested $2.6 million in Ateria Health for a 17.5% stake. Immuron will sell Juvia into the US and Australia.

Label Claims

Protectyn is targeted for chronic use to maintain healthy digestive function and to support the liver by removing harmful LPS toxins. According to the Australian label, the LPS bacterial toxin is associated with 'gut dysbiosis, leaky gut, IBS, fatty liver and metabolic syndrome'. At this point the majority of sales are from the Travelan product.

The company has health benefit label claims for Travelan in Australia and Canada, no claims in the US, and it is considered a food supplement in the UK and Asia. Retail sales have recommenced in the US and the product is expected to be selling into Pharmacies in Canada next year. The company also has a committed online database with 24,000 Facebook followers.

Clinical Programs

Immuron has four clinical programs either underway or in the planning.

Trial 1: Traveller's Diarrhea with the US Department of Defence
In May last year a study was started with US Department of Defence to assess Travelan at high doses to prevent travellers' diarrhea in high-risk areas. The trial is being conducted by the Uniform Services University (part of the DoD) and will recruit 868 soldiers in high-risk areas for gut infections. To date at least 157 of the 868 subjects have been recruited. Immuron's CEO Steven Lydeamore expects recruitment to be completed by the end of this year. The soldiers will receive the high dose Travelan for two days before arriving at their destination and for up to 20 days, with half receiving placebo.

Positive data from this study may allow the company to introduce therapeutic label claims in the US as well as generate large sales to the US DoD.

Trial 2: Phase II Controlled Study with Travelan Funded by US DoD
In January last year Immuron secured $6.2 million in funding from the US DoD to assess a single higher dose of Travelan (1200mg) against E.coli. The eventual aim is to file a BLA (Biologics License Application) with the FDA.

The study will seek to recruit 60 volunteers, who will all receive a strain of the E.coli bacteria, with half receiving a placebo and the other half receiving a single 1200mg dose of Travelan. In previous studies, Travelan has shown to deliver at least 84% protection in controlled studies, however in the two previous studies the drug was taken three times a day (total 600mg and 1200mg).

CRO group Pharmaron CPC will be conducting the study in the US, with an IND application having been approved by the FDA in December last year. The study is expected to start by June this year with the results by year's end. If successful, two additional studies are expected to support the BLA application. It could see the price of Travelan increase significantly with the product sold under prescription only in the US and no longer as an OTC product.

Trial 3: Prevention of Travellers' Diarrhea Targeting E.coli and Campylobacter
Immuron has been working with the US Navy (Naval Medical Research Center) since 2016 to use its technology to develop a product for travellers' diarrhea against the bacteria E.coli and Campylobacter. NMRC is funding the development of the program. In November 2020 Immuron announced that the vaccine, which had been developed by the NMRC and injected into cows, produced high levels of antibodies against the two targeted bacteria.

In May last year the NMRC filed an IND with the FDA for this program, however in July it was informed by the regulator that additional safety information would be required. Additional toxicology data has now been submitted. A response from the FDA is expected shortly with trials to commence once FDA clearance is received.

Trial 4: C.difficile Infection (CDI) Study
Next year Immuron expects to start a Phase II study against the gram-positive bacterium Clostridium difficile (CDI). This will be conducted under an IND in the US with the trial expected to take around 18 months to complete and according to Lydeamore, may include around 60 patients.

First Microbiome Product for CDI Approved by FDA

Last week the first microbiome therapeutic against CDI was approved by the FDA, called VOWST from Seres Therapeutics. VOWST is a live gut bacteria that has been extracted from purified fecal samples from healthy volunteers. The product was assessed on two studies involving 346 subjects. The results showed that CDI recurrence at eight weeks in those who received VOWST was only 12.4% compared to 39.8% in the placebo arm. Seres has a market capitalisation of US$623 million.

Continued over

The therapy has a triple mechanism of action that uses polyclonal antibodies from cows that have been injected with three different vaccines. The aim is for the antibodies to target spores that the bacteria lays, the vegetative cells, and also the toxin that is produced. A Phase I study was conducted previously in Israel, however only nine of the planned 60 patients were recruited.

Summary

Immuron is capitalised at just $18 million with $18.5 million in cash at the end of last year. With accelerating sales, a deep pipeline for follow-on products, and a strong cash balance, Immuron is an appealing investment consideration.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

How Bioshares Rates Stocks

For the purpose of valuation, Bioshares divides biotech stocks into two categories. The first group are stocks with existing positive cash flows or close to producing positive cash flows. The second group are stocks without near term positive cash flows, history of losses, or at early stages of commercialisation. In this second group, which are essentially speculative propositions, Bioshares grades them according to relative risk within that group, to better reflect the very large spread of risk within those stocks. For both groups, the rating "Take Some Profits" means that investors may re-weight their holding by selling between 25%-75% of a stock.

Group A

Stocks with existing positive cash flows or close to producing positive cash flows.

Buy	CMP is 20% < Fair Value
Accumulate	CMP is 10% < Fair Value
Hold	Value = CMP
Lighten	CMP is 10% > Fair Value
Sell	CMP is 20% > Fair Value

(CMP–Current Market Price)

Group B

Stocks without near term positive cash flows, history of losses, or at early stages of commercialisation.

Speculative Buy – Class A
These stocks will have more than one technology, product or investment in development, with perhaps those same technologies offering multiple opportunities. These features, coupled to the presence of alliances, partnerships and scientific advisory boards, indicate the stock is relative less risky than other biotech stocks.

Speculative Buy – Class B
These stocks may have more than one product or opportunity, and may even be close to market. However, they are likely to be lacking in several key areas. For example, their cash position is weak, or management or board may need strengthening.

Speculative Buy – Class C
These stocks generally have one product in development and lack many external validation features.

Speculative Hold – Class A or B or C

Sell

Corporate Subscribers: Cogstate, Opthea, Pharmaxis, Dimerix, Patrys, Antisense Therapeutics, Imugene, Chimeric Therapeutics, Neuren Pharmaceuticals, Aroa Biosurgery, Radiopharm Theranostics, Imricor Medical Systems, Anteris Technologies, Bio-Gene Technology, EBR Systems, Immuron