PITT STREET RESEARCH

Immuron Ltd.

Continually breaking sales records

Share Price: A$0.096

ASX: IMC

Sector: Healthcare

30 July 2024

Immuron (ASX:IMC) is an Australian biotech company developing and commercialising assets that treat gastrointestinal disorders. IMC has 2 flagship commercial products – Travelan and Protectyn – and 3 clinical-stage assets – IMM-529, IMM-124E and CampETEC. FY24 has been a successful year on several fronts for the company, both in respect of its commercial and clinical assets.

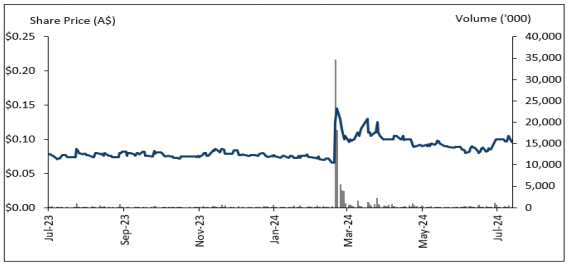
Market cap. (A$m)	21.9
# Shares outstanding (m)	227.8
# Share fully diluted (m)	243.4
Market cap full. dil. (A$m)	23.4
Free float	66.0%
12-months high/low (A$)	0.17 / 0.065
Avg. daily volume ('1000)	429.5
Website	www.immuron.com.au

Source: Company, Refinitiv Eikon, Pitt Street Research

Travelan reaches nearly $5m in sales

Immuron has commercialised Travelan, although only as a dietary supplement in the USA. The company has released unaudited sales for FY24, the 12 months for 30 June 2024, and the company reached a fresh record of sales. Globally, the company's sales reached $4.9m, up 174% on the prior period. Sales for 4Q24 were $1.3m, up 253% on 4Q23. $3.7m of FY24 sales came from Australia, which was up 223%, and $1.1m was from America (up 74%). The company anticipates sales growth continuing into FY25 on the back of increased brand investment and distribution planned for the 12 months ahead.

Share price (A$) and avg. daily volume (k, r.h.s.)



Source: Refinitiv Eikon, Pitt Street Research

Continuing clinical endeavours

The company is pursuing regulatory approval for IMM-124E as a preventative supplement for travellers' diarrhea, and is expected to enter Phase 3 in 2025 following successful interim Phase 2 results, which were the subject of our last note on the company. The full results from Phase 2 are due at the end of July 2024. The strong interim results have led to the company proceeding to a meeting with FDA for a Phase 3 trial. Investors should also expect progress with IMM-529 in FY25 and FY26, as the company has filed a pre-IND (investigational new drug) application with the FDA.

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Valuation range of A$0.25–0.34 per share

We reiterate our valuation of Immuron as first outlined in our initiation report – at A$0.25 per share in a base case scenario and A$0.34 per share in an optimistic (bull) case scenario. There are several upcoming catalysts including ever growing Travelan sales, the full dataset from the IMM-124E trial and initiation of Phase 3. The advancement of IMM-529 and CampETEC in the clinic are opportunities too. Please refer to pages 9-10 for more details on our valuation and the key risks to our thesis.

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The Investment Case for Immuron

There are 6 key reasons for investors to take a look at Immuron.

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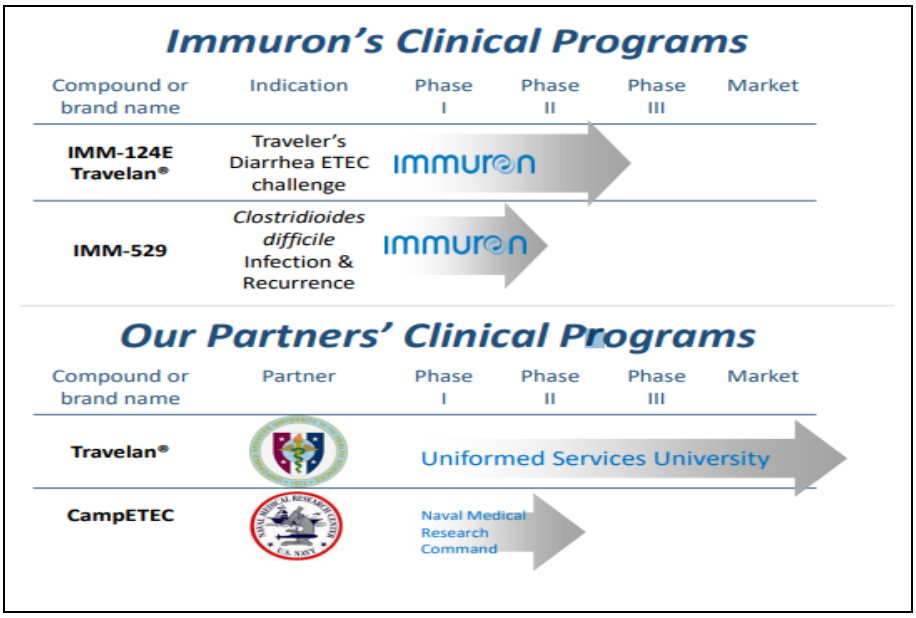
1) **The company offers the best of both worlds,** in offering the stability of having commercialised products (in Travelan and Protectyn) but also offering the upside of multiple clinical stage assets (Figure 1). What's more, the most notable of these clinical-stage stage assets is an asset already commercialised, in IMM-124E - an existing compound in Travelan. The reason Immuron is conducting a clinical trial in the US is because Travelan is only approved as a general dietary supplement and not specifically for traveller's diarrhoea, although it is so approved in Australia and Canada with specific therapeutic claims as a preventative treatment to travellers' diarrhoea. This a unique path to market in that Immuron is testing a clinical asset with comprehensive data supportive of its cause and when it eventually gets market approval as a therapeutic drug in the USA, it will potentially transform the existing Travelan business.
2) **The company is continually breaking sales records with Travelan**. The company recorded nearly A$5m in sales in FY24 and its sales are growing year on year. Indeed, the company's global sales increased 174% year on year and by 223% in Australia.
3) **The company has research and distribution partnerships rivalled by few (if indeed any) ASX biotechs**. These include a notable partnership with the US Department of Defense that has led to two clinical trials (for Travelan and CampETEC) that are currently underway. The company also has well-established distribution capabilities including retail network of more than 3,500 pharmacies in Australia and in the US, that country's largest travel health clinic network (Passport Health) as well as Amazon and Walmart.com.
4) **There's a substantial market for Immuron's assets** - The market potential in the US for Travelan is estimated at US$83m, and the EU market is estimated at US$50m. Given the size of both the global TD and CDI market, there is significant potential upside for the company. As we will outline later in the report, independent third-party data from Lumanity suggests that IMM-124E and IMM-529 could each reach ~US$100m in annual sales in the United States with both being conservative estimates with IMM-529 only accounting for CDI in recurrent cases.
5) **The company is well funded** with over $15m in the bank as at the end of 1HY24. The company has been able to fund its clinical endeavours to date through grants, particularly its IMM-124E trials which were funded by the US military.
6) **Immuron is undervalued at its current price.** We have Immuron at A$0.25-$0.34 per share. We foresee the company being re-rated as it continues to grow Travelan's sales and advances its clinical programs. We observe that once it takes IMM-124E into Phase 3, which could occur in the next 12 months, it will be in an exclusive company of ASX biotechs with an asset in the pivotal Phase III stage. The continued development of IMM-529 also presents potential upside for the company.

Immuron's Clinical Programs

The company's clinical programs are as follows (Figure 1):

Figure 1: Immuron's clinical programs



Source: Company

I. IMM-124E - the API used to manufacture both Travelan and Protectyn. IMM-124E. Travelan is only approved in the US as a general dietary supplement rather than as a preventative treatment for traveller's diarrhea. Immuron is looking to change that by running clinical trials of IMM-124E to obtain US approval for traveller's diarrhea.

II. IMM-529 - an oral formulation intended for patients suffering from recurring Clostridium Difficile Infection (CDI). Immuron has completed preclinical work on IMM-529 and has demonstrated statistically significant (1) Prevention of primary disease (80%, p=0.0052); (2) Protection of disease recurrence (67%, p<0.01) and (3) Treatment of primary disease (78.6%, p<0.0001, TcB HBC).

III. CampETEC - an oral therapeutic targeting Campylobacter and ETEC infections. Immuron is collaborating with the US NMRC for this asset. In 2023, the FDA approved an IND application for CampETEC to test its safety and protective efficacy in a first-in-human study. This study has completed with topline data due in August 2024.

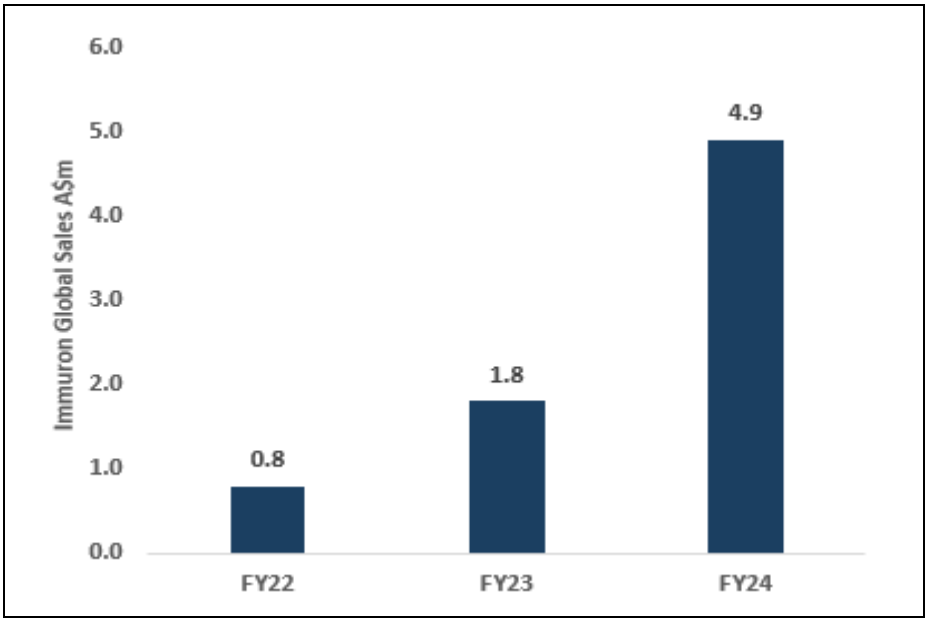
IV. Travelan - The US Department of Defense (DoD) Uniformed Services University is running a randomised, placebo-controlled trial in up to 866 participants. Patients have actively been deployed in the military from both the US and the UK. 77% of participants have been randomised. The US DoD has extended the enrolment period and now expects to complete clinical trial in December 2024 with topline date in 1Q2025.

Travelan: A solid year in FY24 with FY25 set to be even better

Immuron's total sales were just $0.8m in FY22 but reached $1.8m in FY23 (up 136%) and to $4.9m (up 174%) in FY24.

Since initiating coverage on Immuron in November 2023, the company has been a strong year with its Travelan business, on both the clinical and commercial fronts. We'll focus on the latter first. After a crash in sales during the pandemic, in conjunction with international passenger travel numbers, FY23 and FY24 have been years of recovery. Immuron's total sales were just $0.8m in FY22, but reached $1.8m in FY23 (up 136%) and to $4.9m (up 174%) in FY24 (Figure 2).

Figure 2: Immuron's sales



Source: Company

Of the above amount, $3.7m came from Australia. Australian sales were 223% higher than in FY23. $1m sales came in 4Q24 alone, a figure which was triple that recorded in 4Q23. $1.1m in sales came from the USA, a result up 74% on FY24. The 4Q24 result in the USA was $0.3m, up 546% on 4Q23. The balance came from Canada and even though sales were ~$0.1m, this was up 6,637%.

This growth has come in conjunction with repeated increase in travel numbers. CY24 is expected to be the year that international travel numbers return to pre-pandemic levels after bottoming out during the pandemic. Immuron expects further growth in FY25 on the back of planned increased brand investment and distribution. And when Travelan is FDA approved specifically for traveller's diarrhoea, this will provide a further boost for sales.

Immuron's clinical endeavours

IMM-124E

The highlight of the year has been interim topline results from a 60-patient Phase 2 clinical trial in the US with Travelan.

The results (Figure 3) included:

- ETEC-induced moderate to severe diarrhea was reduced by >36% in the Travelan group compared to the placebo group,
- Protective efficacy of once daily dosing was shown to be 50% as effective as the current recommended three times daily dosing regimen,
- 66.7% protective efficacy against ETEC-induced severe diarrhea was observed in the Travelan group compared to the placebo group,
- Statistically significant reduction of 83.3% in the subjects in the Travelan group requiring early antibiotic treatment post challenge compared to the placebo,
- For subjects requiring intravenous rehydration post challenge, 100% were in the placebo group and none were in the Travelan Group, and
- A 55.6% reduction in the number of subjects experiencing adverse events post the ETEC challenge was observed in the Travelan group compared to the placebo group

Figure 3: Immuron's clinical trial results

Event post challenge	Travelan® n = 30 n (%)	Placebo n = 30 n (%)	Reduction in AEs or Symptoms (%)	*P value*
Primary Endpoint				
Number (n) of subjects with ETEC-induced moderate-severe diarrhea	7 (23.3%)	11 (36.7%)	NA	0.399
Protective efficacy [%][1] 95% 2-sided Confidence Interval[2]	**36.4%* (-79.8%, 79.1%)**			
Secondary Endpoints - Safety and tolerability				
Number of subjects with an adverse event (AE) 95% 2-sided Confidence Interval[2]	4 (13.3%) (-3.8%, 37.1%)	9 (30.0%)	55.6%	0.1172
Number of subjects with (AEs) fever, nausea, anorexia, o abdominal pain/cramps rated as moderate to severe 95% 2-sided Confidence Interval[2]	3 (10.0%) (-5.2%, 31.9%)	7 (23.3%)	57.1%	0.1659
Secondary Endpoints – Degree to which a participant experiences diarrheal symptoms				
Number of subjects who experienced severe diarrhea 95% 2-sided Confidence Interval[2]	1 (3.3%) (-5.8%, 19.2%)	3 (10.0%)	66.7%	0.3006
Number of subjects requiring early antibiotic treatment 95% 2-sided Confidence Interval[2]	1 (3.3%) (1.0%, 32.4%)	6 (20.0%)	83.3%	**0.0444**
Number of subjects requiring IV fluids 95% 2-sided Confidence Interval[2]	0 (-0.7%, 20.7%)	3 (10.0%)	100.0%	0.0756

Source: Company

Once the full results are released (which is expected in July 2024), the company will have an end of Phase 2 meeting with the FDA to discuss the Phase 3 registration strategy and planned clinical trials, including recommended dosing. This will include making a Biologics License Application (BLA) for Travelan as a prophylactic medicine for Travelers' diarrhea, that could be used in the US Military. The company is also seeking non-dilutive funding opportunities. The company is hoping to initiate the Phase 3 study in the second half of 2025. Thereafter, trials would take ~2 years enrolling > 1,200 healthy adult subjects across 2 studies to assess the efficacy and safety of Travelan for the prevention of TD.

The company is hoping to initiate the Phase 3 study in the second half of 2025.

It is important to note that participants in the trial may be exposed to other pathogens that can cause traveler's diarrhea, not just ETEC. Although patients in the Phase 2 trial were only exposed to ETEC, there may be other pathogens such as enteroaggregative E.coli (EAEC), campylobacter, shigella and, enteropathogenic E.coli (EPEC). Immuron has pre-clinical data showing broad spectrum activity against up to 180 pathogens. If the trial is a success IMM-124E may have an even broader market than that which the company has envisioned. Immuron will be seeking an indication for prevention of traveler's diarrhea not limited to any specific pathogen.

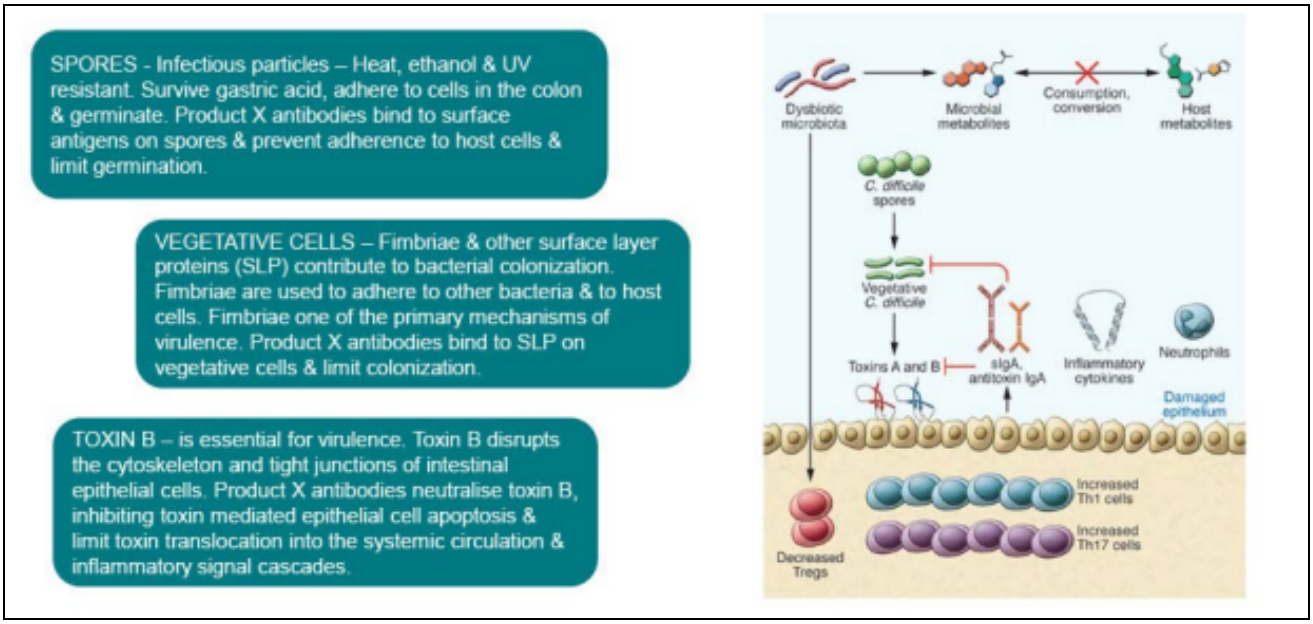
IMM-529

As recapped in our initiation report, IMM-529 is an oral biologic that targets the *Clostridioides difficile* (CDI) bacterium. CDI causes severe and persistent diarrhoea in infected individuals, but can also lead to more severe outcomes, including in the most serious cases, death. Transmission of CDI occurs by ingestion of spores either through person-to-person contact, animal-to-person contact or environment-to-person contact.

CDI has a recurrence rate of 15%–20% and a mortality rate of 5%. It affects over 400,000 people and causes over 30,000 deaths every year, and this is just in the USA.

CDI has a recurrence rate of 15%–20% and a mortality rate of 5%. It affects over 400,000 people and causes over 30,000 deaths every year, and this is just in the USA. It is envisioned that IMM-529 could work as an adjunctive therapy in combination with standard of care antibiotics for the prevention and/or treatment of recurrent CDI. IMM-529 antibodies targeting the bacteria may help to clear the infection and promote a quicker re-establishment of normal gut flora, providing an attractive oral preventative for recurrent CDI (Figure 4).

Figure 4: IMM-529



Source: Company

IMM-529 is behind IMM-124 and is unlikely to be FDA approved for at least 5 years with IND (Investigational New Drug) registration, as well as Phase II and Phase III studies still required. However, as outlined in our initiation report, preclinical studies (conducted in mice, using hyperimmune bovine colostrum produced from immunised dairy cows) have shown remarkable efficacy in all 3 stages of the disease[1]. And what's more, the company has just taken a major step, in making a pre-IND submission which will pave the way for a Phase II clinical trial if approved.

There could be a base case revenue opportunity of US$93m.

Opportunity assessment by Lumanity has indicated that there could be a base case revenue opportunity of US$93m. This is assuming it is only taken up in the subpopulation of CDI patients which have a 2nd recurrence of the disease (estimated at ~31k), but is taken up to a substantial degree (75%). If IMM-529 was taken up at 1st recurrence, up to ~95k patients would be eligible. The drug's oral dosage is likely to place it in good stead because current treatment approaches (such as bezlotoxumab and fecal microbiota transplantation) are expensive and complex in their administration. Greater efficacy may lead to greater use in patients after their first recurrence, increasing the size of the patient population. Even capturing as few as 10% of first recurrence patients adds up to 9,500 patients to the treated pool (potential for some double counting), which could add up to US$48M in yearly revenue.

[1] Prevention of primary disease, protection of disease recurrence and treatment of primary disease.

CampETEC

CampETEC is a new therapeutic targeting Campylobacter and ETEC infections on which Immuron has been collaborating with the Naval Medical Research Command (NMRC) since October 2019. The company has been conducting a first-in human study to test the safety and protective efficacy of CampETEC.

The 30-volunteer study is expecting to report during the current quarter (1QFY25). The company will discuss the results of the trial with the NMRC and FDA before deciding on the path forward.

Our valuation of Immuron

Our valuation of IMC is A$0.25 per share under our base case projection, while our bull case projection placed the valuation at A$0.34 per share.

We continue to reiterate our valuation of the company as outlined in our initiation report of November 2023. Using a SOTP approach (separately valuing the NPVs of IMC's legacy business, IMM-124E and IMM-529) our total valuation is A$0.25 per share under our base case projection, while our bull case projection places the valuation at A$0.34 per share (Figure 5), signifying substantial upside potential when compared with the current market price.

The company's achievements this year have attracted short-term increases in the share price. In our view, if the company continues on its present path in constantly breaking sales records and advancing its clinical programs successfully, increases in shareholder value will be maintained over longer periods of time.

Figure 5: Immuron's SOTP valuation

SOTP valuation	Base Case		Bull Case	
Drugs	**A$m**	**A$ps**	**A$m**	**A$ps**
Legacy business	29.01	0.13	41.21	0.18
IMM-124E	15.70	0.07	23.55	0.10
IMM-529	3.18	0.01	4.32	0.02
rNPV	**47.89**	**0.21**	**69.08**	**0.30**
Cash (close of FY24 - PSR estimate)	9.50	0.04	9.50	0.04
Debt (close of FY24 - PSR estimate)	-	-	-	-
Equity Value	**57.38**	**0.25**	**78.57**	**0.34**
Current Price		0.096		0.096
Upside		162%		259%

Source: Pitt Street Research

Key risks for Immuron

We see the following major risks for our investment thesis on Immuron:

- **Uptake risk:** There is a risk that Immuron may not be able to gain traction in its target markets. There is no guarantee that Immuron and its distributors will secure a higher-than-expected specific number of purchase orders for its existing and new products. If this risk materialises, Immuron will likely report financial results below the forecasts, which could adversely affect its valuation.
- **Clinical risk:** There is a risk that the clinical programmes of IMM-124E and IMM-529, sponsored by Immuron, may not meet their primary or secondary endpoints. The success rate for clinical trials varies significantly across technologies and is typically lower in earlier stages. Although the risk for IMM-124E has reduced somewhat after recent results, it has not entirely been eliminated given more trials will have to be conducted with it.
- **Regulatory risk:** There is a risk that approval in highly regulated markets, such as the US and Europe, takes longer than expected, resulting in a delay in attaining revenue generation status.
- **Timing risk:** There is a risk that Immuron's clinical programmes may take longer to execute than expected, negatively affecting investor sentiment towards the company.
- **Competition risk:** There is a 'what if' scenario in which new and/or existing competitors develop a superior and more affordable product targeting the same market opportunity as Immuron. If this risk materialises, it could hinder the company's market share growth and margins.
- **Forex risk:** When commercialised, Immuron's earnings will be in the local currency of applicable markets. Currency fluctuations can impact the company's total earnings in AUD.

Appendix I - Analyst certification

Stuart Roberts, lead analyst on this report, has been an equities analyst since 2002.

- Stuart obtained a Master of Applied Finance and Investment from the Securities Institute of Australia in 2002. Previously, from the Securities Institute of Australia, he obtained a Certificate of Financial Markets (1994) and a Graduate Diploma in Finance and Investment (1999).
- Stuart joined Southern Cross Equities as an equities analyst in April 2001. From February 2002 to July 2013, his research speciality at Southern Cross Equities and its acquirer, Bell Potter Securities, was Healthcare and Biotechnology. During this time, he covered a variety of established healthcare companies, such as CSL, Cochlear and Resmed, as well as numerous emerging companies. Stuart was a Healthcare and Biotechnology analyst at Baillieu Holst from October 2013 to January 2015.
- After 15 months over 2015–2016 doing Investor Relations for two ASX-listed cancer drug developers, Stuart founded NDF Research in May 2016 to provide issuer-sponsored equity research on ASX-listed Life Sciences companies.
- In July 2016, with Marc Kennis, Stuart co-founded Pitt Street Research Pty Ltd, which provides issuer-sponsored research on ASX-listed companies across the entire market, including Life Sciences companies.
- Since 2018, Stuart has led Pitt Street Research's Resources Sector franchise, spearheading research on both mining and energy companies.

Nick Sundich, lead analyst on this report, is an equities research analyst at Pitt Street Research.

- Nick obtained a Bachelor of Commerce/Bachelor of Arts from the University of Sydney in 2018. He has also completed the CFA Investment Foundations program.
- He joined Pitt Street Research in January 2022. Previously he worked for over three years as a financial journalist at Stockhead.
- While at university, he worked for a handful of corporate advisory firms.

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