PITT STREET RESEARCH

Hydrix Ltd.

Guardian doesn't need Australia

After three years of steady progress with the Guardian device, Hydrix (ASX:HYD) appeared to encounter an impediment. Upon receiving advice from Australia's TGA that the company's application for the Guardian Device was unlikely to be approved, it decided to withdraw the application with a view toward resubmitting at a later date.

We can understand investors being surprised with this decision considering the device was FDA approved back in 2021. But we think investor reaction implies belief that the success of Hydrix was predicated on Australian rollout, when this is not the case. Australia is just one of eight markets that Hydrix is aspiring to distribute Guardian in and accounts for just 5% of the combined population of those exclusive markets. Guardian is already commercialised in Singapore and Malaysia, with Thailand FDA regulatory review in process (possible approval in CY23), with applications to follow in Hong Kong and Japan.

Hydrix Services performing well & Hydrix Ventures companies reaching milestones

We also think the adverse reaction depicts that investors have been disregarding the Hydrix Services and Hydrix Ventures divisions as value drivers of the business or that they have been impacted by adverse macroeconomic conditions. Hydrix Services' 1HY23 revenues were up 24% from the prior corresponding period. And Hydrix Ventures investee companies have significant milestones awaiting in the coming months.

Valuation of $0.166-$0.224 per share reiterated

We last valued Hydrix at $0.166 per share base case and $0.224 per share bull case in our previous report dated 25 January and we reiterate our valuation, noting that the key driver of value was the company's Services business. Our Guardian sales assumptions were more modest and geographical agnostic. And investee companies of Hydrix Ventures are unlikely to have been impacted by the equity market volatility, being private companies. Key risks are outlined on page 8.

Share Price: A$0.038

ASX: HYD

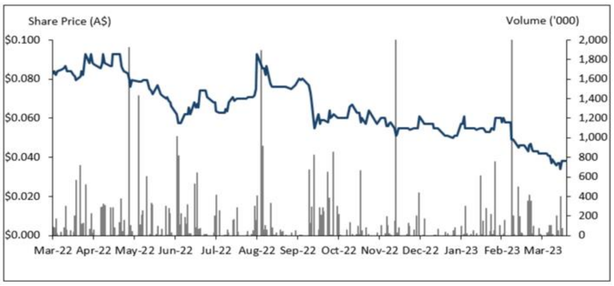
Sector: Life Sciences

30 March 2023

Market Cap. (A$ m)	9.6
# Shares outstanding (m)	254.2
# Share fully diluted (m)	341.6
Market Cap Full. Dil. (A$m)	13.0
Free Float	85.0%
12-months high/low (A$)	0.93 / 0.034
Avg. daily volume ('1000)	188.1
Website	www.hydrix.com

Source: Company, Pitt Street Research

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



Source: Refinitiv Eikon, Pitt Street Research

Valuation metrics	
Fair valuation range (A$)	0.166-0.224
WACC	14.5%
Assumed terminal growth rate	2.0%

Estimates: Pitt Street Research

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Guardian progressing, even without Australia

Hydrix is a diversified company with three divisions.

As outlined in our initiation report published last November, Hydrix is a diversified company with three divisions. A core **Hydrix Services** business that provides outsourced design and engineering services to third-party product developer clients. **Hydrix Ventures,** an investment arm that has minority interest states in four early stage medtech companies – outlined later in this note. And a third division, **Hydrix Medical** that is business unit focused on the distribution of cardiovascular devices.

The Guardian device, licensed from AngelMed, was the foundation of the Hydrix Medical business and the 'golden goose' of the entire entity, as judged by investor reaction to news around commercial milestones.

Three years of progress with the Guardian

The Guardian device is a cardiac monitor implanted in a similar fashion to a single chamber pacemaker. It uses a patented artificial intelligence software to detect in real-time when a coronary artery is closing, alerting the patient to seek medical help. It offers improved care, improved clinical experience and reduced costs in being able to identify asymptomatic heart attacks and other Acute Coronary Syndrome (ACS) events.

In the last three years, Hydrix has made solid progress with the Guardian Device.

In the last three years, Hydrix has made solid progress with the Guardian Device. In March 2020, it acquired exclusive rights to distribute the device in eight Asia-Pacific jurisdictions, securing its first disruptive cardiac device for distribution – including, Australia, Singapore, Malaysia, Hong Kong and Japan. The device was approved by the FDA in June 2021, paving the way for approval in Singapore and Malaysia in mid-2022 and investors had presumed Australia was to come.

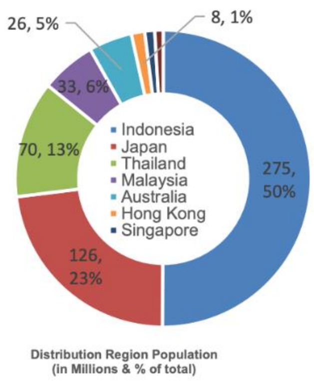
TGA: Are we there yet?

Hydrix applied to the TGA in July 2021 for inclusion in the Australian Register of Therapeutic Goods (ARTG). This would facilitate its commercialisation in Australia. On 15 February 2023, Hydrix was advised that its application for regulatory approval was not going to be accepted. The TGA advised that AngelMed's clinical evidence did not demonstrate that the patient benefits sufficiently outweighed the risks. 12 days later, Hydrix decided to withdraw the application with a view to resubmitting at a later date, with further patient data.

The adverse share price reaction implies investors are surprised by this decision and think it is a setback big enough to impact on the revenue and earnings of the entire company. Investors are right to be surprised, as it is approved by the FDA on the basis of clinical evidence provided that the benefits outweighed the risks – the regulatory authorities in Malaysia and Singapore agreed. And indeed this is a setback for Australian patients and for commencing sales in Australia. But it does not impact on the company's current and nearterm revenue or earnings prospects.

Australia's population represents just 5% of the eight countries in the Asia-Pacific where Hydrix has exclusive distribution rights. In Singapore and Malaysia, Hydrix already has access to a population of 41 million and that's before you consider countries where approval is still to come, namely Indonesia, Japan, Hong Kong and Thailand as well as New Zealand (Figure 1 on page 4). All eight markets combined represent a population of 500m and Australia is just over 5% of this.

Figure 1: Hydrix's market opportunity



Country / Agency	Appl. Date	Status
USA / FDA	n/a	Approved
Singapore / HSA	16-Aug-21	Approved
Malaysia / MOH	27-Dec-21	Approved
Thailand / Thai FDA	12-Oct-21	In process
New Zealand / MMDSA	11-Aug-21	WAND notified
Hong Kong	-	In process
Japan	-	In process
Indonesia	-	In planning

Source: Company

Of all the countries where Hydrix is aspiring to obtain approval, we think Thailand is likely to be next considering submission for approval with Thailand's FDA was made to the regulator in October 2021. This market alone is more than 2.5 times the size of Australia. Hong Kong and Japan are likely to come thereafter. The company has engaged a Japanese Clinical Research Organisation to develop the regulatory and reimbursement pathway to market and distribute the Guardian in Japan.

Beyond having significant populations, all these countries have a big cardiovascular disease burden that is increasing. In Thailand, for instance, Coronary Heart Disease deaths were 51,305, or 11.53% of total deaths in 2020 according to the World Health Organisation. Even in Japan, a country with a high life expectancy, Statista estimates that there were over 205,000 deaths from cardiovascular diseases generally in 2020. And Indonesia experiences over 600,000 deaths from cardiovascular diseases annually. The Guardian device can reduce the disease burden for countries where it is approved by regulators, by alerting users to seek medical attention.

Hydrix Medical has good prospects in the years ahead

We turn our attention to our model for Hydrix and highlight three points to investors.

First, Hydrix Services is and will continue to be the more important revenue driver for the business. Even in FY27, we project it will still account for 75% of revenues (Figure 2 on page 5).

Second, our assumptions for Guardian sales were modest. We assumed 30 devices were sold in FY23, 100 in FY24, 250 in FY25, 420 in FY26 and 600 in FY27. We think that even if the Guardian was not approved in any further jurisdictions, this would be a reasonable forecast. But assuming it will enter further markets, we think this is a conservative estimate.

And third, we see potential for Hydrix Medical to distribute further medtech devices that we have not accounted for in our current model. Hydrix has told shareholders that it is actively engaged in discussions with several emerging USA and European cardiovascular technology products to distribute their products in Australia and South-East Asia. Products being evaluated include medical software-as-a-service and other highly specialised products used, to monitor and diagnose cardiovascular diseases and in surgical intervention procedures to help address heart failure.

Figure 2: Financial projections for Hydrix's results

Profit & Loss (AUD'000)	2020	2021	2022	2023	2024	2025	2026	2027
Hydrix Services Revenue	*14,934*	*7,374*	*10,322*	*14,219*	*15,745*	*17,401*	*19,188*	*21,107*
Hydrix Medical Revenue	*0*	*104*	*3*	*195*	*673*	*1,741*	*3,027*	*4,475*
Sales from Customers / Business Operations	***14,934***	***7,478***	***10,325***	***14,414***	***16,418***	***19,142***	***22,215***	***25,582***
Other Income	954	1,851	133	146	161	177	195	214
Interest Income	12	15	10	19	21	83	91	128
Total Revenue	**15,900**	**9,344**	**10,468**	**14,579**	**16,599**	**19,402**	**22,501**	**25,925**
Operating expenses	(16,307)	(15,533)	(14,409)	(17,484)	(17,472)	(17,275)	(16,873)	(17,915)
EBITDA	**(407)**	**(6,189)**	**(3,940)**	**(2,905)**	**(873)**	**2,127**	**5,628**	**8,010**
Depn & Amort	(1,161)	(2,447)	(1,142)	(313)	(575)	(1,134)	(1,756)	(2,451)
EBIT	**(1,568)**	**(8,636)**	**(5,082)**	**(3,218)**	**(1,448)**	**993**	**3,873**	**5,559**
Finance Cost	(1,305)	(1,110)	(464)	(528)	(430)	(352)	(308)	(264)
Profit/(Loss) before tax	**(2,873)**	**(9,746)**	**(5,546)**	**(3,746)**	**(1,878)**	**641**	**3,564**	**5,295**
Tax expense	(347)	0	0	0	0	(135)	(713)	(953)
NPAT	**(3,219)**	**(9,746)**	**(5,546)**	**(3,746)**	**(1,878)**	**506**	**2,851**	**4,342**

Estimates: Pitt Street Research

Hydrix Services the primary momentum driver of the company

The Hydrix Services business delivers design, engineering and regulatory services, helping clients achieve breakthroughs in the development of new products. It offers services from small-scale proof of concept feasibility projects for start-ups to large-scale, multi-year, advanced engineering projects.

The Hydrix Services division has, and will remain for some time, the underlying momentum driver of the company's revenues.

The Hydrix Services division has, and will remain for some time, the underlying momentum driver of the company's revenues. 1HY23 revenues for the Services division were up 24% from the prior corresponding period. The performance led us to upgrade our valuation on the company given our FY23 projections were behind what the company had achieved as well as what it was and is on track to achieve. We also note that Hydrix Services turned from a cash operating loss of $1.1m in 1HFY22 to a $0.2m cash operating profit in 1HFY23 (equals EBITDA less cash operating rent amortised and excludes one-time charges/benefits).

This can be attributed to major client wins, driven by work that the company has achieved. One example was ANSTO, who Hydrix helped develop an advanced radiation imaging product solution (CORIS360). It was used to successfully locate a radioactive capsule in outback Western Australia. It is also attributable to the 1st generation product the company is developing for Cyban (see Ventures below), noting the company announced the next major product development stage contract in February for $1.45m, helping to underpin the next six months revenue outlook.

Hydrix Services has undertaken significant expansion in the USA in recent months, hiring a second team member and advancing a new USA medtech client to a second stage development contract in January with the potential to undertake further product development stages.

Hydrix Ventures companies awaiting major milestones

Hydrix Ventures has minority investments in AngelMed (the owner of the Guardian device), as well as three other medtech companies: Gyder, Cyban and Memphasys. Gyder Surgical is developing a non-invasive surgical navigation system to improve alignment in hip replacement surgeries. Cyban is developing a next-generation non-invasive brain oxygen monitoring device that can help prevent further brain injuries. And Memphasys is working on Felix, a device for generating better quality sperm for use in IVF procedures. Figure 3 outlines our valuation of Hydrix Ventures companies, as per our initiation report.

Figure 3: Hydrix Ventures investee companies valuation

	HV investment stake post-dilution (%)	Company valuation (A$m)	HV share valuation (A$m)
Memphasys	1.00%	17.8	0.2
Cyban	3.70%	131.4	4.9
Gyder Surgical	7.50%	137.8	10.3
Angel Medical Systems	2.00%	681.5	13.6
TOTAL (A$m)			**29.0**
Diluted Shares ('000)			308.5
Per share price (A$)			**0.094**
Holding company discount (%)			-50%
Effective valuation per share (A$ cents)			**0.047**

Estimates: Pitt Street Research

Although private companies have not been immune from revaluations amidst the 'Tech Wreck' of CY22, this has typically only occurred when companies have had to raise capital. Hydrix's stake in Angel Medical Systems will re-rate in conjunction with Guardian's commercial progress. There has also been progress with Hydrix's other investee companies.

Gyder Surgical's first generation product was completed. A Medical Device Single Audit Program review was completed as a precursor to making an application for inclusion onto the Australian Register of Therapeutic Goods and a 510K application submitted to the US Food & Drug Administration (FDA). In late February 2023, Hydrix received equity in lieu of completing the product development milestone. Two further equity payment milestones become due and payable when the product is accepted onto the Australian Register of Therapeutic Goods and when the product is granted FDA approval. Pending approvals, Gyder Surgical anticipates commencing commercial sales in the USA and Australia in CY23.

Turning to Cyban, it reported in February that one of its clinical trials demonstrated a major breakthrough in that its non-invasive brain monitor delivers equivalent results to invasive intracranial pressure (ICP) monitoring to offer a simple and safe alternative way to treat critical brain injuries. Development has continued on Cyban's 1st generation product, with input from Hydrix Service's division.

Another is Memphasys (ASX: MEM) which has the Felix system that sorts healthy sperm to optimise outcomes from IVF treatments. Two peer reviewed globally significant journals reported Memphasys' positive results from clinical testing that found that the system outperforms the current market standard, the density gradient centrifugation (DGL) method.

Reiterated valuation of $0.166-$0.225 per share

In our initiation report, published 24 November 2022, we valued Hydrix at A$0.153 per share base case and A$0.206 per share bull case. Investors interested in a more detailed outline should view our initiation report.

To briefly re-cap here, we used a blended DCF and peer group valuation for the Hydrix Services and Hydrix Medical businesses and Hydrix Ventures at $0.047 per share, using a SOTP valuation, taking into account all four companies in the portfolio. We used a 14.5% WAAC reflecting a 16.5% cost of equity and a 7.5% post-tax cost of debt.

There were three differences between our base and bull cases: First, slightly stronger growth in the Hydrix Services Division; Second, higher Guardian sales in the Hydrix Medical Division; and Third, a halved discount attributed to the company to account for the premium companies on overseas exchanges trade at relative to ASX companies.

We reiterate our valuation of Hydrix at $0.166 per share base case and $0.225 per share bull case.

In January, we updated our DCF valuation in January on account of its strong 1HY23 results, thereby increasing our valuation to $0.166 per share base case and $0.225 per share bull case. We increased our FY23 results and while retaining the same growth rates for future years, this improved the company's results from FY24 onwards as they were based on year to year growth. We reiterate our valuation (Figures 4 and 5).

Figure 4: Weighted average valuation for Hydrix (base)

Valuation	Weighting (%)	Share price (A$)
DCF	50.0%	0.087
Relative valuation	50.0%	0.151
Business Value		**0.119**
Hydrix Ventures		0.047
Composite Value		**0.166**
Current Price		0.036
Upside/Downside (%)		361.1%

Estimates: Pitt Street Research

Figure 5: Weighted average valuation for Hydrix (bull)

Valuation	Weighting (%)	Share price (A$)
DCF	50.0%	0.155
Relative valuation	50.0%	0.201
Business Value		**0.178**
Hydrix Ventures		0.047
Composite Value		**0.224**
Current Price		0.036
Upside/Downside (%)		522.2%

Estimates: Pitt Street Research

Figure 6: DCF value in A$ cents using various WACCs (base case)

Sensitivity						
WACC	**14.5%**					
Terminal Growth	**2.00%**					
Implied Price	**0.087**	*10.5%*	*12.5%*	*14.5%*	*16.5%*	*18.5%*
Change in Terminal Growth Rate	*0.50%*	13.7	10.3	8.0	6.2	4.9
	1.00%	14.3	10.7	8.2	6.4	5.1
	1.50%	15.1	11.1	8.5	6.6	5.2
	2.00%	15.7	11.5	**8.7**	6.8	5.3
	2.50%	16.6	12.0	9.1	7.0	5.4
	3.00%	17.6	12.6	9.4	7.2	5.6
	3.50%	18.7	13.2	9.8	7.4	5.8

Factors supporting a re-rating of Hydrix

The Hydrix stock is currently trading below our valuation. We see four factors supporting a re-rating:

– Increase in traction for the Hydrix Services business;

– Regulatory approval of Guardian in other target markets, particularly Thailand;

– Increased adoption of the Guardian device in its existing markets of Singapore and Malaysia (with potential to appoint sub distributor to accelerate sales there);

– Strong progression across venture companies as they reach key commercial inflection stages.

Risks

We see the following key risks associated with Hydrix:

– **Regulatory risk:** Hydrix requires approval from respective regulators across countries to be able to market and distribute Guardian cardiovascular devices. There exists a risk of either being denied the approval or unexpected delay in receiving. Either of those cases may impact the revenue growth prospects, particularly if it were important markets for the company from a revenue perspective. The investor reaction to the TGA outcome, even though Australia was one of the smaller targets for the company, depicts that investors are playing close attention to this risk.

– **Execution risk**: There exists a risk that the Guardian device may not attract the kind of reimbursement it is looking for. This could be due to increased competition from companies offering alternative solutions. This will necessitate higher capex into research, sales and marketing. Consequently, this may impact the expected profitability trajectory for Hydrix.

– **Capital risk**: Considering that a lot of companies in the medtech space are chasing private capital, there exists a risk of higher cost of capital for Hydrix. With inflationary pressure continuing across globe, higher cost of capital will reduce the fundamental return for Hydrix's investors.

– **Market risk**: There is the risk that the investee companies in Hydrix Ventures suffer a delay in reaching their commercial inflection stage (difficulty in raising enough capital, delay in product trials, regulatory hurdle etc.). This would impact the valuation proposition for Hydrix.

- **Macroeconomic risk**: A downturn in macroeconomic conditions could cause existing and would-be Hydrix Services clients to cut back expenditure on R&D projects. This will cause a decrease in Hydrix's revenue and thus impact our expected trajectory for the company.

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 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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The analyst has received assistance from the company in preparing this document. The company has provided the analyst with communication with senior management and information on the company and industry. As part of due diligence, the analyst has independently and critically reviewed the assistance and information provided by the company to form the opinions expressed in the report. Diligent care has been taken by the analyst to maintain an honest and fair objectivity in writing this report and making the recommendation.