EDISON

AdAlta

Development update

Moving into CAR-T

Pharma & biotech

AdAlta has announced a collaboration with Carina Biotech, a private Australian company, in which the two companies will work together to develop chimeric antigen receptor T cell (CAR-T) therapies for solid tumours. Under the agreement, AdAlta will discover and optimise proprietary i-bodies on up to five undisclosed tumour antigen targets, from which Carina will generate bi-specific CAR-T cells and identify optimal candidates. We believe the CAR-Ts will be autologous, generated from a patient's own cells. The two companies will jointly fund pre-clinical proof of concept studies in mouse tumour models and jointly own the products developed under the collaboration. We believe it will likely be several years before a candidate enters the clinic and AdAlta does not expect this collaboration to have a material impact on its current cash runway.

Year end	Revenue (A$m)	PBT* (A$m)	EPS* (A$)	DPS (A$)	P/E (x)	Yield (%)
06/20	3.8	(5.9)	(0.04)	0.0	N/A	N/A
06/21e	4.0	(5.5)	(0.02)	0.0	N/A	N/A
06/22e	3.2	(7.6)	(0.03)	0.0	N/A	N/A
06/23e	3.2	(7.7)	(0.03)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

CAR-T therapies revolutionised cancer treatment

CAR-T therapies work by engineering the body's immune T-cells to recognise cancer cells as they would invading or diseased cells. There are currently five approved CAR-T therapies, all for blood cancers. The first two, Kymriah from Novartis and Yescarta from Gilead, were approved in 2017 and had combined sales of over US$1bn in 2020.

Solid tumours remain a major unmet need

There are currently no approved CAR-T therapies for solid tumours, mainly due to toxicity. If the target antigen is also found in normal cells, catastrophic toxicities can result. AdAlta and Carina believe that bi-specific CAR-Ts that target two tumour antigens could reduce the chance of damaging healthy tissue and could also reduce the probability that tumour cells are missed.

Products in collaboration jointly owned

Under the terms of the collaboration, AdAlta and Carina will jointly own the products developed under it. On an individual product basis, the companies may decide to co-develop any product, out-license it to third parties or either party may license the other company's share in the product.

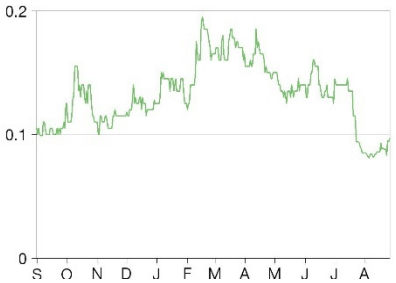
Valuation: A$75m or A$0.30 per basic share

We are increasing our valuation to A$75m or A$0.30 per basic share, from A$68m or A$0.28 per basic share, mainly due to rolling forward our net present valuation (NPV). This was partially offset by lower net cash. We do not currently value the Carina collaboration due to its early stage.

31 August 2021

Price	**A$0.10**
Market cap	**A$24m**
	A$1.38/US
Net cash (A$m) at 30 June 2021	4.1
Shares in issue	245.2m
Free float	78.6%
Code	1AD
Primary exchange	ASX
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	4.3	(28.1)	(3.0)
Rel (local)	3.0	(32.2)	(21.4)
52-week high/low		A$0.20	A$0.08

Business description

AdAlta is an Australian healthcare company focused on using its proprietary i-body discovery platform to target diseases, with an initial focus on conditions involving fibrosis. Its lead programme is AD-214 for the treatment of idiopathic pulmonary fibrosis, currently in Phase I. AdAlta has also licensed its platform to GE Healthcare for the purpose of diagnostic imaging. The company has recently announced a CAR-T collaboration with Carina Biotech.

Next events

Addition of two more internal products to pipeline	H2 CY21

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Edison profile page

AdAlta collaboration with Carina Biotech

Under the announced agreement, AdAlta will discover and optimise proprietary i-bodies on up to five undisclosed tumour antigen targets, from which Carina will generate CAR-T cells, including bi-specific and dual CAR-T cells, and identify optimal candidates. The first two targets have been selected for the collaboration with in vitro proof of principle having been established for one of them.

CAR-T therapies have helped revolutionise the treatment of blood cancers and work by engineering the body's immune T-cells to recognise cancer cells as they would invading or diseased cells. Novartis's Kymriah was the first CAR-T therapy approved in the United States (in 2017) and was approved for relapsing B-cell acute lymphoblastic leukaemia in children and young adults. Kymriah consists of a one-time treatment that had an 83% complete response rate in clinical trials with patients who did not respond to standard treatments. Due to these results and a costly manufacturing process, Kymriah was priced at a premium of US$475,000 for the treatment. Kymriah sales in 2020 were US$474m with current consensus expectations for 2025 sales at US$1.2bn according to Evaluate Pharma. A second therapy, Yescarta, was approved later in 2017 in patients with large-B-cell lymphomas whose cancer has progressed after receiving at least two prior treatment regimens. The therapy demonstrated a 51% complete response rate and has a price of US$373,000 per treatment. Sales in 2020 for Yescarta were US$563m with consensus expectations for US$1.3bn in sales in 2025 according to Evaluate Pharma. It is important to note that Gilead acquired Yescarta through its purchase of Kite Pharmaceuticals for US$11.9bn. In total there are currently five approved CAR-T therapies (see Exhibit 1), all for blood cancers.

Exhibit 1: Currently approved CAR-T therapies

Product	Manufacturer	Indication	FDA approval date	2020 sales (US$m)	Consensus 2025 sales (US$m)
Kymriah	Novartis	Acute lymphoblastic leukaemia, large B cell lymphoma	August 2017	474	1,156
Yescarta	Gilead	Large B cell lymphoma	October 2017	563	1,294
Tecartus	Gilead	Mantle cell lymphoma	July 2020	44	547
Breyanzi	Bristol Myers Squibb	Large B cell lymphoma	February 2021	N/A	1,120
Abecma	Bristol Myers Squibb	Multiple myeloma	March 2021	N/A	1,366

Source: AdAlta, EvaluatePharma

The focus of the collaboration will be solid tumours that have no approved CAR-T therapies. The main concern with CAR-T is that if the target antigen is also found in normal cells, catastrophic toxicities can result. In one case involving a breast cancer patient who received an HER2 targeting CAR-T, just 15 minutes after cell infusion the patient started experiencing respiratory distress and then died five days after treatment from multi-organ failure due to systematic microangiopathic injury.[1] Of course, there are other issues that have hampered solid tumour CAR-T development, including suboptimal infiltration into tumour tissue and the immunosuppressive tumour microenvironment affecting efficacy.[2] AdAlta and Carina believe that bi-specific and dual CAR-T cells that target two tumour antigens could reduce the chance of damaging healthy tissue and/or reduce the probability that tumour cells are missed.

1 Morgan et al., Case Report of a Serious Adverse Event Following the Administration of T Cells Transduced With a Chimeric Antigen Receptor Recognizing ErbB2. *Molecular Therapy* vol. 18 no. 4, 843–851 Apr. 2010

2 Marofi et al., CAR T cells in solid tumors: challenges and opportunities. *Stem Cell Research and Therapy* (2021) 12:81

Valuation

We are increasing our valuation to A$75m or A$0.30 per basic share, from A$68m or A$0.28 per basic share, mainly due to rolling forward our NPV. This was partially offset by lower net cash. We do not currently value the Carina collaboration due to its early stage. This may change as the collaboration advances and we receive more information on the targets and specific indications.

Exhibit 2: AdAlta valuation table

Product	Main indication	Status	Probability of successful commercialisation	Approval year	Peak sales (A$m)	Economics	rNPV (A$m)
AD-214	IPF	Phase I	15%	2028	718	100.0%	70.4
Total							70.4
Net cash (as of 30 June 2021)							4.1
Total firm value (A$)							75
Total basic shares (m)							245.2
Value per basic share (A$)							0.30
Options (m)							7.9
Total number of shares (m)							253.1
Diluted value per share (A$)							0.29

Source: Edison Investment Research

Financials

The company recently reported FY21 results. Operating cash burn was A$4.8m for the year (vs A$5.9m in FY20) and the company reported A$4.1m in net cash (A$5.8m in gross cash and A$1.7m in short-term debt) at 30 June 2021. Following the annual results we have increased our estimate for FY22 SG&A expense by A$1.4m due to a higher run rate, but left everything else largely unchanged. We have introduced FY23 estimates, which feature an operating cash burn of A$7.1m. We estimate that AdAlta will likely need to raise an additional A$12m through the end of FY23 (up from A$11m previously), barring additional cash received from licensing deals.

Exhibit 3: Financial summary

A$'000s	2020	2021	2022e	2023e
Year end 30 June	AIFRS	AIFRS	AIFRS	AIFRS
PROFIT & LOSS				
Revenue	3,828	3,984	3,168	3,199
Cost of Sales (including R&D)	(7,012)	(6,234)	(7,169)	(7,240)
Gross Profit	(3,185)	(2,249)	(4,001)	(4,041)
Sales, General and Administrative Expenses	(1,265)	(2,623)	(2,728)	(2,837)
EBITDA	(5,798)	(5,389)	(7,494)	(7,644)
Operating Profit (before amort. and except.)	(5,840)	(5,418)	(7,524)	(7,673)
Intangible Amortisation	0	0	0	0
Exceptionals	(70)	(115)	0	0
Operating Profit	(5,910)	(5,534)	(7,524)	(7,673)
Net Interest	(96)	(95)	(56)	(58)
Other	0	0	0	0
Profit Before Tax (norm)	(5,936)	(5,513)	(7,579)	(7,730)
Profit Before Tax (FRS 3)	(6,006)	(5,628)	(7,579)	(7,730)
Tax	0	0	0	0
Deferred tax	(0)	(0)	(0)	(0)
Profit After Tax (norm)	(5,936)	(5,513)	(7,579)	(7,730)
Profit After Tax (FRS 3)	(6,006)	(5,628)	(7,579)	(7,730)
Average Number of Shares Outstanding (m)	164.0	234.3	250.0	252.5
EPS - normalised (c)	(3.62)	(2.35)	(3.03)	(3.06)
EPS - Reported ($)	(0.04)	(0.02)	(0.03)	(0.03)
Dividend per share (c)	0.0	0.0	0.0	0.0
BALANCE SHEET				
Fixed Assets	177	72	73	75
Intangible Assets	0	0	0	0
Tangible Assets	99	72	73	75
Other	78	0	0	0
Current Assets	6,731	8,978	5,241	5,097
Stocks	0	0	0	0
Debtors	3,364	3,108	3,108	3,108
Cash	3,367	5,791	2,055	1,911
Other	0	78	78	78
Current Liabilities	(3,205)	(2,663)	(937)	(937)
Creditors	(1,014)	(976)	(937)	(937)
Short term borrowings	(2,191)	(1,687)	0	0
Long Term Liabilities	0	0	(5,000)	(12,000)
Long term borrowings	0	0	(5,000)	(12,000)
Other long term liabilities	0	0	0	0
Net Assets	3,702	6,386	(622)	(7,765)
CASH FLOW				
Operating Cash Flow	(5,889)	(4,782)	(7,051)	(7,142)
Net Interest	0	0	0	0
Tax	0	0	0	0
Capex	(2)	(2)	(2)	(2)
Acquisitions/disposals	0	0	0	0
Financing	1,626	8,123	0	0
Dividends	0	0	0	0
Other	0	0	0	0
Net Cash Flow	(4,265)	3,339	(7,053)	(7,144)
Opening net debt/(cash)	(5,556)	(1,175)	(4,104)	2,945
HP finance leases initiated	0	0	0	0
Exchange rate movements	0	(15)	0	0
Other	(116)	(396)	5	0
Closing net debt/(cash)	(1,175)	(4,104)	2,945	10,089

Source: company accounts, Edison Investment Research

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