EDISON

AdAlta

Development update

Validation from GE Healthcare

Pharma & biotech

AdAlta recently announced that its collaboration with GE Healthcare is moving into the next stage as GE Healthcare has selected multiple i-bodies from AdAlta's platform to progress into preclinical development. Additionally, the two companies have agreed to amend their agreement as AdAlta will now provide manufacturing support for both preclinical and clinical development for these candidates. It will also be conducing certain preclinical studies. These activities will earn AdAlta additional research fees, although the exact size of these has not been disclosed.

Year end	Revenue (A$m)	PBT* (A$m)	EPS* (A$)	DPS (A$)	P/E (x)	Yield (%)
06/19	3.5	(5.9)	(0.05)	0.0	N/A	N/A
06/20	3.8	(5.9)	(0.04)	0.0	N/A	N/A
06/21e	3.2	(6.1)	(0.02)	0.0	N/A	N/A
06/22e	3.3	(6.2)	(0.02)	0.0	N/A	N/A

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

Targeting granzyme B

As mentioned previously, the target at the focus of the collaboration with GE Healthcare is granzyme B, a known marker of T-cell activation and hence an early biomarker for immunotherapy response in tumours. Initially, the commercial market focus would be to support pharmaceutical companies in enhancing their clinical trials. Subsequently, the goal would be to gain approvals for the product to be used as a routine diagnostic and patient stratification tool.

Entering a large diagnostic imaging market

The granzyme B candidates are classified as positron emission tomography (PET) imaging agents. According to market research highlighted by the company, the largest PET imaging agents generate more than US$400m in annual sales and the diagnostic radiopharmaceuticals market is forecast to exceed US$6.4bn by 2027.

Initiated dosing of Part B of AD-214 Phase I trial

Following the positive results from Part A of the AD-214 Phase I trial, the company has initiated Part B, a blinded, placebo-controlled, multiple ascending dose (MAD) study in 12–24 healthy volunteers dosed at 5–15mg/kg every two weeks. So far, eight participants have received 5mg/kg of AD-214 or placebo with no reported dose-limiting adverse events to date. This study should be completed by year-end CY21.

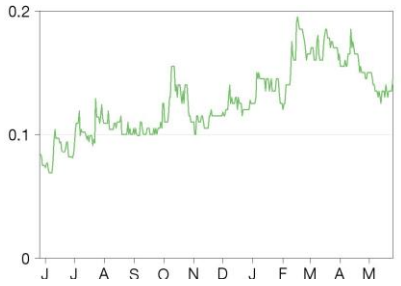
Valuation: A$68m or A$0.28 per basic share

We have slightly adjusted our valuation for AdAlta from A$70m (or A$0.29 per share) to A$68m (or A$0.28 per basic share) due exclusively to lower reported net cash. While progress has been made in the GE Healthcare collaboration, we do not yet include it in our valuation as timing for entry into clinical trials as well as financial details have not been disclosed. The company had A$6.0m in cash at 31 March 2021 and we estimate will likely need to raise an additional A$11m through the end of FY23, barring additional licensing deals.

26 May 2021

Price	**A$0.15**
Market cap	**A$36m**
	A$1.29/US$
Net cash (A$m) at 31 March 2021	6.0
Shares in issue	245.2m
Free float	78.7%
Code	1AD
Primary exchange	ASX
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	(3.3)	(9.4)	83.0
Rel (local)	(3.7)	(12.4)	42.7
52-week high/low	A$0.20		A$0.07

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.

Next events

Second co-development deal	Mid-CY21
AD-214 Phase Ib initiation	Q3 CY21

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Edison profile page

GE Healthcare moving forward with granzyme B

In September 2019, AdAlta licensed its i-body platform to GE Healthcare for diagnostic imaging purposes in combination with PET tracing. The objective is to identify molecular markers of activated T-cells, which could help in the selection and monitoring of patients who are receiving immunotherapy. The initial focus of the collaboration is granzyme B, which has been shown to be a potentially helpful early biomarker for immunotherapy response in tumours. GE Healthcare has now selected multiple i-bodies from AdAlta's platform to progress into preclinical development. Additionally, the two companies have agreed to amend their agreement as AdAlta will now provide manufacturing support for both preclinical and clinical development for these candidates. AdAlta will also be conducing certain in vitro preclinical studies. These activities will earn AdAlta additional research fees, although the exact size of these has not been disclosed. As of 31 December 2020, AdAlta had received A$1.15m in milestones and research fees as part of the collaboration.

With regards to the AD-214 programme in idiopathic pulmonary fibrosis (IPF) and interstitial lung disease (ILD), it continues to progress through Phase I. As a reminder, in March AdAlta announced preliminary results from Part A of the Phase I programme for AD-214 in 42 healthy volunteers who received either a single dose of AD-214 or placebo. AD-214 was very well tolerated in single doses up to 20mg/kg. There were no dose-limiting or serious adverse events (adverse events were mostly mild with three grade 2 adverse events) and no concerning clinical laboratory results. Additionally, AD-214's pharmacokinetics increased proportionally with the dose and there was high sustained receptor occupancy. There was also evidence of CXCR4 engagement through transient increases of white blood cell and stem cell increases (signs of CXCR4 inhibition) as well as transient increases in SDF-1 (a natural ligand of CXCR4).

In April, the company progressed the programme into Part B, a blinded, placebo-controlled, MAD study in 12–24 healthy volunteers dosed at 5–15mg/kg every two weeks. So far, eight participants have received 5mg/kg of AD-214 or placebo with no reported dose-limiting adverse events to date. Part B should be completed by year-end CY21 with data available as early as H1 CY22. These data should enable an IND filing in CY22 to begin the Phase II programme. Additionally, this safety package would be expected to cover all intravenous indications for AD-214.

The company expects to commence a separate two-arm Phase Ib study in Q3 of CY21, which will seek to demonstrate AD-214 distribution and CXCR4 receptor occupancy in patients with fibrotic disease, as well as seek initial indications of efficacy (which could help open the partnership window). The first arm will feature a radio-labelled version of AD-214 for PET imaging and will have approximately 12 patients with fibrotic disease (including around six with IPF/ILD). The second arm will test a maximum of six doses of 5–10mg/kg over 18 weeks in six IPF/ILD patients with and without PET imaging. Both arms will be open label and on top of standard of care. As a reminder, preclinical studies indicated a target human therapeutic dose of 10mg/kg given intravenously either weekly or every other week.

The company has stated that a number of Asian region and multinational pharmaceutical companies are actively monitoring the progress of AD-214. Also, the company is aiming to add three more assets to its pipeline in CY21. With regards to internal assets, the company is evaluating a shortlist of potential targets implicated in fibrosis, inflammation and/or oncology, with those internal programmes expected to be announced in H2 CY21. AdAlta also continues to forecast that it will secure a second co-development partner (like GE Healthcare) in the middle of CY21.

Valuation

We have slightly adjusted our valuation for AdAlta from A$70m (or A$0.29 per share) to A$68m (or A$0.28 per basic share) due exclusively to lower reported net cash (at 31 March). While progress has been made in the GE Healthcare collaboration, we do not yet include it in our valuation as timing for entry into clinical trials as well as financial details have not been disclosed.

Exhibit 1: 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%	62.4
Total							62.4
Net cash (as at 31 March 2021)							6.0
Total firm value (A$)							68
Total basic shares (m)							245.2
Value per basic share (A$)							0.28
Options (m)							30.2
Total number of shares (m)							275.4
Diluted value per share (A$)							0.25

Source: Edison Investment Research

Financials

The company reported A$6.0m in cash at 31 March 2021, burning A$2.0m during the quarter. We have not made changes to our financial estimates as this is approximately in line with our forecasts. We estimate that AdAlta will likely need to raise an additional A$11m through the end of FY23, barring additional licensing deals.

Exhibit 2: Financial summary

A$'000s	2019	2020	2021e	2022e
Year end 30 June	AIFRS	AIFRS	AIFRS	AIFRS
PROFIT & LOSS				
Revenue	3,539	3,828	3,244	3,276
Cost of Sales (including R&D)	(7,354)	(7,012)	(7,082)	(7,153)
Gross Profit	(3,815)	(3,185)	(3,838)	(3,877)
Sales, General and Administrative Expenses	(1,315)	(1,265)	(1,316)	(1,368)
EBITDA	(5,957)	(5,798)	(5,920)	(6,011)
Operating Profit (before amort. and except.)	(5,989)	(5,840)	(5,961)	(6,052)
Intangible Amortisation	0	0	0	0
Other	(827)	(1,348)	(766)	(766)
Exceptionals	20	(70)	0	0
Operating Profit	(5,969)	(5,910)	(5,961)	(6,052)
Net Interest	51	(96)	(100)	(104)
Other	0	0	0	0
Profit Before Tax (norm)	(5,938)	(5,936)	(6,062)	(6,157)
Profit Before Tax (FRS 3)	(5,918)	(6,006)	(6,062)	(6,157)
Tax	0	0	0	0
Deferred tax	(0)	(0)	(0)	(0)
Profit After Tax (norm)	(5,938)	(5,936)	(6,062)	(6,157)
Profit After Tax (FRS 3)	(5,918)	(6,006)	(6,062)	(6,157)
Average Number of Shares Outstanding (m)	118.4	164.0	250.0	252.5
EPS - normalised (c)	(5.02)	(3.62)	(2.42)	(2.44)
EPS - Reported ($)	(0.05)	(0.04)	(0.02)	(0.02)
Dividend per share (c)	0.0	0.0	0.0	0.0
BALANCE SHEET				
Fixed Assets	141	177	164	166
Intangible Assets	0	0	0	0
Tangible Assets	138	99	86	88
Other	3	78	78	78
Current Assets	9,169	6,731	6,945	6,466
Stocks	0	0	0	0
Debtors	3,613	3,364	3,364	3,364
Cash	5,556	3,367	3,580	3,102
Other	0	0	0	0
Current Liabilities	(1,819)	(3,205)	(1,125)	(1,125)
Creditors	(1,819)	(1,014)	(1,125)	(1,125)
Short term borrowings	0	(2,191)	0	0
Long Term Liabilities	0	0	0	(5,000)
Long term borrowings	0	0	0	(5,000)
Other long-term liabilities	0	0	0	0
Net Assets	7,491	3,702	5,984	507
CASH FLOW				
Operating Cash Flow	(5,816)	(5,889)	(5,295)	(5,476)
Net Interest	0	0	0	0
Tax	0	0	0	0
Capex	(171)	(2)	(2)	(3)
Acquisitions/disposals	0	0	0	0
Financing	9,237	1,626	7,796	0
Dividends	0	0	0	0
Other	0	0	0	0
Net Cash Flow	3,250	(4,265)	2,498	(5,479)
Opening net debt/(cash)	(2,306)	(5,556)	(1,175)	(3,580)
HP finance leases initiated	0	0	0	0
Exchange rate movements	0	0	0	0
Other	0	-116	-93	0
Closing net debt/(cash)	(5,556)	(1,175)	(3,580)	1,898

Source: company reports, Edison Investment Research

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