EDISON

AdAlta

Development update

Moving to an inhaled formulation

Pharma & biotech

AdAlta has announced it will be moving forward with an inhaled formulation of AD-214 into efficacy studies in patients with idiopathic pulmonary fibrosis (IPF) rather than the original intravenous (IV) formulation. Preclinical studies with a radiolabelled version of AD-214 have indicated that IV dosing leads to much of the administered drug being rapidly distributed through the liver and cleared, rendering it unavailable to deliver a therapeutic effect. The company believes the advantages of an inhaled formulation will include a more direct form of administrations for lung diseases, potentially lower drug doses required for efficacy, and lower costs to manufacture and administer.

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.

Next steps for inhaled formulation development

With the new inhaled formulation, the company will need to conduct additional preclinical toxicology (with a focus on lung toxicity) and efficacy studies. Short bridging studies in healthy volunteers will also be needed. The company believes all these can be done with minimal delay to previously announced development timelines (i.e. time to Phase II efficacy data is largely unchanged).

Current Phase I study concluding

With the decision to move to an inhaled formulation, the company is concluding its Phase I programme for the IV formulation, which recently completed dosing of its first multiple dose cohort of eight subjects (six on drug and two on placebo) at 5mg/kg. After just two doses of AD-214, receptor occupancy was 100% and no drug induced tolerance occurred. Adverse events were mild (grade one) except for infusion-related reactions in two patients receiving AD-214, and one receiving placebo, which were grade two.

GE collaboration and internal pipeline on track

In May, AdAlta announced GE Healthcare is moving forward with multiple i-bodies that target granzyme B, a known marker of T-cell activation and hence an early biomarker for immunotherapy response in tumours. The collaboration on granzyme B remains on track. AdAlta is also expected to initiate discovery on two additional i-body targets by the end of CY21.

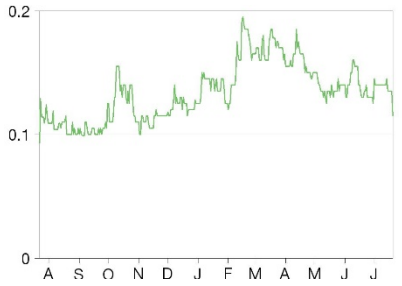
Valuation: A$68m or A$0.28 per basic share

We are maintaining our valuation of A$68m or A$0.28 per basic share as we continue to expect a launch of AD-214 in 2028 and the formulation change does not materially affect this forecast.

22 July 2021

Price	**A$0.14**
Market cap	**A$33m**
	A$1.36/US$
Net cash (A$m) at 31 March 2021	6.0
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	(11.5)	(28.1)	26.2
Rel (local)	(10.4)	(30.5)	2.5
52-week high/low		A$0.20	A$0.09

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	H2 CY21

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Edison profile page

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Investment summary

AdAlta has announced the decision to move forward with an inhaled formulation of AD-214 in IPF rather than the original IV formulation. Preclinical studies with a radiolabelled version of AD-214 have indicated that IV dosing leads to much of the drug that is administered being rapidly distributed through the liver and cleared, rendering it unavailable to deliver a therapeutic effect at the tested dose. Importantly, the company believes this rapid liver clearance is specific to the anti-CXCR4 i-body and will not apply to other i-bodies.

The company believes the advantages of an inhaled formulation will include a more direct form of administrations for lung diseases, potentially lower drug doses required for treatment effect, and lower costs to manufacture and administer. However, this may potentially be a troublesome mode of action as it might be difficult to have the patients inhale enough of the drug into their lungs if they are short of breath due to their lung disease although IPF patients frequently inhale salbutamol and steroids for relief of symptoms. It is worth noting there are three development programmes for inhaled treatments for IPF in clinical development and one in preclinical (see Exhibit 1) and AdAlta reports significant clinical interest in inhaled administration.

Exhibit 1: Inhaled development programmes for IPF

Drug	Company	Administration	Status
Tyvaso (Inhaled treprostinil)	United Therapeutics	3 breaths four times daily	Phase III
TD-139/GB-0139	Galecto/PharmAkea	Inhaled, 10mg once a day	Phase IIb
AP01 (aerosolized pirfenidone)	Avalyn Pharma	Inhaled, 100mg twice daily	Phase I/II
PRS-220	Pieris Pharmaceuticals	Inhaled	Preclinical

Source: AdAlta, company websites, clinicaltrials.gov

AdAlta has initiated discussions with contract research organisations to assist in selecting an approved delivery device and executing preclinical inhalation studies in appropriate toxicology (with a focus on lung toxicity) and efficacy models. The company will also need to run short bridging studies in healthy volunteers. Management believes all these can be done with minimal delay to previously announced timelines for development as much of the data needed to progress the inhaled version (such as systemic toxicity studies) have been already collected in the IV programme, which has been conducted at what will likely be much higher doses of the drug than needed for inhalation delivery, according to the company.

With the decision to move to an inhaled formulation, the company is concluding its current Phase I programme for the IV formulation, which recently completed dosing of its first multiple dose cohort of eight subjects (six on drug and two on placebo) at 5mg/kg. Originally, this Phase I study was intended to assess doses up to 15mg/kg and the company did receive approval to move to the 10mg/kg level by the Human Research Ethics Committee before the decision to conclude the trial early. At the 5mg/kg level, there were no dose-limiting toxicities, serious adverse events or concerning clinical laboratory results. After just two doses of AD-214, receptor occupancy was 100% and no drug induced tolerance occurred. Adverse events were mild (grade one) except for infusion-related reactions in two patients receiving AD-214, and one receiving placebo, which were grade two and resolved rapidly once the infusions ended. These infusion reactions were mainly characterised by flushing, tingling and pain, were likely specifically related to the IV formulation and may not be an issue for an inhaled version.

Valuation

We are maintaining our valuation of A$68m or A$0.28 per basic share as we continue to expect a launch of AD-214 in 2028 and the formulation change does not materially affect this forecast. Note

that the value per diluted share increased from A$0.25 to A$0.27 as 23.3m options expired on 30 June 2021 (7.9m remain).

Exhibit 2: AdAlta valuation

Product	Main Indication	Status	Probability of successful commercialization	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 of 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)							7.9
Total number of shares (m)							253.1
Diluted value per share (A$)							0.27

Source: Edison Investment Research

Financials

The company reported A$6.0m in net cash at 31 March 2021, burning A$2.0m during the most recent quarter. In June the company announced a loan facility with Radium capital in which it will borrow funds roughly equivalent to the accrued R&D tax incentive rebate, which will be repaid once the rebate is received. Due to the facility, the company received A$1.68m before the end of FY21 on 30 June 2021 and will repay that amount by 31 October 2021, which is when the rebate is expected to be paid by the Australian government. The annualised interest on this facility is 14%. We estimate that AdAlta will likely need to raise an additional A$11m through the end of FY23, barring additional licensing deals.

Exhibit 3: Financial summary

A$'000s	2019	2020	2021e	2022e
Year end 30 June	AIFRS	AIFRS	AIFRS	AIFRS
PROFIT & LOSS				
Revenue	3,539	3,828	3,244	3,276
Cost of Sales (including R&D)	(7,354)	(7,012)	(7,082)	(7,153)
Gross Profit	(3,815)	(3,185)	(3,838)	(3,877)
Sales, General and Administrative Expenses	(1,315)	(1,265)	(1,316)	(1,368)
EBITDA	(5,957)	(5,798)	(5,920)	(6,011)
Operating Profit (before amort. and except.)	(5,989)	(5,840)	(5,961)	(6,052)
Intangible Amortisation	0	0	0	0
Other	(827)	(1,348)	(766)	(766)
Exceptionals	20	(70)	0	0
Operating Profit	(5,969)	(5,910)	(5,961)	(6,052)
Net Interest	51	(96)	(178)	(98)
Other	0	0	0	0
Profit Before Tax (norm)	(5,938)	(5,936)	(6,139)	(6,150)
Profit Before Tax (FRS 3)	(5,918)	(6,006)	(6,139)	(6,150)
Tax	0	0	0	0
Deferred tax	(0)	(0)	(0)	(0)
Profit After Tax (norm)	(5,938)	(5,936)	(6,139)	(6,150)
Profit After Tax (FRS 3)	(5,918)	(6,006)	(6,139)	(6,150)
Average Number of Shares Outstanding (m)	118.4	164.0	250.0	252.5
EPS - normalised (c)	(5.02)	(3.62)	(2.45)	(2.43)
EPS - Reported ($)	(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	8,547	6,395
Stocks	0	0	0	0
Debtors	3,613	3,364	3,364	3,364
Cash	5,556	3,367	5,183	3,030
Other	0	0	0	0
Current Liabilities	(1,819)	(3,205)	(2,805)	(1,125)
Creditors	(1,819)	(1,014)	(1,125)	(1,125)
Short term borrowings	0	(2,191)	(1,680)	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	5,906	435
CASH FLOW				
Operating Cash Flow	(5,816)	(5,889)	(5,372)	(5,470)
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)	2,421	(5,472)
Opening net debt/(cash)	(2,306)	(5,556)	(1,175)	(3,503)
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)	(3,503)	1,970

Source: company reports, Edison Investment Research

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