EDISON

AdAlta

Development update

Preliminary Part A results

Pharma & biotech

Part A of the AD-214 Phase I has been completed in 42 healthy volunteers who received a single dose of either AD-214 or placebo. There were no dose limiting or serious adverse events and no concerning clinical laboratory results. Additionally, AD-214 pharmacokinetics increased proportionally with the dose with evidence seen of CXCR4 engagement and high sustained receptor occupancy. AdAlta will now be investigating dosing every two weeks for AD-214 in the Part B portion of the study.

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.

Remainder of Phase I programme redesigned

Following the Part A results, AdAlta has redesigned the remainder of the Phase I programme, forgoing a single ascending dose study in interstitial lung disease (ILD) and idiopathic pulmonary fibrosis (IPF) patients in favour of a multiple ascending dose (MAD) study in healthy volunteers (Part B) and a concurrently run (starting in Q3 CY21) separate Phase Ib in patients with IPF/ILD and other fibrotic diseases.

Phase II IND-ready data package as early as H1 CY22

Part B of the redesigned Phase I will be a blinded, placebo-controlled MAD study in 12–24 patients dosed at 5–15mg/kg every two weeks. This data should be available as early as H1 CY22 and will enable an IND filing to begin the Phase II programme. Additionally, this safety package would cover all intravenous indications for AD-214.

A busy remainder to CY21

Besides progressing through the Phase I programme, AdAlta is currently also expecting GE Healthcare to commence pre-clinical development of an i-body against granzyme B, a known marker of T-cell activation, in Q2 CY21. Additionally, the company is expecting a second external partnership to be announced, around the middle of the year, and two new internal targets in discovery.

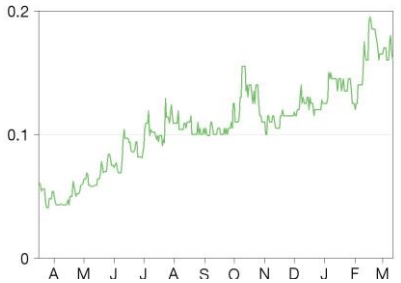
Valuation: A$70m or A$0.29 per basic share

We have increased our valuation for AdAlta to A$70m (or A$0.29 per share), from A$60m (or A$0.25 per basic share) previously, due to an increase in the probability of success for AD-214 from 12.5% to 15% following the release of the preliminary Part A data and our increased confidence that the programme will progress. Note that we only attribute value to AD-214 as it is the only programme in human clinical trials, though this could change once trials in additional indications are commenced. The company had A$8.1m in cash at 31 December 2020 and we estimate will likely need to raise an additional A$11m through the end of FY23, barring additional licensing deals.

15 March 2021

Price	**A$0.19**
Market cap	**A$45m**
	A$1.30/US$
Net cash (A$m) at 31 December 2020	8.1
Shares in issue	245.2m
Free float	95.1%
Code	1AD
Primary exchange	ASX
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	15.6	48.0	136.4
Rel (local)	16.7	45.3	81.0
52-week high/low	A$0.20	A$0.04	

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

AD-214 Phase I Part B initiation	Q2 CY21
AD-214 Phase Ib initiation	Q3 CY21

Analysts

Maxim Jacobs	+1 646 653 7027
Nathaniel Calloway	+1 646 653 7036

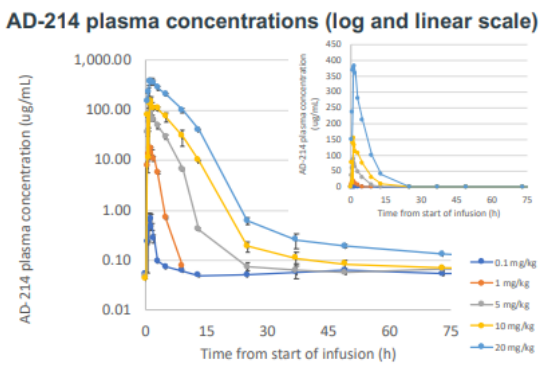
healthcare@edisongroup.com

Edison profile page

AD-214 trial update

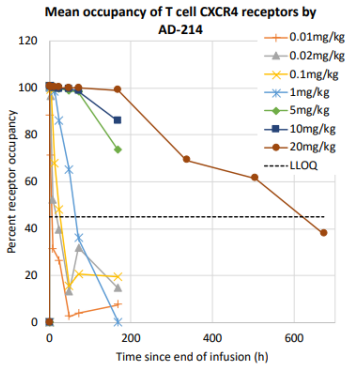
AdAlta recently announced preliminary results from Part A of the Phase I programme for AD-214 n 42 healthy volunteers who received either a single dose of AD-214 or placebo. AD-214 was very well tolerated in single doses up to 20mg/kg. There were no dose limiting or serious adverse events (adverse events were mostly mild with three grade 2 adverse events) and no concerning clinical laboratory results. Additionally, AD-214 pharmacokinetics increased proportionally with the dose and there was high sustained receptor occupancy (see Exhibits 1 and 2). 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).

Exhibit 1: AD-214 pharmacokinetics



Source: AdAlta

Exhibit 2: AD-214 receptor occupancy



Source: AdAlta

Due to these results, the company has re-designed its Phase I programme. Initially, Part A was to be followed by Part B, a single-dose study in ILD/IPF patients that was then to be followed by Part C, studying weekly dosing in ILD/IPF patients over four weeks. Now Part B will be a blinded, placebo-controlled MAD study in 12–24 healthy volunteers dosed at 5–15mg/kg every two weeks. This study should be completed by year-end CY21, with data available as early as H1 CY22, which will enable an IND filing to begin the Phase II programme. Additionally, this safety package would cover all intravenous indications for AD-214.

Concurrent with Part B, 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 seeking initial indications of efficacy (which could help open the partnership window). The first arm will feature a radio-labelled version of AD-214 for positron emission tomography (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.

Valuation

We have increased our valuation for AdAlta to A$70m or A$0.29 per share, from A$60m or A$0.25 per basic share previously, due to an increase in the probability of success for AD-214 from 12.5% to 15% following the release of the preliminary Part A data and our increased confidence that the programme will progress. Note that we only attribute value to AD-214 as it is the only programme in human clinical trials, though this could change once trials in additional indications are commenced.

Exhibit 3: 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 of 31 December 2020)							8.1
Total firm value (A$)							70
Total basic shares (m)							245.2
Value per basic share (A$)							0.29
Options (m)							30.2
Total number of shares (m)							275.4
Diluted value per share (A$)							0.26

Source: Edison Investment Research

Financials

AdAlta reported A$8.1m in cash on its balance sheet at the end of December 2020. Historically, the company has had a relatively low burn rate in terms of operating cash flow, of about A$5.9m in FY20 and A$5.8m in FY19. In H1 of FY21, the burn rate was only A$0.8m, benefiting from the receipt of a A$3.1m R&D tax incentive refund for FY20. We estimate AdAlta will likely need to raise an additional A$11m through the end of FY23 (at which point AD-214 should be in the midst of Phase II testing), which we model as illustrative long-term debt, barring additional licensing deals.

Exhibit 4: 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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Frankfurt +49 (0)69 78 8076 960
Schumannstrasse 34b
60325 Frankfurt
Germany

London +44 (0)20 3077 5700
280 High Holbom
London, WC1V 7EE
United Kingdom

New York +1 646 653 7026
1185 Avenue of the Americas
3rd Floor, New York, NY 10036
United States of America

Sydney +61 (0)2 8249 8342
Level 4, Office 1205
95 Pitt Street, Sydney
NSW 2000, Australia