EDISON

Arovella Therapeutics

Financial update

Refocused pipeline towards iNKT cell therapy

Pharma & biotech

Arovella is progressing on its lead product, ALA-101 (CAR19-iNKT) targeting blood cancers and has selected a CMO for the production of plasmid and lentiviral vector, with the company intending to finalise iNKT cell manufacturer in Q1 CY22. Legacy product, Zolpimist, an oro-mucosal spray for insomnia, expects to generate commercial sales in Australia (through Arovella's partner STADA) starting from Q3 CY22. Following a recent fund raise of A$6.7m (excluding financing costs) in Q1 CY22, we estimate that the company has sufficient cash to run its iNKT studies and to manage its operating activities until CY23 (an acceleration in cash burn due to iNKT cell therapy related programs). Our valuation for Arovella stands at A$30.5m or A$0.05 per basic share.

Year end	Revenue (A$m)	PBT* (A$m)	EPS* (A$)	DPS (A$)	P/E (x)	Yield (%)
06/20	0.5	(3.6)	(0.03)	0.0	N/A	N/A
06/21	0.3	(3.4)	(0.01)	0.0	N/A	N/A
06/22e	0.4	(7.5)	(0.01)	0.0	N/A	N/A
06/23e	2.4	(5.8)	(0.01)	0.0	N/A	N/A

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

Recent capital raise extends runway to end-FY23

Arovella raised A$6.7m through two rounds of financing in Q1 CY22. The first round of financing raised A$4.6m through institutional investors and the second round raised A$2.2m through a share purchase plan. The company intends to utilise the funds for the development of iNKT cell therapy as well as for potential acquisitions of new technologies in the field of oncology.

Consolidating its iNKT franchise

Arovella has selected a plasmid and vector manufacturer for its lead programme, ALA-101 (CAR19-iNKT), and the production process for the lentiviral vector commenced in January. Post vector production, the company will start the manufacturing of iNKT cells (a contract manufacturer is expected to be finalised in Q1 CY22). In the case of ZolpiMist, partner Teva received early approval from Chile's Ministry of Health in October. Arovella's Australian-market partner STADA is expected to generate initial Zolpimist sales in Q3 CY22 and Arovella will be entitled to royalties.

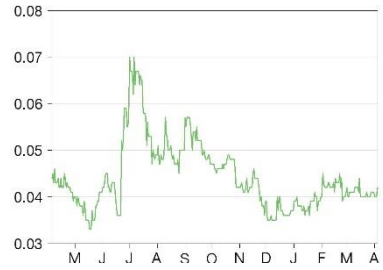
Valuation: A$30.5m or A$0.05 per basic share

We have increased our valuation for Arovella to A$30.5m or A$0.05 per basic share, from A$25m or A$0.05 per basic share, mainly reflecting higher cash levels from recent capital raising activity. We believe its current pro forma net cash position (A$11m) extends the runway to CY23. We are not yet including either of the CAR-iNKT programmes in our valuation but intend to do so when they enter the clinic. Given the sales of similar products and/or the possibility of an acquisition, the resulting changes to our valuation could be meaningful.

5 April 2022

Price	**A$0.04**
Market cap	**A$26m**
	A$1.37/US$
Pro forma net cash (A$m) at 31 December 2021	11.0
Proforma Shares in issue	658.8m
Free float	98.4%
Code	ALA
Primary exchange	ASX
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	2.4	5.0	(4.5)
Rel (local)	(3.1)	6.4	(13.8)
52-week high/low	A$0.07		A$0.03

Business description

Arovella Therapeutics has historically been a drug delivery company focusing on developing oro-mucosal spray versions of established medicines. It has ex-North America rights to ZolpiMist, the spray version of Ambien for insomnia. It recently acquired a CAR-iNKT programme for haematological malignancies and a DKK1 antibody that has potential in multiple myeloma and solid tumours.

Next events

Progress on iNKT development	2022

Analyst

Nidhi Singh +91 828 754 8220

healthcare@edisongroup.com

Edison profile page

Arovella Therapeutics pipeline update

Historically a drug delivery company focused on reformulating established drugs into oro-mucosal spray (via its OroMist platform) formulations for better bioavailability, Arovella pivoted its focus towards the immune-oncology space (in particular cell therapies) following the in-licensing of two chimeric antigen receptors (CARs) based immunotherapies in CY21 (both in preclinical stage). The first was an invariant natural killer T (iNKT) cell therapy platform in-licensed from Imperial College London in July 2021. The platform can be combined with CARs to target blood cancers (for more detail, see our previous report A potentially transformational acquisition). This was followed by the in-licensing of a novel monoclonal antibody targeting a Dickkopf-1 (DKK1) peptide from MD Anderson Cancer Center in December 2021 (for more detail, see Acquiring DKK1 rights).

Lead asset ALA-101 (CAR19-iNKT) allows dual targeting of CD1d and CD19 and is being developed as an 'off-the-shelf treatment' for blood cancers. The drug has so far has shown robust preclinical activity against CD19-expressing cancers. During Q222, Arovella selected a contract manufacturing organisation (CMO) for the production of two important components for the therapy, plasmid and lentiviral vector. After completing production of the lentiviral vector, the company will start manufacturing the final component, the iNKT cells. The company expects to finalise the CMO for iNKT cell manufacturing in Q1 CY22.

The second immunotherapy asset, ALA-104 (DKK1-CAR-iNKT), aims to combine the DKK1 targeting technology with the company's iNKT cell therapy platform and test DKK1-CAR-iNKT cells in cancer models in 2022. Over the next few months, Arovella will seek to confirm that DKK1 does not target healthy cells and that it can combine with the iNKT cell therapy platform. It plans to initiate preclinical studies across relevant tumour types (including multiple myeloma, pancreatic cancer, lung cancer and triple-negative breast cancer) and develop and initiate a manufacturing strategy.

Legacy asset ZolpiMist is an oro-mucosal spray version of Ambien (Sanofi's blockbuster) for the treatment of insomnia and has been out-licensed to Teva in Mexico, Brazil and Chile and to STADA Pharmaceuticals in Australia (with an option to expand to New Zealand). ZolpiMist's registration was approved by Chile's Ministry of Health in October 2021. Teva Pharmaceuticals applied for a Marketing Authorisation Application in May 2021 in Chile and received approval in this jurisdiction in October 2021, earlier than its prior expectation of April 2022. This approval is in addition to the existing ZolpiMist approval in Australia. Commercial sales for ZolpiMist are likely to start in Q3 CY22 in Australia, which should represent initial global sales of the product. The company's previous commercial agreements for Singapore, Malaysia, the Philippines and South Korea with subsidiaries of Mitsubishi Tanabe, had been terminated in CY21. The company is also working on a number of other projects using its OroMist platform, including anagrelide (for the treatment of high platelet counts[1] in cancer patients), sumatriptan (migraine), cannabinoids and others.

[1] OroMist is Arovella's drug delivery platform, using oro-mucosal technology spanning broad range of drug classes through either the cheeks, gums, tongue or floor of the mouth. The technology is designed to provide better bioavailability as it is absorbed directly into the blood stream through the oral mucosa.

Exhibit 1: Arovella Therapeutics pipeline

Programme	Indications	Status	Partner
Cell therapy			
ALA-101 (CAR19-iNKT)	CD19 expression lymphomas	Preclinical	
ALA-102	Undisclosed	Discovery	
ALA-103	Undisclosed	Discovery	
ALA-104 (DKK1-CAR-iNKT)	Multiple myeloma and solid tumours	Preclinical	
OroMist platform			
ZolpiMist	Short-term insomnia	Registered	Teva, STADA
ALA-001 (Sumatriptan)	Migraine	Preclinical	Strides
ALA-018 (Anagrelide)	Solid tumours and thrombocytosis	Reformulation	
ALA-021 (pharmaceutical grade cannabis)	Multiple	Reformulation	Cann Pharma Australia
ALA-023	Undisclosed	Preclinical	Sanofi

Source: Arovella Therapeutics

H222 fund-raising

In February 2022, the company issued 120,230,220 shares to institutional investors, including Merchant, a specialist life sciences investor, raising gross proceeds of A$4.6m (A$0.038 per share, a 2.5% discount to the market price). In addition, the directors also contributed to the placement, adding A$160k to the gross proceeds. In late January, the company launched a A$1.5m share purchase plan (SPP) to raise additional capital from existing shareholders. The SPP issue was oversubscribed with the bids of over A$2.5m and hence Arovella enhanced the offer to A$2.0m. Further in March 2022, the company issued 57,052,548 shares (as part of previous SPP and placement of directors), worth A$2.2m (gross), on the same terms (A$0.038 per share) as to the institutional investors in previous capital raise.

With these two rounds of fund-raising, the current pro forma net cash position (31 December 2021) stands at A$11.0m, which we believe should be sufficient to fund manufacturing of components for the CAR19-iNKT cell therapy, preclinical studies for DKK1-CAR-iNKT and operational activities until CY23. The management expects a further equity raising in FY23.

Valuation

We have increased our total valuation of Arovella to A$30.5m or A$0.05 per basic share from A$25m or A$0.05 per basic share, reflecting higher cash levels due the recent capital raising activity. However, the per share impact has been minimal, due to the additional shares issued as part of the fund-raising. We are not yet including either of the CAR-iNKT programmes in our valuation but intend to do so when they enter the clinic. Given the sales of similar products and/or any acquisition, the resulting changes to our valuation could be meaningful.

Exhibit 2: Arovella Therapeutics Valuation

Product	Main Indication	Status	Probability of successful commercialization	Approval year	Peak sales (A$m)	Economics	rNPV (A$m)
ZolpiMist	Insomnia	Registered (Australia) , pre-registration (other regions)	70%	2020	17.3	Double digit royalties	19.5
Total							19.5
Net cash (as of 31 December 2021) + Subsequent equity raise in Jan 2022							11.0
Total firm value (A$m)							30.5
Total basic shares (m)							658.8
Value per basic share (A$)							0.05
Options (m)							94.1
Total number of shares (m)							752.9
Diluted value per share (A$)							0.04

Source: Edison Investment Research

H122 financials

For the half-year period ending 31 December 2021 (H122), the company reported A$22.6k in revenue, down 91% compared to the same period a year ago, mainly due to the decline in sales/licensing of goods (H1 FY21: A$0.11m) and zero reported co-development revenue (H1 FY21: A$0.13m). The co-development revenue in H121 was mainly related to Laboratorios Ordesa and Zelira Therapeutics, which decided not to progress ahead in their respective agreements. In H122, the company did not receive any export market development grant or COVID-19 assistance, which were part of operating income last year. There has been an acceleration in operating cash burn (A$2.3m in H122 versus A$1.9m in H121) due to iNKT cell therapy development activities; it is included in our estimates for FY22 and beyond.

The company had net cash of A$4.2m as at 31 December 2021 (A$4.4m gross cash offset by A$0.2m in lease liabilities). Due to additional rounds of funding, the pro forma net cash position stands at A$11.0m (adjusted for lease liabilities), with a total of 658.8m shares outstanding. While we previously estimated that the company would raise A$12.5m through illustrative debt by the end of FY23, following the A$6.7m (gross) equity raise in Q1 CY22, we now assume that its remaining funding requirements before the end of FY23 will be A$8.3m (raised through illustrative debt).

Exhibit 3: Financial summary

A$'000s	2020	2021	2022e	2023e
Year end 30 June	AIFRS	AIFRS	AIFRS	AIFRS
PROFIT & LOSS				
Revenue	533	257	380	2,447
Cost of Sales	(201)	(223)	(707)	(849)
Gross Profit	332	35	(327)	1,598
Sales, General and Administrative Expenses	(4,259)	(3,529)	(3,670)	(3,817)
Research and Development Expense	(285)	(542)	(3,000)	(3,120)
EBITDA	(3,413)	(3,129)	(6,997)	(5,339)
Operating Profit (before amort. and except.)	(3,636)	(3,332)	(7,204)	(5,527)
Intangible Amortisation	(349)	(449)	(356)	(356)
Other	799	907	0	0
Exceptionals	(5,973)	(1,239)	0	0
Operating Profit	(9,958)	(5,021)	(7,559)	(5,883)
Net Interest	22	(27)	(272)	(282)
Other	0	0	0	0
Profit Before Tax (norm)	(3,613)	(3,359)	(7,475)	(5,809)
Profit Before Tax (FRS 3)	(9,936)	(5,047)	(7,831)	(6,166)
Tax	0	0	0	0
Deferred tax	(0)	(0)	(0)	(0)
Profit After Tax (norm)	(3,613)	(3,359)	(7,475)	(5,809)
Profit After Tax (FRS 3)	(9,936)	(5,047)	(7,831)	(6,166)
Average Number of Shares Outstanding (m)	142.3	330.9	569.5	658.1
EPS - normalised (c)	(2.78)	(1.15)	(1.37)	(0.94)
EPS - Reported ($)	(0.07)	(0.02)	(0.01)	(0.01)
Dividend per share (c)	0.0	0.0	0.0	0.0
BALANCE SHEET				
Fixed Assets	4,673	3,344	3,400	3,397
Intangible Assets	4,251	2,911	2,918	2,924
Tangible Assets	365	381	347	338
Other	57	52	136	136
Current Assets	2,035	7,343	7,233	9,738
Stocks	22	0	0	0
Debtors	869	534	789	947
Cash	977	6,717	6,083	8,430
Other	166	92	362	362
Current Liabilities	(2,022)	(1,695)	(2,580)	(2,949)
Creditors	(2,010)	(1,689)	(2,509)	(2,878)
Short term borrowings	(12)	(6)	(71)	(71)
Long Term Liabilities	(550)	(11)	(122)	(8,381)
Long term borrowings	(4)	(3)	(115)	(8,373)
Other long-term liabilities	(545)	(8)	(8)	(8)
Net Assets	4,135	8,982	7,931	1,806
CASH FLOW				
Operating Cash Flow	(2,884)	(3,545)	(6,947)	(5,369)
Net Interest	0	0	0	0
Tax	0	0	0	0
Capex	(388)	(515)	(535)	(542)
Acquisitions/disposals	0	0	0	0
Financing	0	9,856	6,742	0
Dividends	0	0	0	0
Other	0	0	0	0
Net Cash Flow	(3,272)	5,797	(741)	(5,911)
Opening net debt/(cash)	(4,260)	(961)	(6,709)	(5,897)
HP finance leases initiated	0	0	0	0
Exchange rate movements	0	0	0	0
Other	-27	-50	-71	0
Closing net debt/(cash)	(961)	(6,709)	(5,897)	14

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 Holborn
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