EDISON

Arovella Therapeutics

Development update

Acquiring DKK1 rights

Pharma & biotech

Arovella Therapeutics (formerly SUDA Pharmaceuticals) has announced it has in-licensed the rights to a novel monoclonal antibody that targets the Dickkopf-1 (DKK1) peptide from MD Anderson Cancer Center (for undisclosed upfront and development milestones as well as single digit royalties). DKK1 has been shown to promote tumour metastasis across a variety of tumour types. The company plans to combine the DKK1 targeting technology with its recently acquired invariant natural killer T (iNKT) cell therapy platform and test DKK1-CAR-iNKT cells (under programme name ALA-104) in cancer models in 2022.

Year end	Revenue (A$m)	PBT* (A$m)	EPS* (A$)	DPS (A$)	P/E (x)	Yield (%)
06/20	0.5	(4.0)	(0.03)	0.0	N/A	N/A
06/21	0.3	(3.8)	(0.01)	0.0	N/A	N/A
06/22e	0.5	(7.1)	(0.01)	0.0	N/A	N/A
06/23e	2.5	(6.0)	(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.

DKK1 shows promise across tumour types

DKK1 has been shown to promote tumour metastasis across multiple solid tumours including, lung, breast, liver, oesophageal, gastric, pancreatic, cervical and bladder cancers. DKK1 also appears to be overexpressed on multiple myeloma cells and DKK1-CAR-T cells have shown promising efficacy results in multiple myeloma mouse models while sparing healthy tissue.

ALA-104 next steps

Over the next 12 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 and develop/initiate a manufacturing strategy.

ALA-101 update

ALA-101 (CAR19-iNKT) is being developed as an off-the-shelf treatment for blood cancers and so far has shown strong preclinical activity against CD19-expressing cancers. The company is developing the clinical plan for ALA-101 and, following selection of the manufacturer, expects to commence manufacturing of the lentiviral vector shortly.

Valuation: A$25m or A$0.05 per basic share

We have adjusted our Arovella valuation from A$26m or A$0.05 per basic share (A$0.05 per diluted share), to A$25m or A$0.05 per basic share (A$0.04 per diluted share) mainly due to slightly lower cash levels. 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 recent acquisition activity in this space, the resulting changes to our valuation could be meaningful.

21 December 2021

Price	**A$0.04**
Market cap	**A$17m**
	A$1.39/US$
Net cash (A$m) at 30 September 2021	5.1
Shares in issue	480.9m
Free float	86.8%
Code	ALA
Primary exchange	ASX
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	(18.2)	(26.5)	(5.3)
Rel (local)	(16.8)	(27.2)	(13.7)
52-week high/low		A$0.07	A$0.03

Business description

Arovella Therapeutics (formerly SUDA Pharmaceuticals) 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, which has potential in multiple myeloma and solid tumours.

Next events

Progress on iNKT development	2022

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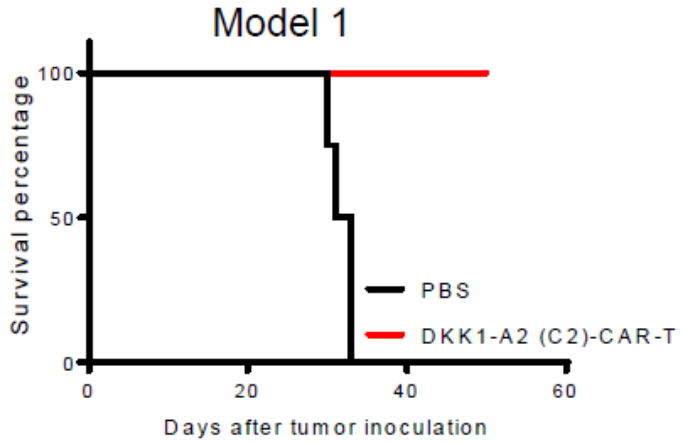
Edison profile page

Continuing to build the pipeline

Arovella has announced it has in-licensed the rights to a novel monoclonal antibody that targets the DKK1 peptide from the MD Anderson Cancer Center for undisclosed upfront and development milestones as well as single-digit royalties. DKK1 has been shown to promote tumour metastasis across a variety of solid tumour types including, lung, breast, liver, oesophageal, gastric, pancreatic, cervical and bladder cancers.[1] DKK1 also appears to be overexpressed on multiple myeloma cells.[2] DKK1-CAR-T cells have shown promising efficacy results in multiple myeloma mouse models in which all treated mice were alive at 50–60 days while untreated mice succumbed to cancer at 30–40 days (see Exhibit 1). Importantly, healthy cells were spared and no weight loss was seen. The company has also indicated that DKK1-CAR-T cells also showed promise in pancreatic, lung and triple-negative breast cancer models.

Exhibit 1: DKK1-CAR-T cells in multiple myeloma mouse model



Source: Arovella Therapeutics

Over the next 12 months, the company will seek to confirm DKK1 does not target healthy cells, that it can combine with the iNKT cell therapy platform (which may enable an off-the shelf product), initiate preclinical studies across relevant tumour types and develop/initiate a manufacturing strategy.

Exhibit 2: Updated 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

1 Zhu et al., Expression and Role of Dickkopf-1 (Dkk1) in Tumors: From the cells to the patients. *Cancer Management and Research* 2021:13 659–675

2 Qian et al., Dickkopf-1 (DKK1) is a widely expressed and potent tumor-associated antigen in multiple myeloma. *Blood* 2007 Sep 1; 110(5): 1587–1594.

ZolpiMist updates

In August, Mitsubishi Tanabe Korea announced its intention not to proceed with the licence and supply agreement for ZolpiMist in South Korea. However, the next day Arovella announced that STADA Pharmaceuticals Australia entered into a licence and distribution agreement for Australia (where ZolpiMist was approved on 29 July 2020). Arovella received an upfront payment of A$170,000 and will receive a A$40,000 milestone payment on regulatory approval of an enhancement of the spray unit (which will incorporate a user-friendly, child-resistant lock). Additionally, Arovella will receive a 10% royalty on sales. Commercial sales are expected to start in Q3 CY22.

Valuation

We have decreased our Arovella valuation from A$26m or A$0.05 per basic share (A$0.05 per diluted share), to A$25m or A$0.05 per basic share (A$0.04 per diluted share) mainly due to slightly lower cash levels. 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 (US$563m in sales in 2020 for Yescarta, the CAR-T from Gilead) and recent acquisition activity (such as Kuur, an iNKT company purchased by Athenex for US$70m upfront and US$115m in potential milestones) in this space, the resulting change to our valuation could be meaningful. We have not made meaningful changes to our ZolpiMist valuation after the partnership changes as our Mitsubishi Tanabe Korea estimates were conservative and the STADA Australia agreement may offer similar returns.

Exhibit 3: Arovella valuation

Product	Main indication	Status	Probability of successful commercialisation	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	19.6
Total							19.6
Net cash (as of 30 September 2021)							5.1
Total firm value (A$m)							**24.7**
Total basic shares (m)							480.9
Value per basic share (A$)							**0.05**
Options (m)							76.0
Total number of shares (m)							556.9
Diluted value per share (A$)							**0.04**

Source: Edison Investment Research

Financials

The company reported A$5.1m in cash at 30 September 2021 with operating cash burn of A$1.6m during Q1 FY22. This was an acceleration from the A$0.9m burn seen in Q4 FY21 due to the upfront costs associated with the iNKT licensure. Note that in FY21, the company reported A$3.5m in operating cash burn for the year and had A$0.5m in investing cash outflows. In June, Arovella raised A$3.65m through the issuance of 96.2m shares at A$0.038 per share to help fund development of the iNKT cell therapy platform. We have made minor changes to our FY22 estimates, including a reduction of expected revenues by A$0.5m as we had expected some royalties from Mitsubishi Tanabe Korea in that year and STADA Australia sales likely will not start until FY23. We have also increased SG&A expense estimates by A$0.3m. Additionally, in November, Arovella announced the receipt of an Australian R&D tax incentive of A$0.5m, which we have booked for FY22 in other income.

We have introduced FY23 forecasts, which feature A$2.4m in revenues (with royalties from Teva and STADA territories) and A$5.4m in operating cash burn. We continue to forecast an additional A$12.5m in financing through FY23 (modelled as illustrative debt). Financing needs will likely accelerate as the pipeline programmes mature and enter the clinic and we will update our estimates accordingly.

Exhibit 4: Financial summary

A$'000s	2020	2021	2022e	2023e
Year end 30 June	AIFRS	AIFRS	AIFRS	AIFRS
PROFIT & LOSS				
Revenue	533	257	520	2,447
Cost of Sales	(201)	(223)	(267)	(321)
Gross Profit	332	35	253	2,126
Sales, General and Administrative Expenses	(4,543)	(4,070)	(4,233)	(4,402)
Research and Development Expense	0	0	(3,000)	(3,120)
EBITDA	(3,413)	(3,129)	(6,456)	(5,396)
Operating Profit (before amort. and except.)	(3,985)	(3,781)	(7,108)	(6,049)
Intangible Amortisation	0	0	0	0
Other	799	907	524	0
Exceptionals	(5,973)	(1,239)	0	0
Operating Profit	(9,958)	(5,021)	(7,108)	(6,049)
Net Interest	22	(27)	(28)	(29)
Other	0	0	0	0
Profit Before Tax (norm)	(3,963)	(3,808)	(7,136)	(6,077)
Profit Before Tax (FRS 3)	(9,936)	(5,047)	(7,136)	(6,077)
Tax	0	0	0	0
Deferred tax	(0)	(0)	(0)	(0)
Profit After Tax (norm)	(3,963)	(3,808)	(7,136)	(6,077)
Profit After Tax (FRS 3)	(9,936)	(5,047)	(7,136)	(6,078)
Average Number of Shares Outstanding (m)	142.3	330.9	481.0	485.8
EPS - normalised (A$)	(0.03)	(0.01)	(0.01)	(0.01)
EPS - Reported (A$)	(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	3,722	4,106
Intangible Assets	4,251	2,911	3,129	3,347
Tangible Assets	365	381	541	707
Other	57	52	52	52
Current Assets	2,035	7,343	7,877	6,964
Stocks	22	0	0	0
Debtors	869	534	534	534
Cash	977	6,717	7,251	6,338
Other	166	92	92	92
Current Liabilities	(2,022)	(1,695)	(1,689)	(1,689)
Creditors	(2,010)	(1,689)	(1,689)	(1,689)
Short term borrowings	(12)	(6)	0	0
Long Term Liabilities	(550)	(11)	(7,511)	(12,511)
Long term borrowings	(4)	(3)	(7,503)	(12,503)
Other long term liabilities	(545)	(8)	(8)	(8)
Net Assets	4,135	8,982	2,399	(3,130)
CASH FLOW				
Operating Cash Flow	(2,884)	(3,545)	(6,445)	(5,385)
Net Interest	0	0	0	0
Tax	0	0	0	0
Capex	(388)	(515)	(521)	(528)
Acquisitions/disposals	0	0	0	0
Financing	0	9,856	0	0
Dividends	0	0	0	0
Other	0	0	0	0
Net Cash Flow	(3,272)	5,797	(6,966)	(5,913)
Opening net debt/(cash)	(4,260)	(961)	(6,709)	252
HP finance leases initiated	0	0	0	0
Exchange rate movements	0	0	0	0
Other	(27)	(50)	6	0
Closing net debt/(cash)	(961)	(6,709)	252	6,165

Source: Company reports, Edison Investment Research. Note: The company does not separately disclose R&D expenses but we have provided a forecast for future years. Also, FY20 results have been restated by the company.

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