EDISON

Prima BioMed

Initial TACTI-mel data

Initial LAG-3 combo data presented

Pharma & biotech

Prima BioMed has presented encouraging early signs of efficacy from the TACTI-mel trial of IMP321 in combination with Keytruda, with one of the six melanoma patients in the first (1mg/kg) cohort experiencing a complete response. Recruitment in the second cohort is complete and the final cohort is expected to be fully recruited by Q317. Preliminary efficacy data from the 15-patient, run-in phase of the AIPAC breast cancer study are expected mid-year (recruitment in the 226-patient Phase IIb component is ongoing). Our valuation is unchanged at A$252m (12c per share).

Year end	Revenue (A$m)	PBT* (A$m)	EPS* (c)	DPS* (c)	P/E (x)	Yield (%)
06/15	1.3	(12.9)	(0.9)	0.0	N/A	N/A
06/16	1.9	(13.7)	(0.6)	0.0	N/A	N/A
06/17e	1.3	(12.7)	(0.6)	0.0	N/A	N/A
06/18e	10.6	(4.0)	(0.2)	0.0	N/A	N/A

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

A complete response in low-dose TACTI-mel cohort

The TACTI-mel trial is using IMP321 (Prima's LAG-3-based antigen presenting cell activator) to enhance efficacy in melanoma patients who have had a suboptimal initial response to the PD1 immune checkpoint inhibitor Keytruda. A presentation to the Immune Checkpoint Inhibitors conference in Boston showed that that one of the six patients (17%) in the first cohort experienced a complete response (CR). Even though there is only one patient with a CR, the initial CR rate compares favourably with rates of 2-6% seen in Merck's Phase III trials of Keytruda monotherapy in melanoma. The combination has been well tolerated so far. Recruitment in the third and highest (30mg) dose cohort is expected to complete in Q317, so we expect efficacy data from the final cohort in H118.

Initial efficacy data from AIPAC run-in due mid-year

Initial efficacy data are expected mid-2017 (possibly at ASCO in June) from the 15 metastatic breast cancer patients treated with IMP321 in combination with paclitaxel during the safety run-in phase of the AIPAC study (the response rate in a previous Phase I study was 50%). Dosing began in January in the 226-patient randomised Phase IIb component of AIPAC; top-line PFS data could mature sometime between late 2018 and mid-2019. Patients will receive either 30mg of IMP321 or placebo, in combination with paclitaxel.

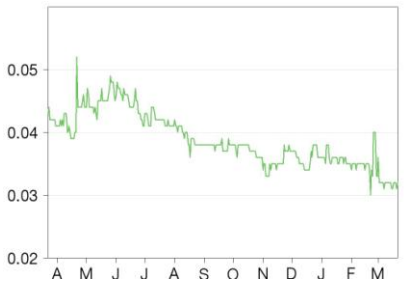
Valuation: Unchanged at A$252m, 12c per share

Our valuation is unchanged at A$252m, which is equal to 12c per share on an undiluted basis or 8c per share after accounting for dilution from options, warrants and convertible notes. Guidance is that the cash balance of A$16.6m at 31 December will be sufficient to fund operations through Q1 CY18, excluding any milestone payments from partners Novartis and GSK. Milestone revenue (we model ~A$9m in FY18) would extend the cash runway.

22 March 2017

Price	**A$0.033**
Market cap	**A$69m**
	US$0.76/A$
Gross cash (A$m) at 31 December 2016	16.6
Shares in issue	2,079.7m
Free float	93%
Code	PRR
Primary exchange	ASX
Secondary exchange	NASDAQ

Share price performance



%	1m	3m	12m
Abs	(5.9)	(13.5)	(7.3)
Rel (local)	(5.6)	(15.9)	(34.7)
52-week high/low	A$0.05		A$0.03

Business description

Prima BioMed is an ASX-listed biotechnology company focused on cancer immunotherapy. Its pipeline is based on three products using a LAG-3 immune control system: IMP321 for cancer chemo-immunotherapy and partnered products IMP731 (GSK) and IMP701 (Novartis).

Next events

AIPAC immune monitoring and activity data from run-in phase	Mid-2017
Further TACTI-mel dose escalation safety and activity data	2017
IMP761 preclinical data	2017

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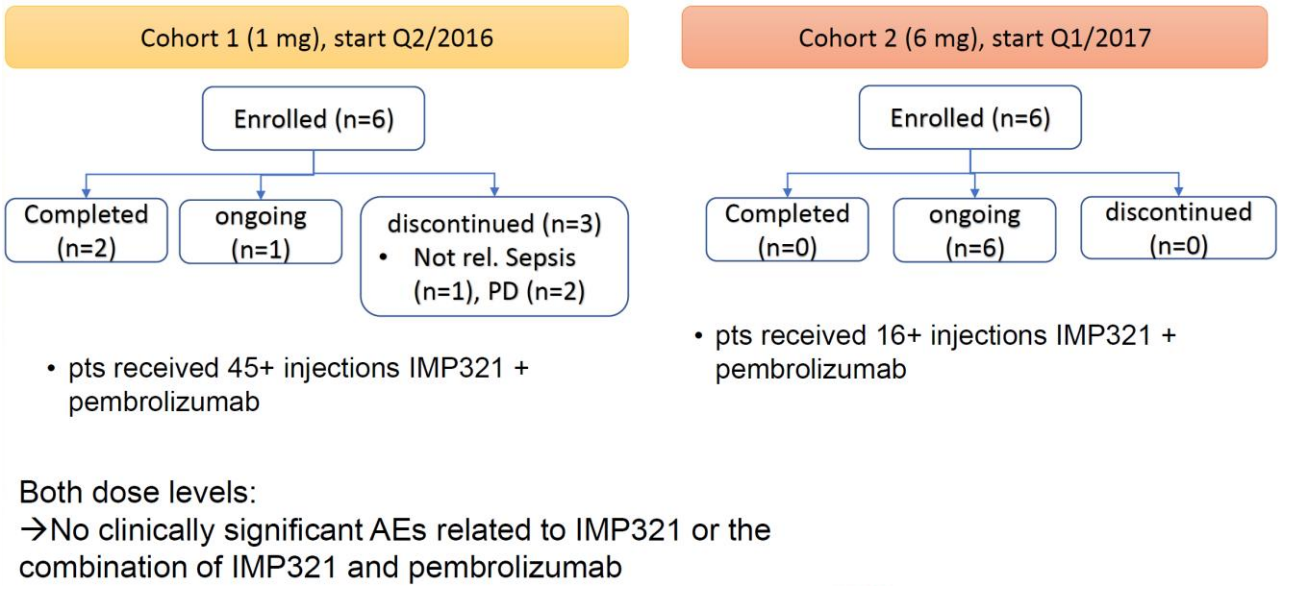
Complete responder in first TACTI-mel cohort

On 16 March Prima's chief medical and scientific officer, Dr Frédéric Triebel, presented an update on the Phase I TACTI-mel trial, including preliminary efficacy data from the first cohort, at the Immune Checkpoint Inhibitors conference in Boston, Massachusetts. This study will test three doses of IMP321 (1, 6 and 30mg/kg) in combination with the anti-PD-1 immune checkpoint inhibitor Keytruda (pembrolizumab, Merck) in 18 patients with advanced melanoma. Recruitment in the first two cohorts is complete, as shown in Exhibit 1.

The trial is investigating IMP321 in subjects who have had a suboptimal response to initial treatment with Keytruda. Subjects are assessed after they have undergone three cycles (nine weeks) of treatment with Keytruda; patients with stable disease or slow progression not requiring urgent intervention are eligible to participate in the trial and receive IMP321, starting with the fifth Keytruda cycle at week 13.

Six patients were enrolled in the first dose cohort (1mg/kg every two weeks), which began in Q216. The second cohort of six patients is fully recruited, and all subjects continue to receive three-weekly injections of Keytruda and fortnightly injections of IMP321 at 6mg/kg. No clinically significant adverse events related to IMP321 or the combination of IMP321 with Keytruda have been observed at either dose level so far. Recruitment in the third and highest (30mg) dose cohort is expected to complete in Q317.

Exhibit 1: TACTI-mel Phase I status and preliminary results

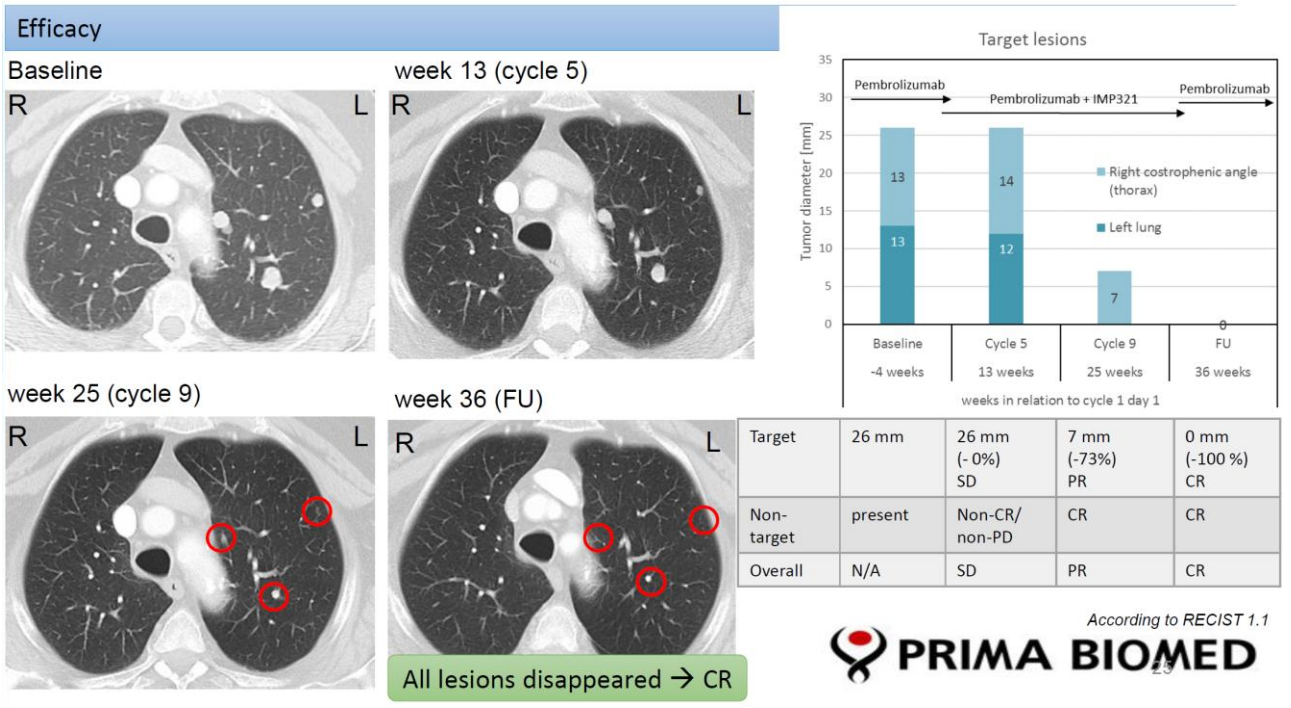


Source: Prima BioMed presentation at Immune Checkpoint Inhibitors conference, Boston, Massachusetts

One of the six patients receiving the lowest dose of IMP321 experienced a complete response (CR, Exhibit 2). After the completion of four cycles (12 weeks) of Keytruda monotherapy there was no shrinkage in this patient's tumours, but after four cycles of combination therapy with Keytruda and low dose IMP731 the lung metastases had shrunk by 73%; 23 weeks after initiation of IMP321 combination therapy the tumours had disappeared altogether. Of the other five patients, two experienced disease progression (tumour growth), one withdrew due to unrelated sepsis and there is no information about the other two, although they appear to have completed 26 weeks of treatment with IMP321 without disease progression. One should not read too much into a single tumour response, particularly given that the dose of IMP321 was low and delayed responses are a well-recognised feature of therapy with ICI, but it is encouraging that the tumour shrinkage appears

to have coincided with the initiation of combination therapy. Again, while the number of patients is small, the preliminary CR rate of 17% (1/6) compares favourably with CR rates of 2-6% seen in Phase III trials of Keytruda monotherapy in melanoma.

Exhibit 2: TACTI-mel first cohort (1mg/kg IMP321) complete responder and preliminary results



Target	26 mm	26 mm (- 0%) SD	7 mm (-73%) PR	0 mm (-100 %) CR
Non-target	present	Non-CR/ non-PD	CR	CR
Overall	N/A	SD	PR	CR

Source: Prima BioMed presentation at Immune Checkpoint Inhibitors conference, Boston, Massachusetts

Exhibit 3: Financial summary

A$'000s	2014	2015	2016	2017e	2018e
Year end 30 June	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS					
Revenue	2,020	1,336	1,949	1,253	10,564
R&D expenses	0	(8,952)	(7,060)	(7,271)	(7,489)
SG&A expenses	2,020	(5,723)	(6,983)	(7,122)	(7,336)
EBITDA	(14,003)	(13,345)	(12,093)	(13,141)	(4,262)
Operating Profit (before GW and except.)	(14,395)	(13,671)	(12,275)	(13,144)	(4,269)
Intangible Amortisation	(54)	(1,015)	(1,993)	(1,877)	(1,708)
Exceptionals	0	(18,338)	(47,468)	0	0
Operating Profit	(14,450)	(33,024)	(61,736)	(15,021)	(5,976)
Other	407	538	(1,716)	0	0
Net Interest	713	192	256	418	244
Profit Before Tax (norm)	(13,275)	(12,940)	(13,735)	(12,727)	(4,025)
Profit Before Tax (IFRS)	(13,330)	(32,294)	(63,196)	(14,603)	(5,732)
Tax	(14)	142	1,181	0	0
Profit After Tax (norm)	(13,289)	(12,798)	(12,554)	(12,727)	(4,025)
Profit After Tax (IFRS)	(13,343)	(32,152)	(62,015)	(14,603)	(5,732)
Average Number of Shares Outstanding (m)	1,220.1	1,490.1	2,236.3	2,061.6	2,073.1
EPS - normalised (c)	(1.1)	(0.9)	(0.6)	(0.6)	(0.2)
EPS - IFRS (c)	(1.1)	(2.2)	(2.8)	(0.7)	(0.3)
Dividend per share (c)	0.0	0.0	0.0	0.0	0.0
Gross Margin (%)	N/A	N/A	N/A	N/A	N/A
EBITDA Margin (%)	N/A	N/A	N/A	N/A	N/A
Operating Margin (before GW and except.) (%)	N/A	N/A	N/A	N/A	N/A
BALANCE SHEET					
Fixed Assets	694	22,960	20,883	19,031	17,347
Intangible Assets	117	22,662	20,852	18,975	17,267
Tangible Assets	577	298	32	56	79
Other	0	0	0	0	0
Current Assets	24,684	8,023	21,671	8,919	4,871
Stocks	0	0	0	0	0
Debtors	196	315	168	168	168
Cash	23,200	6,760	20,880	8,128	4,080
Other	1,287	948	623	623	623
Current Liabilities	(2,771)	(4,380)	(1,472)	(1,472)	(1,472)
Creditors	(2,669)	(2,791)	(1,444)	(1,444)	(1,444)
Short term borrowings	0	(1,508)	(0)	(0)	(0)
Short term leases	0	0	0	0	0
Other	(102)	(80)	(28)	(28)	(28)
Long Term Liabilities	(15)	(1,914)	(5,765)	(5,765)	(5,765)
Long term borrowings incl. conv. note	0	0	(5,027)	(5,027)	(5,027)
Long term leases	0	0	0	0	0
Other long term liabilities	(15)	(1,914)	(737)	(737)	(737)
Net Assets	22,592	24,690	35,317	20,714	14,981
CASH FLOW					
Operating Cash Flow	(14,908)	(7,785)	(11,594)	(13,141)	(4,262)
Net Interest	705	0	284	418	244
Tax	(24)	(2)	0	0	0
Capex	(104)	(49)	(27)	(28)	(30)
Acquisitions/disposals	0	(20,913)	130	0	0
Financing	6,845	7,745	27,229	0	0
Dividends	0	0	0	0	0
Other	(158)	(164)	0	0	0
Net Cash Flow	(7,643)	(21,168)	16,022	(12,752)	(4,048)
Opening net debt/(cash)	(30,023)	(23,200)	(5,251)	(15,852)	(3,100)
HP finance leases initiated	0	0	0	0	0
Other	820	3,220	(5,421)	0	0
Closing net debt/(cash)	(23,200)	(5,251)	(15,852)	(3,100)	948

Source: Company accounts, Edison Investment Research

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