Prima BioMed

Clinical update

The leader in LAG-3

Pharma & biotech

Prima BioMed has progressed to the final stage of dose selection for its Phase IIb trial of IMP321 in breast cancer, and is on track to commence randomization in Q416. IMP321 is a soluble LAG-3 fusion protein that doubled tumor response rates in Phase IIa. Separately, partner Novartis has expanded its Phase I LAG-3 program in solid tumors and GSK plans to move its partnered autoimmune drug into Phase II this year. With the company's development of in-house and partnered LAG-3 programs on track, our valuation increases slightly to $215m ($3.12/ADR).

Year end	Revenue (US$m)	PTP (US$m)	EPADR ($)	DPADR ($)	P/E (x)	Gross yield (%)
06/14	1.5	(10.1)	(0.25)	0.0	N/A	N/A
06/15	1.0	(9.8)	(0.20)	0.0	N/A	N/A
06/16e	1.6	(11.5)	(0.21)	0.0	N/A	N/A
06/17e	0.8	(11.2)	(0.16)	0.0	N/A	N/A

Note: Converted at A$1/US$0.76 for the table above and throughout the note.

First cohort in AIPAC safely treated

The first six patients have safely completed treatment in the AIPAC Phase IIb trial of IMP321 in breast cancer. No drug-related serious adverse events were observed and data demonstrated activation of blood monocytes/dendritic cells and CD8 T-cells. Recruitment is underway in the second cohort of nine patients who will receive 30mg of IMP321 in combination with paclitaxel, compared to 6mg in the first cohort. Results for both cohorts are expected in Q416; the trial will then move to the randomization phase in 196 patients.

Further in-house and partnered trials underway

Prima initiated a Phase I study of IMP321 plus the anti-PD1 checkpoint inhibitor Keytruda in melanoma in Q116. The combination increased response rates in preclinical studies. Partner Novartis has expanded its Phase I/II study of LAG525 in combination with a PD1 inhibitor in solid tumors from 240 to 416 subjects. GSK expects to move its licensed anti-LAG-3 antibody program into Phase II in autoimmune/inflammatory disease this year.

LAG-3: An APC activator and checkpoint inhibitor

The partnered programs exploit the immune checkpoint inhibitor function of membrane-bound LAG-3 to either stimulate (Novartis) or inhibit (GSK) immune responses, while the in-house programs exploit the separate capacity of soluble LAG-3 to activate antigen-presenting cells to initiate an immune response.

Valuation: Up slightly to $215m, $3.12 per ADR

Our valuation increases to $215m (previously $207m), with a slightly lower valuation of CVac after out-licensing to Sydys more than offset by rolling forward our DCF model to FY17. Our valuation is equal to $3.12 per ADR on an undiluted basis (previously $3.02) or $2.12 per ADR after accounting for dilution from options, warrants and convertible notes (unchanged). We forecast that an extra $6m will be needed to fund operations until end FY18.

1 August 2016

Price	**US$0.93**
Market cap	**US$64m**
	ADR/Ord conversion ratio 30/1
Gross cash ($m) at 30 June 2016	15.9
ADRs in issue	68.7m
ADR code	PBMD
ADR exchange	NASDAQ
Underlying exchange	ASX
Depository	BNY

ADR share price performance

52-week high/low	155c	80c

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). It has out-licensed CVac, an autologous dendritic cell vaccine.

Next events

Results of AIPAC dose-finding cohorts and recommended Phase II dose	Q416
Start randomized phase of AIPAC	Q416
GSK to initiate Phase II LAG-3 trial in autoimmune disease	2016

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Investment summary

Company description: LAG-3 immunotherapy programs

Prima BioMed is an ASX-listed immunotherapy company headquartered in Sydney, Australia, which is focused on developing products based on the LAG-3 pathway, following the acquisition of the private French immunotherapy company Immutep in December 2014. Its lead product IMP321 is in Phase II in breast cancer and in Phase I in combination with the checkpoint inhibitor Keytruda – Prima retains all the product rights except for China (partnered with Eddingpharm). IMP731 is in Phase I with GSK for autoimmune diseases, while IMP701 is in Phase I for solid tumors with Novartis. Prima previously conducted Phase II trials for the dendritic cell vaccine CVac in ovarian and pancreatic cancer, but has out-licensed the program to Sydys Corporation. The company has facilities in Paris, France; Leipzig and Berlin, Germany; and its headquarters are in Sydney, Australia.

Valuation: DCF valuation of $215m, $3.12/ADR

Our DCF valuation is $215m or $3.12/ADR ($2.12/ADR fully diluted). The fully diluted value per share is based on potential dilution from the 1.3bn options, warrants and convertible notes that would be in the money at the undiluted valuation of $3.12/ADR, including an assumption that the $10.5m Ridgeback Capital convertible note is converted to 688m shares at 2c/share. There would be further upside if the LAG-3 products progress and if studies indicate broader potential in new indications. GSK has indicated that it expects to progress the IMP731 program into Phase II in 2016, which would provide upside to our current valuation. The next catalysts include results from the two dose-finding cohorts in the Phase II study of IMP321 in metastatic breast cancer (MBC) in Q416, which would followed by the initiation of the 196-patient randomization phase. We also anticipate newsflow from the ongoing Phase I trial of IMP701 with Novartis.

Financials: Cash position of $15.9m

Prima BioMed acquired French private immunotherapy company Immutep in December 2014 for a total consideration of $20m. In H116 Prima raised $10m (gross) through equity issues and raised a further c $10m through the issue of a convertible note to Ridgeback Capital (first announced in May 2015). The Ridgeback notes mature in 2025 and can be converted into 688m shares (ie 2c per share). Ridgeback was also issued 380m warrants, which are exercisable at 2.37-2.5c per share and expire in 2020-25. Prima accounted for the financing transaction, including the issue of the warrants, as a share based payment to a strategic investor (Ridgeback) valued at $36m, in the H116 accounts. The fair value of the convertible note, estimated at $3.6m, is recorded as a non-current financial liability, with the balance recorded in equity. Gross cash position at the end of June 2016 was $15.9m. Operating cash burn in FY16 was $8.8m; we forecast a 30% increase in FY17 to $11.5m. Our forecasts indicate that Prima has a cash reach beyond the end of FY17, but that an extra $6m will be needed to fund operations until end FY18.

Sensitivities: Relying on LAG-3

Prima is exposed to clinical, regulatory and commercialization risks typical of all biotech companies. The key sensitivity is clinical progress of its pipeline of LAG-3 candidates, primarily the internally funded IMP321. While Prima has funds to initiate the randomization stage of the IMP321 Phase II study in MBC, it would require a partnership or alternative forms of funding to complete the study and advance IMP321 further. Existing partnerships with big pharma reduce the financial and execution risk for IMP701 and IMP731; in addition, if the Phase I study of IMP701 reveals evidence of efficacy, this could lead GSK to extend the study to additional indications including RA and MS, which could increase the potential peak sales and therefore the value of the product. Separately, progress with CVac depends on partner Sydys raising sufficient funds to progress development.

Focus shifted to LAG-3 with Immutep acquisition

In December 2014 Prima BioMed completed the acquisition of French private immunotherapy company Immutep for a total consideration of $20m. Immutep had a pipeline of three products, two of which are partnered, based on pathways in the Lymphocyte Activation Gene 3 (LAG-3) immune control mechanism. Subsequently, Prima took the strategic decision to prioritize the development of its lead LAG-3 product IMP321, a first-in-class fusion protein over its previous sole product CVac (a dendritic cell therapy) and has recently out-licensed CVac to Sydys Corporation.

The Immutep acquisition brought established relationships with Eddingpharm, GSK and Novartis, together with potential milestones of over $100m plus royalties. Immutep's founder, Professor Frédéric Triebel, a leading expert on LAG-3, joined Prima BioMed as CMO/CSO.

Exhibit 1: Prima BioMed combined pipeline

Product /Partner	Indication	Status	Notes
IMP321/**Eddingpharm**, (China)	Metastatic breast cancer + chemotherapy; melanoma + Keytruda; metastatic renal cancer	Phase IIb/ Phase I Phase IIa ready	Clinical trials underway as an antigen-presenting cell (APC) activator combined with chemotherapy or immune checkpoint inhibitor. WuXi AppTec China produces IMP321 under terms of partnership with Eddingpharm, to US European and Chinese GMP standards.
GSK2831781/IMP731/**GSK** (worldwide)	Autoimmune disease/plaque psoriasis	Phase I	Depleting anti-LAG-3 antibody, depletes activated T-cells. Phase I trial in healthy subjects and patients with plaque psoriasis started January 2015, data in 2017. Potential milestone payments of up to $100m + royalties.
IMP701/**Novartis** (worldwide)	Cancer and chronic infectious disease	Phase I	Antagonist anti-LAG-3 antibody, activates T-cell proliferation, immune checkpoint blocker. Phase I trial started June 2015, expanded to 416 pts (vs 240) June 2016.
CVac/**Sydys** (worldwide except Israel), **Neopharm** (Israel)	Second remission ovarian cancer, pancreatic cancer	Phase II	Prima terminated a Phase IIb study in second remission ovarian cancer, CAN-004B, and a Phase IIa study in pancreatic cancer, CAN-301, to focus its resources on IMP321. Out-licensed to Sydys Corporation in May 2016. Potential milestone payments of $293m + low single-digit royalties.

Source: Prima BioMed

Success of checkpoint inhibitors highlights the potential of immunotherapy

Cancer immunotherapy is used to enhance the ability of the immune system to attack and kill tumor cells. Immunotherapy harnesses the patient's own immune system via a range of mechanisms, either activating it to detect and destroy tumor cells or blocking signaling mechanisms, which tumors exploit to suppress anti-tumor immune responses.

The potential of immunotherapy to improve patient outcomes has been highlighted by the success in melanoma, lung, renal and bladder cancers of the drugs Yervoy (ipilimumab), Keytruda (pembrolizumab), Opdivo (nivolumab) and Tecentriq (atezolizumab) that block the CTLA4 or PD1/PD-L1 immune checkpoint inhibitor (ICI) pathways.

Many tumors are able to escape immune attack by activating pathways in the immune system that act as checkpoints to dampen down immune responses when they are no longer needed, such as after a viral infection has been eliminated.

There are a number of these immune checkpoint pathways that can be activated in the tumor microenvironment to suppress immune responses in addition to PD1 and CTLA4, including LAG-3, OX40, TIM3 and GITR.

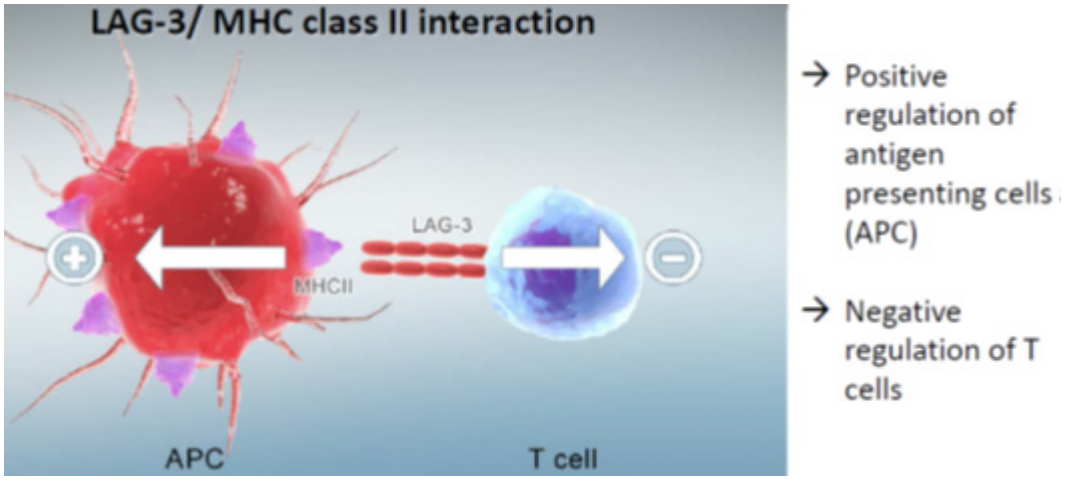
Responses to the approved ICI drugs Yervoy, Keytruda, Opdivo and Tecentriq are frequently long-lasting, but response rates to single agent ICI therapy are often low, typically in the range 10-30%. This has led to increased interest in other immunotherapies that can be used either on their own or in combination with PD1 or CTLA4 ICI drugs to increase the proportion of patients who respond to therapy and to increase the efficacy in other types of cancers.

LAG-3: Promising immunotherapy target can play multiple roles

LAG3 is of particular interest as an immunotherapy because in different circumstances it can either act as an ICI and suppress T-cell activity or stimulate the activity of antigen-presenting cells and help initiate an anticancer immune response (Exhibit 2). LAG-3 exists in both soluble and membrane-bound forms, which have different functions.

LAG-3 is expressed on activated T-cells, natural killer cells, B-cells and a small subset of dendritic cells known as plasmacytoid dendritic cells. LAG3 is not expressed by resting T-cells, but is upregulated several days after T-cell activation. It is significant to note that LAG3 is upregulated on so-called exhausted T-cells (which have impaired function following prolonged exposure to antigen) compared with effector or memory T-cells.

Exhibit 2: LAG-3 activates antigen-presenting cells, but downregulates T-cells



Source: Company presentation

LAG3 binds strongly to major histocompatibility complex (MHC) class II molecules expressed on the surface of antigen-presenting cells (APCs), including dendritic cells.

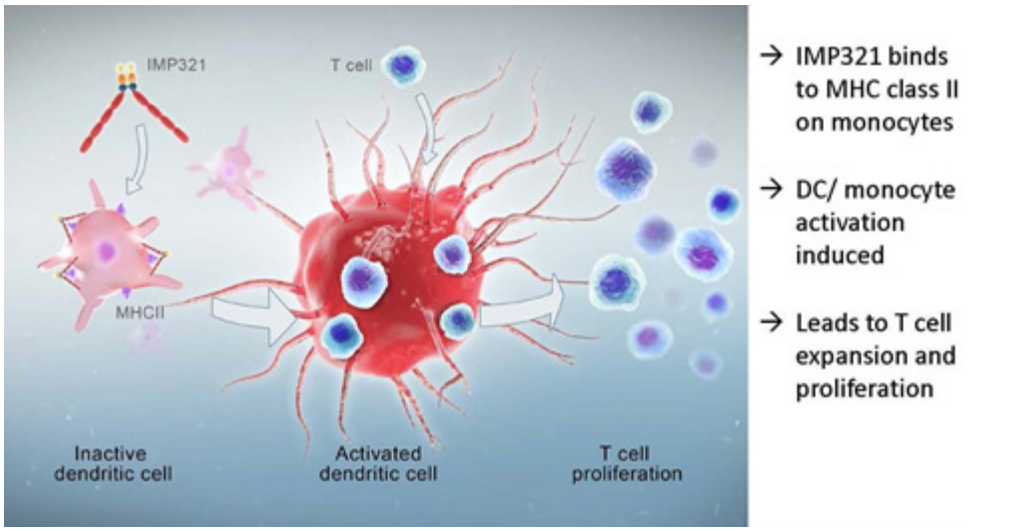
In certain configurations (eg multiplexed LAG-3 on the membrane or cross-linked soluble LAG-3), this binding to surface MHC molecules activates the APCs to mature and transport tumor antigens to the lymph nodes for presentation to T-cells. In turn, this increased antigen presentation stimulates the reactivation and expansion of cytotoxic $CD8^+$ T-cells, which can circulate to the tumor via the bloodstream and attack and kill tumor cells, thereby activating and amplifying the anti-tumor immune response.

In addition to the ability to activate APCs, membrane bound LAG-3 can act as a classical inhibitory immune checkpoint in T-cells. This inhibitory effect occurs when membrane-bound LAG-3 on the surface of an activated T-cell binds to MHC class II molecules on an APC at the same time as adjacent T-cell receptors (TCR) are bound to MHC class I molecules on the APC that is bearing an antigen fragment.

In-house IMP321 program uses soluble LAG3 to activate APCs

Prima BioMed's lead product IMP321 is a LAG-3 Ig fusion protein that is based on the soluble form of LAG-3 and can activate APCs. These activated APCs process tumor antigens, including those released from cells killed by chemotherapy, transport the antigens to lymph nodes and present the tumor antigens to T lymphocytes, thus activating and amplifying the immune response, as summarized in Exhibit 3.

Exhibit 3: IMP321 LAG-3 fusion protein activates APCs

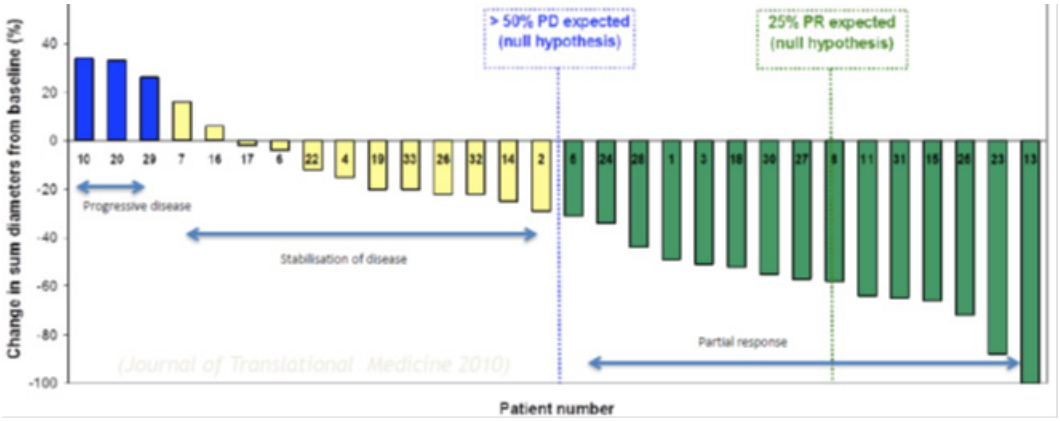


Source: Prima AGM presentation 2015. Note: DC = dendritic cell.

Previous studies conducted by Immutep before its acquisition by Prima focused on the use of IMP321 in combination with chemotherapy and as an adjuvant to cell therapy vaccines to stimulate APC activity.

In a previous Phase I/IIa study in MBC (n=30) conducted by Immutep, administration of IMP321 the day after chemotherapy induced a doubling of the tumor response rate to 50% vs 25% over six months (in comparison to a historical cohort of chemotherapy-only patients), as shown in Exhibit 4.

Exhibit 4: IMP321 Phase IIa breast cancer responses compared to historical control group



Source: Company presentation. Note: Data based on Brignone et al. *Journal of Translational Medicine* 2010, 8:71. The waterfall plot presents the percentage of change in the sum of tumor diameters observed after treatment (six months) for individual patients. Historical data obtained for a group receiving paclitaxel alone (*J Clin Oncol* 2009 27 (30) 4966-72) are presented as dotted lines.

First cohort in AIPAC safely treated

In December 2015 Prima initiated the AIPAC (Active Immunotherapy PAClitaxel) Phase II trial of IMP321 in patients with MBC who are HER2 negative and therefore ineligible for treatment with Herceptin. The trial will recruit approximately 211 patients at 30 sites in six European countries.

The first cohort of six patients who received 6mg of IMP321 in combination with paclitaxel has safely completed treatment. No drug-related serious adverse events were observed and data demonstrated activation of blood monocytes/dendritic cells and CD8 T-cells. Recruitment is underway in the second cohort of nine patients who will receive 30mg of IMP321, which will

complete the open-label, safety run-in stage of the trial. The results for both cohorts will be presented and compared in Q416 to confirm the recommended Phase II dose of IMP321.

The trial will then move to a randomized, placebo-controlled, double-blind stage where 196 patients will receive six months of treatment with paclitaxel plus either IMP321 or placebo. After six months, paclitaxel treatment will cease and responders and patients with stable disease will continue to receive either IMP321 or placebo monotherapy for a further 12 months. The trial will recruit MBC patients who have not undergone prior chemotherapy for metastatic disease and are hormone receptor-positive and HER2 negative.

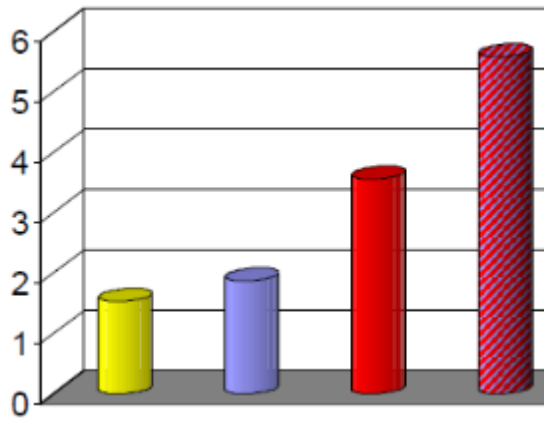
The primary endpoint from the randomized stage of the trial is improvement in progression-free survival (PFS), while overall survival (OS) is a secondary endpoint; tumor biomarkers will also be monitored. The European regulator (EMA) has indicated that this trial could be sufficient to support a marketing authorization if it achieves certain (undisclosed) clinical endpoints.

The company expects the trial to take about three years to complete, so results should be available in early 2019. Positive results could potentially allow Prima to file for approval in Europe in 2019, with approval possible in 2020. US approval could potentially be achieved in 2023 following a Phase III trial.

Phase I combination study with Keytruda began in January

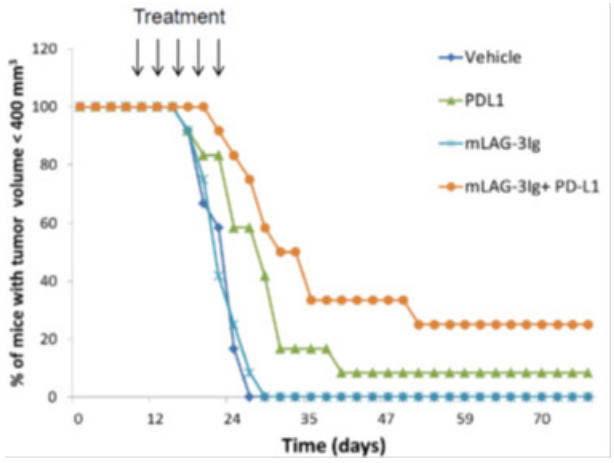
In January 2016 Prima initiated a Phase I trial called TACTI-mel (Two ACTive Immunotherapies in melanoma). This trial is testing IMP321 in combination with the anti-PD1 immune checkpoint inhibitor Keytruda (pembrolizumab, Merck) in 24 patients with unresectable or metastatic melanoma. Patients will receive ascending subcutaneous doses of IMP321 up to 30mg per injection. The study will evaluate anti-tumor activity and the nature of the immune response at various doses, in addition to safety, pharmacokinetics and pharmacodynamics.

Exhibit 5: Combining IMP321 with PD-1 blocking antibody increases activation of cytotoxic T-cells



Source: Company presentation. Note: Yellow bar = control; blue = anti-PD1 mAb alone; red = IMP321 alone; pink = IMP321 + anti-PD1 mAb. Y axis = % of activated cytotoxic $CD8^+$ T-cells among human white blood cells stimulated with antigenic peptides.

Exhibit 6: Combining LAG-3 fusion protein with PD-L1 blocking antibody reduces tumor growth in mice



Source: Company presentation. Note: In a mouse colon cancer model, treatment with the mouse equivalent of IMP321 (mLAG-3Ig) combined with a PD-L1 blocking antibody (orange line) inhibited tumor growth more than either treatment alone.

This study is of particular interest because it combines the APC activation properties of IMP321, which helps to initiate an immune response, with an ICI which 'releases the brakes' on the immune effector cells, enabling a stronger immune response. Prima has shown in preclinical studies that combining IMP321 with immune checkpoint inhibitors increased the strength of an anti-cancer immune response and the speed and level of tumor regression. Exhibit 5 shows that combining IMP321 with a PD-1 blocking antibody increased the activation of cytotoxic T-cells when human white blood cells (peripheral blood mononuclear cells) were stimulated with a peptide antigen *in*

vitro. Similarly, in a mouse model of colon cancer, combination therapy with the mouse analogue of IMP321 (mLAG-3Ig) plus a PD-L1 blocking antibody inhibited tumor growth to a greater degree than either treatment on its own (Exhibit 6).

Combining two immunotherapy treatments with different mechanisms of action has already been proven to be an effective strategy. The FDA approved the combination of the ICIs Yervoy (ipilimumab) and Opdivo (nivolumab) in patients with advanced melanoma. Patients treated with the combination experienced a 60% overall response rate compared to 11% in those treated with Yervoy alone.

Investigator-initiated study of intra-tumoral injection of IMP321

Prima announced earlier this month that it will participate in an investigator-sponsored collaborative study of intratumoral injection of IMP321. The new clinical trial, INSIGHT, will explore the potential for IMP321 to act as an activator of dendritic cells found within solid tumors.

The study, which will be led by Professor Doctor Salah-Eddin Al-Batran at the Northwest University Hospital in Frankfurt, Germany, will commence once it has received regulatory and ethics approval. As the trial is investigator-initiated it will not require significant resource commitment from Prima.

Partnered programs target membrane bound LAG-3 on T-cells

Prima has partnerships with Novartis and GSK for two separate programs, which use monoclonal antibodies (mAbs) to target membrane-bound LAG-3 in different ways. Each of the pharma partners has commenced a clinical trial program based on the in-licensed LAG-3 drug.

Novartis has expanded LAG525 (IMP701) Phase I/II trial

IMP701, which is partnered with Novartis, is an antagonist mAb, which blocks the LAG-3-mediated inhibitory signal given to tumor-infiltrating T-cells and thus activates T-cell proliferation. LAG525 is Novartis's humanized version of IMP701, which it has taken into clinical development.

In June 2015 Novartis commenced a Phase I/II trial of LAG525 under its collaboration and licensing agreement with Prima. The Phase I trial (ClinicalTrials.gov Identifier: NCT02460224) is testing LAG525 as a single agent, as well as in combination with its in-development anti-PD1 immune checkpoint inhibitor PDR001, in patients with solid tumors.

In June 2016 Novartis added a third treatment group to the trial and increased the size of the trial to 416 patients, a substantial increase from the original target of 240 patients. The third treatment arm involves treating Japanese patients with LAG525 as a single agent.

Novartis has also tightened the focus of the trial to melanoma, lung and renal cancers, having previously also included bowel and nasopharyngeal cancers. Following the expansion in trial size, the estimated completion date has been pushed back to August 2018.

The fact that Novartis is trailing LAG525 in combination with PDR001 underscores the potential that it sees for synergistic combinations between drugs that target LAG3 and PD1/L1 checkpoint inhibitors. We take this expansion of the trial size as a positive sign, which may indicate that Novartis has seen encouraging initial results from the study. PDR001 is currently in Phase II development in nasopharyngeal carcinoma.

Novartis has not disclosed which cancers it intends to target for subsequent development of LAG525; in our forecasts, we assume that the initial indication will be non-small cell lung cancer

(NSCLC), which has already been successfully targeted by the PD1 immune checkpoint inhibitors pembrolizumab (Keytruda, Merck) and nivolumab (Opdivo, Bristol-Myers Squibb).

GSK plans to move its LAG-3 program into Phase II in 2016

Prima's second out-licensed LAG-3 program utilizes LAG-3 in a different way to target autoimmune disease. It is based on IMP731, which is a cytotoxic mAb that will kill the few LAG-3+ activated T-cells that infiltrate autoimmune disease sites.

In animal studies IMP731 was shown to target and selectively deplete LAG-3 marked T-cells, leaving normal T-cells intact. This offers an interesting new approach compared with standard treatments such as corticosteroids, which inhibit T-cells indiscriminately, suppressing immunity. The approach is potentially applicable to the wider autoimmune disease population; diseases such as multiple sclerosis and rheumatoid arthritis are associated with chronically stimulated T-cells.

IMP731 is under development by partner GlaxoSmithKline (GSK), which in-licensed the program from Prima (Immutep) in 2011. GSK has developed a humanized form of the IMP731 mAb, which it has termed GSK2831781. GSK dosed the first patient in a Phase I study of GSK2831781 in January 2015 in patients with plaque psoriasis. GSK2831781 aims to kill the few activated LAG-3 positive T-cells that are autoreactive in autoimmune disease. At its R&D day in November 2015 GSK indicated that it expects to progress its anti-LAG-3 program into Phase II trials in immuno-inflammatory disease in 2016, with the potential for a regulatory filing in a 2021-25 time frame. The Phase II trial does not appear to have commenced yet.

Licensing agreement with Sydys to advance CVac program

In May 2016 Prima announced an agreement to out-license CVac to Sydys Corporation (OTC: SYYC, www.sydyscorp.com), a publicly traded New York company that has been repurposed to develop the CVac assets. There was no upfront payment, but Prima received a 9.9% equity stake in Sydys at the time of closing. Should CVac be successfully commercialized, Prima could receive $293m in development, regulatory and commercial milestone payments for achieving set commercial sales targets, in addition to low single-digit royalties on sales. The deal removes any requirement to fund further development of CVac, while allowing Prima to participate in upside if the vaccine proves effective in future clinical trials.

In addition to the licensing arrangement, Prima has transferred its contracts and some inventory and equipment to Sydys. Prima CEO Marc Voigt will join the board of Sydys.

Valuation

We have updated our risk-adjusted DCF valuation to account for the CVac license deal and have rolled forward our risk-adjusted DCF model to FY17. Our valuation of Prima has increased slightly to $215m (previously $207m) or $3.12 per ADR (undiluted, previously $3.02 per ADR) with a lower valuation for the CVac program more than offset by rolling forward our model to FY17. On a fully diluted basis our valuation is unchanged at $2.12 per ADR, after taking into account the options, warrants and convertible notes on issue. Other core valuation assumptions are unchanged. Exhibit 7 summarizes the constituent parts of our valuation, which is based on a discount rate of 12.5%. Prima's primary listing is on the ASX under the code PRR; each NASDAQ-listed ADR represents 30 ordinary shares. Our undiluted valuation equals A$0.14 per ASX-listed ordinary share at current exchange rates.

We have altered our forecasts for CVac following the out-licensing to Sydys. As the ongoing development is contingent on Sydys raising further capital to fund clinical trials of CVac, we lower our overall likelihood of success for the program to 20% from 30%.

No details have been provided on the split of the $293m of potential CVac milestone payments. In our model we assume $13m on filing for approval in the US, $100m for approval in first disease indication, $40m on approval in a second indication plus sales-based milestones totaling $150m. Milestones are risked at 25% for the earliest down to 10% for the last sales milestone. We assume a 4% royalty rate (previously 12%). Our overall valuation of CVac falls to $21m from $33m, with most of the value now represented by the potential milestone payments.

Gross cash balance at end FY16 was $15.9m. For valuation purposes we deduct the $10.5 face value of the Ridgeback Capital convertible note in calculating end-FY16 net cash of $5.4m as shown in Exhibit 7. We note that this is different to the accounting treatment of the convertible note, which includes only the $3.6m estimated fair value of the convertible note as a non-current liability with the remainder treated as equity, resulting in a balance sheet net cash figure of $12.3m as shown in Exhibit 9.

Our peak sales estimates for IMP321 and IMP701/LAG525 are based on pricing per patient of $60k and $40k in the US and Europe, respectively. The marketed ICIs Keytruda, Nivolumab and Tecentriq are all priced at about $12,500 per month ($150k per year) in the US, which suggests that our pricing assumptions may be conservative depending on the approved indications, duration of treatment and total cost of combination therapies.

Exhibit 7: DCF valuation of Prima BioMed

Value driver	Launch date	Likelihood of success	Peak sales ($m)	Royalty	Value($)	Value per ADR ($)
IMP321-MBC	2020 (EU), 2023 (US)	35%	971	17.5%	143.9	2.09
IMP321+anti-PD1 ICI-melanoma	2024	15%	480	17.5%	19.9	0.29
IMP321 milestones - assume partnered post PII in MBC	$225 estimated risk-adjusted milestones from out-licensing North American and European rights.				38.3	0.56
IMP731-autoimmune disease	2022	15%	1,079	8%	28.2	0.41
Potential IMP731 milestones from GSK	$90m of total $100m in risk-adjusted milestones from GSK				14.4	0.21
IMP701-solid tumors (lung cancer)	2024	15%	2,440	5%	28.0	0.41
Potential IMP701 milestones from Novartis	$20m in risk-adjusted milestones from Novartis				2.4	0.03
CVac-ovarian cancer	2020	20%	343	4%	4.1	0.06
Potential milestones CVac	$293m Sydys milestones risk-adjusted to 10-25%				17.0	0.25
Grants					0.0	0.00
R&D expenses					(8.6)	(0.13)
Admin expenses					(8.5)	(0.12)
Capex					(0.0)	(0.00)
Tax					(70.0)	(1.02)
Net cash	FY16e forecast net cash (including $10.5m convertible note at face value)				5.4	0.08
Total					214.6	3.12

Source: Edison Investment Research

Exhibit 8 shows that in addition to the 2,062m Prima shares currently in issue, there are a further 1,379m potential shares that could be issued on the exercise of options, warrants and convertible notes, including 1,301m that would be in the money at our $3.12 per ADR undiluted valuation. Exhibit 8 shows that after taking into account these potential shares, our diluted valuation is $2.12 per ADR. Prima is likely to require additional funding to complete the IMP321 clinical trials; our diluted valuation of $2.12 per ADR does not take into account potential dilution from any future capital raising.

The breadth of the LAG-3 pipeline means there could be further upside if Prima or its partners launch additional products into the clinic or broaden the indications being studied.

We include risk-adjusted milestones payable by current partners GSK for IMP731, Novartis for IMP701 and Sydys for CVac, plus milestones from prospective deals for IMP321. Possible catalysts include results of the second AIPAC dose-finding cohort and recommended Phase II dose, the start

of the randomized phase of AIPAC, progression of the licensed anti-LAG-3 antibody into Phase II by GSK or news on partnering, all of which could provide upside to our current valuation.

Exhibit 8: Potential further dilution and value per ADR

	Average exercise price per ADR equivalent ($)	m
Current number of shares		68.7
Ridgeback convertible note potential shares	0.46	22.9
Ridgeback warrants	0.54	12.7
Listed options	4.56	2.6
Unlisted options	1.19	5.1
Performance rights	0.00	2.7
Total in-the-money potential shares		43.4
Total potential diluted number of shares		112.1
Net cash raised from options and CN exercise		$23
Valuation (above plus additional cash)		$238
Diluted value per share		$2.12

Source: Edison Investment Research

Financials

Prima acquired Immutep for $20m in H115. In H116 Prima raised $10m (gross) through equity issues and raised a further $10m through the issue of a convertible note to Ridgeback Capital (first announced in May 2015). The 13,750,828 convertible notes issued to Ridgeback have a face value of A$1.00 per note, mature on 4 August 2025 and accrue interest at a rate of 3% pa, which may also be converted into shares. Each note can be converted into 50 shares (ie equivalent to A$0.02/share or $0.46/ADR) for a total of 688m shares (22.9m ADR). Ridgeback was also issued warrants equivalent to 12.7m ADR which are exercisable at ~$0.54 per ADR and expire in 2020-25. Prima accounted for the financing transaction, including the issue of the warrants, as a share-based payment to a strategic investor (Ridgeback) valued at $36m, in the H116 accounts. The fair value of the convertible note, estimated at $3.6m, is recorded as a non-current financial liability, with the balance recorded in equity. Gross cash position at the end of June 2016 was $15.9m. Operating cash burn in FY16 was $8.8m, a 50% increase over the previous year; we forecast a further 30% increase in FY17 to $11.5m. Our forecasts indicate that Prima has a cash reach beyond the end of FY17, but that an extra $6m will be needed to fund operations until end FY18.

Sensitivities

Prima is exposed to the same clinical, regulatory and commercialization risks as all biotech companies. The key sensitivity is clinical progress of its pipeline of LAG-3 candidates, primarily the internally funded IMP321. While Prima has funds to initiate the randomization stage of the IMP321 Phase II study in MBC, it would require a partnership or alternative forms of funding to complete the study and advance IMP321 further. Existing partnerships with big pharma reduce the financial and execution risk for IMP701 and IMP731; in addition, if the Phase I study of IMP701 reveals evidence of efficacy, it could lead GSK to extend the study to additional indications including RA and MS, which could increase the potential peak sales and therefore the value of the product. Separately, progress with CVac depends on partner Sydys raising sufficient funds to progress development.

Exhibit 9: Financial summary

US$000s	2014	2015	2016e	2017e
Year end 30 June	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS				
Revenue	1,535	1,015	1,635	840
Cost of Sales	0	0	0	0
Gross Profit	1,535	1,015	1,635	840
EBITDA	(10,643)	(10,142)	(10,515)	(11,473)
Operating Profit (before GW and except.)	(10,940)	(10,390)	(10,725)	(11,476)
Intangible Amortization	(41)	(772)	(1,350)	(1,429)
Exceptionals	0	(13,937)	(36,045)	0
Operating Profit	(10,982)	(25,099)	(48,120)	(12,905)
Other	309	409	(1,002)	0
Net Interest	542	146	216	317
Profit Before Tax (norm)	(10,089)	(9,835)	(11,511)	(11,159)
Profit Before Tax (IFRS)	(10,131)	(24,543)	(48,906)	(12,587)
Tax	(10)	108	427	0
Profit After Tax (norm)	(10,100)	(9,727)	(11,084)	(11,159)
Profit After Tax (IFRS)	(10,141)	(24,435)	(48,479)	(12,587)
	0.0	0.0	0.0	0.0
Average Number of Shares Outstanding (m)	1,220.1	1,490.1	1,614.9	2,061.6
Average Number of ADRs Outstanding (m)	40.7	49.7	53.8	68.7
EPS - normalized (c)	(0.8)	(0.7)	(0.7)	(0.5)
EPS - IFRS (c)	(0.8)	(1.6)	(3.0)	(0.6)
Dividend per share (c)	0.0	0.0	0.0	0.0
Earnings per ADR - normalized ($)	(24.8)	(19.6)	(20.6)	(16.2)
Earnings per ADR - IFRS (c)	(24.9)	(49.2)	(90.1)	(18.3)
Dividend per ADR (c)	0.0	0.0	0.0	0.0
Gross Margin (%)	N/A	N/A	N/A	N/A
EBITDA Margin (%)	N/A	N/A	N/A	N/A
Operating Margin (before GW and except.) (%)	N/A	N/A	N/A	N/A
BALANCE SHEET				
Fixed Assets	528	17,450	15,899	14,489
Intangible Assets	89	17,223	15,874	14,445
Tangible Assets	439	226	26	44
Other	0	0	0	0
Current Assets	18,760	6,098	16,532	5,355
Stocks	0	0	0	0
Debtors	149	240	174	174
Cash	17,632	5,137	15,868	4,691
Other	978	720	490	490
Current Liabilities	(2,106)	(3,329)	(2,893)	(2,893)
Creditors	(2,029)	(2,121)	(2,843)	(2,843)
Short term borrowings	0	(1,146)	(0)	(0)
Short term leases	0	0	0	0
Other	(77)	(61)	(49)	(49)
Long Term Liabilities	(11)	(1,455)	(4,597)	(4,597)
Long term borrowings incl. conv. note	0	0	(3,571)	(3,571)
Long term leases	0	0	0	0
Other long term liabilities	(11)	(1,455)	(1,026)	(1,026)
Net Assets	17,170	18,764	24,941	12,353
CASH FLOW				
Operating Cash Flow	(11,330)	(5,917)	(8,851)	(11,473)
Net Interest	536	0	216	317
Tax	(18)	(1)	0	0
Capex	(79)	(37)	(21)	(22)
Acquisitions/disposals	0	(15,894)	132	0
Financing	5,202	5,886	17,338	0
Dividends	0	0	0	0
Other	(120)	(125)	(325)	0
Net Cash Flow	(5,809)	(16,088)	8,490	(11,177)
Opening net debt/(cash)	(22,818)	(17,632)	(3,991)	(12,297)
HP finance leases initiated	0	0	0	0
Other	623	2,447	(182)	(1)
Closing net debt/(cash)	(17,632)	(3,991)	(12,297)	(1,119)

Source: Prima Biomed accounts, Edison Investment Research. Note: Solely for the convenience of the reader the financial summary table has been converted to US$ at a rate of US$0.76 to A$1. Novogen reports statutory accounts in Australian dollars. These translations should not be considered representations that any such amounts have been or could be converted into US dollars at the assumed conversion rate.

Contact details	Revenue by geography
Level 7, 151 Macquarie Street, Sydney, NSW 2000 +61 (0)2 9276 1224 www.primaBioMed.com.au	N/A

Management team

Chairman: Lucy Turnbull AO	CEO/CFO: Marc Voigt
Non-executive chairman since October 2010. Lawyer and prominent business leader, highly active in the Australian not-for-profit sector, especially in medicine. Officer of the Order of Australia. Previously active in politics, including as Lord Mayor and deputy Lord Mayor of Sydney; wife of current Australian minister of communications and former opposition leader, The Hon. Malcolm Turnbull MP.	Appointed in October 2011, having joined as GM of European operations. Previously CFO/CBO at Revotar Biopharmaceuticals and Medical Enzymes, and an investment manager for a German biotech venture fund. Holds an MBA from Free University of Berlin. Based in Berlin, where Prima's European operations are located. Mr Voigt was appointed CEO in July 2014.
CSO/CMO: Dr FrédéricTriebel, MD PhD	**CTO: Dr Sharron Gargosky**
A founder and medical and scientific director at Immutep, Dr Triebel discovered the LAG-3 gene while working at the Institut Gustave Roissy Paris, where he was involved in running Phase I/II immunology studies and headed up a research group. Previously, from 1991 to 1996, Dr Triebel was a director of an INSERM unit.	Joined Prima in August 2010. Previously CSO at Pulse Health and held CSO and BD positions at Hyperion Therapeutics, Ucyclyd Pharma and Diagnostic System Laboratories. Holds BSc and PhD in biochemistry from University of Adelaide and completed post-doctoral fellowship at Stanford University.

Principal shareholders as per 2015 annual report	(%)
Innoven Tactical Investment Fund	2.5%
Lucy Turnbull	0.9

Companies named in this report

BMS, Eddingpharm, GSK, Merck, Novartis, WuXi AppTec, Neopharm, Sydys Corporation