

# Healthcare: Biotech

#### Important disclosures can be found on pages 6 - 10 of this report.

## Prima BioMed Ltd. (PBMD – \$2.57\*)

Armadale, Victoria, Australia January 24, 2017

STOCK DATA								
52-Week Range	\$4.1	3 – \$1.70						
3-Month ADTV			93,916					
Market Cap (mil)			\$5,327.9					
Shares Outstandi		2,073.1						
Beta		0.50						
Fiscal Year-End		June						
EARNINGS DATA								
Adj. EPS	2015A	2016A	2017E					
H1	\$(0.50)	\$(2.87)	\$(0.36)					
H2	H2 \$(1.52)							
FY \$(2.02) \$(2.76) \$(0.53								
EPA (Earnings per A	DR) for each pe	riod is adjus	ted for					
the AUD vs. USD spot exchange rates on June 30 and								

the AUD vs. USD spot exchange rates on June 30 and December 31. Quarterly EPS may not sum to total due to rounding.

	4Q16
Short Interest	158,045.0

#### BALANCE SHEET DATA

	1H17
Cash & Equivalents	\$20.9
Current Assets	\$21.7
Total Assets	\$42.6
Total Liabilities	\$7.2
Total Stockholder Equity	\$35.3
Total Debt	\$0.0
In millions of Australian dollars (AUD). Share	count

reflects NASDAQ-traded ADR. 1 ADR = 100 ASX-traded common shares.

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### **Company Update**

Outperform Price Target: \$6.00

# Green Shoots from Broad Clinical Progress Are Emerging

#### Summary and Recommendation

On January 20, Prima BioMed announced the first patient dosing in the enlarged randomized portion of the AIPAC Phase IIb study with IMP321 in metastatic breast cancer (mBC). We think clinical progress with IMP321 is significantly under-appreciated, as the latest news is the seventh announcement since late November 2016. We also point to multiple value inflection points in 2017 that we think could be positive catalysts. PBMD also continues to make progress with its Phase I trial in melanoma (TACTI-mel), testing IMP321 plus a PD-1 blocking antibody (Keytruda), a hot immunotherapeutic anti-cancer strategy, and recently added a LAG-3 agonist antibody, IMP761, to its internal pipeline. We reiterate our Outperform rating.

#### **Key Points**

- AIPAC's progress is impressive. AIPAC is a Phase IIb trial of the chemoimmunotherapy IMP321 plus paclitaxel in hormone receptor-positive mBC. In December 2016, PBMD announced initial safety data from the first cohort. Results at the 6 mg and 30 mg dosage levels confirmed the safety and tolerability of IMP321, with no drug-related serious adverse events. We think the data significantly de-risked the remainder of the trial, as immune monitoring also confirmed IMP321 as an effective antigen presenting cell (APC) activator and enhances the immune response (increased level of monocytes, dendritic cells, and CD8+ T cells). We look for the initial safety run-in data from both cohorts to be presented in mid 2017.
- TACTI-mel is also making big strides. We look for TACTI-mel to position IMP321 with potential for future consideration in synergistic combination with immune checkpoint therapies. The TACTI-mel trial is in Australia and will recruit up to 24 patients. Interim data from the first cohort (eight patients) were reported in December 2016 and indicated IMP321 was safe and tolerable in melanoma patients. Dosing of the second patient cohort (n=6 with unresectable or metastatic melanoma that had a sub-optimal response to Keytruda), to primarily confirm that IMP321's safety will also look for anti-tumor activity and the immune response to the combination, was announced earlier this month. We look for further data from TACTI-mel to be positive catalysts in 2017.
- IMP761 added to internal pipeline. In addition to IMP321, PBMD is developing a humanized IgG4 monoclonal antibody (MAb), IMP761, which could be the first agonist antibody to LAG-3. The discovery is important as a checkpoint agonist like IMP761 could allow for fine-tuning of the immune response to a checkpoint protein, such as temporarily switching off the inflammatory response and, thus, see potential application in autoimmune diseases. IMP761 is in the preclinical stage of study.
- The activity of partners grows. PBMD's partners, Novartis (NVS) and GlaxoSmithKline (GSK), also have several clinical and pre-clinical LAG-3 programs underway. GSK has exclusive rights to IMP731 for autoimmune disease applications, and NVS has exclusive rights to IMP701, which also has anti-LAG-3 oncology applications. New clinical trials have been initiated in the past 12 months. Thus, we anticipate news flow from these programs, as well as from collaborations with Cytilimic and WuXi Biologics, to grow in 2017.

TM	Debatable Point	Our Thoughts	Time Frame	Impact
The Debate <sup>TM</sup>	Is there a significant market opportunity for another checkpoint inhibitor?	Prima BioMed is currently conducting TACTI-mel, a Phase I clinical trial evaluating treatment with IMP321 in combination with pembrolizumab (a PD-1 checkpoint inhibitor) in patients with metastatic melanoma. Although the cancer immunotherapy space is very competitive, several immune system checkpoint protein-targeted therapeutics have been approved by the FDA since 2011 by gaining initial approvals in one type of tumor and then gaining additional approvals in other tumor types, especially in hard-to-treat cancers. We believe approvals for additional tumor types are likely to be announced in the coming months, showing that there continue to be unmet medical needs in treating cancer and, thus, room for novel therapies like IMP321.	3 to 6 Months	<b>(</b>
	Is the combination of a chemotherapy with IMP321 potent?	An antigen presenting cell (APC) activator like IMP321 given after chemotherapy induces APCs to mature and transport tumor antigens (debris from apoptotic tumor cells) to the lymph nodes for presentation to T cells, whose cytotoxic activity is then stimulated (increased monocyte, dendritic cell, natural killer, and memor CD8 T cell counts) and sustained. Importantly, only a low concentration of IMP321 is required to show activity on APCs, which appears to be sustained for at least six months, making IMP321 a very potent immune system activator.	12 to 24 Months	
	Can positive results from the AIPAC Phase IIb trial gain IMP321 regulatory approval?	AIPAC is a randomized, placebo-controlled study in metastatic breast cancer (mBC) whose primary goal is to compare combined treatment with IMP321 plus standard chemotherapy (paclitaxel) versus paclitaxel alone. We expect positive results from this study based on a comparison of previous trials with IMP321 in mBC versus historical controls from the ECOG 2100 study in mBC, which showed only 10% of patients treated with IMP321 progressed versus 50% who progressed in the historical control group. We believe AIPAC's design is registrational in quality, as it is being conducted under the auspices of scientific advice from the European Medicines Agency and, upon achievement of certain clinical endpoints, could lead to full marketing authorization for IMP321 in the EU.	2 Years+	

# **Investment Thesis**

We believe the current valuation of Prima BioMed is disconnected from our estimation of the significant value PBMD has created in advancing its clinical-stage product pipeline. Specifically, whereas PBMD had one active clinical program in 2014, it now has three novel product candidates in clinical development (IMP321, IMP731, and GSK 2831781), with the latter two rapidly being advanced by two partners committed to their full evaluation.

# Valuation

We use a discounted cash flow (DCF) methodology to arrive at our 12-month price target of \$6. See attached for the detailed DCF valuation analysis.

# Catalysts/Milestones

- **1Q17**: Present preclinical results for the anti-PD-1/IMP321 combination.
- 1H17: Interim results (complete safety run-in phase) from the AIPAC Phase IIb study with IMP321 plus paclitaxel.

# Valuation

We use a discounted cash flow (DCF) methodology to arrive at our 12-month price target of \$6.00 for PBMD shares. Using the matrix below, a discount rate of 25% was applied, based on the availability of mid-stage efficacy data for IMP321 and, thus, below-average risk relative to other drug candidates in mid-stage development. A 1% terminal growth rate was used, which we believe is conservative as IMP321 has potential for approval in other cancers, expansion of future sales into regions outside the initial target markets of U.S./EU/Japan, and likely pricing power (2%–3% annual price increases).

General Matrix of Discount Rate Assumptions versus Clinical Stage of Development

		Relative Risk	
Clinical Stage	Below Average	Average	Above Average
Preclinical	55%	60%	65%
IND	45%	50%	55%
Phase I	35%	40%	45%
Phase II	25%	30%	35%
Phase III	15%	20%	25%
Approved	10%	13%	15%

Source: Company reports and FBR Research

The following assumptions were used in our methodology:

- IMP321 demonstrates safety as a treatment for patients with mBC.
- Prima's anticipated partner for IMP321 development gains U.S. approval in mBC in the calendar first half of the year 2020 and one year later in the EU and Japan.
- IMP321 late-stage development and commercialization is out-licensed by 2019 for a \$25 million up-front payment and additional milestone payments, based on clinical and regulatory achievements, plus low-double-digit royalties on IMP321 sales in U.S. and ex-U.S. markets.
- Application of a 25% discount rate to free cash flows, as we note: (1) Targeting immune checkpoint pathways is a validated approach in anti-cancer drug development; (2) IMP321 has already completed one Phase II study; and (3) thus, IMP321 has below-average regulatory risk.
- A 1% terminal growth rate was used, driven by potential approval of IMP321 in other tumor types, expansion of future sales into regions outside the initial target markets of U.S./EU/Japan, and pricing power. (We estimate 2%–3% annual price increases.)

(in \$000s except share count and EPS)	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028
EBITDA	(12,013)	(12,675)	(18,728)	12,337	2,139	29,712	19,814	59,649	112,765	168,871	217,006	245,469	250,892
Working Capital, Taxes and Other	(15,247)	(14,708)	(18,246)	10,222	6,860	31,903	31,909	84,967	152,052	220,134	275,324	305,082	248,364
Cash from Operations	(11,310)	(11,141)	(16,434)	30,773	14,990	18,087	17,028	38,782	76,448	118,049	155,458	180,064	187,929
Capex	103	(2,033)	(2,074)	(2,115)	(2,157)	(2,201)	(2,245)	(2,289)	(2,335)	(2,382)	(2,430)	(2,478)	(2,528)
Free Cash Flow (FCF)	(11,207)	(13,174)	(18,508)	28,657	12,832	15,886	14,783	36,492	74,113	115,667	153,028	177,586	185,401
Weighted Average Shares	22,363	24,779	29,412	33,955	34,150	37,430	39,299	41,261	43,321	45,485	47,756	50,141	52,646
FCF Per Share	(\$0.50)	(\$0.53)	(\$0.63)	\$0.84	\$0.38	\$0.42	\$0.38	\$0.88	\$1.71	\$2.54	\$3.20	\$3.54	\$3.52
Terminal Value													\$965,629
NPV Calculation													
Discount Rate	25%		_										
Terminal Growth Rate	1%			\$6	•								
Total NPV of FCF per share	\$ 2.65			φC	•								
Plus: PV of Terminal Value per share	\$ 3.40												
Price per share	\$ 6.04												

**DCF** Valuation Analysis

Source: Company reports and FBR Research

# Risks

**Commercial.** Prima BioMed is a development-stage biopharmaceutical firm that does not have a track record of successfully commercializing products. The company's long-term future hinges on its ability to bring IMP321 to market and possibly survive against competing companies with similar products.

**Clinical.** Drug development is an inherently risky business, requiring significant investment of both time and capital. However, the company has multiple drugs in its pipeline, each in multiple trials to treat different diseases. This effectively "lightens the load" on a drug candidate failing to obtain final approval since that drug may approved for another use and the company's other target could show greater success.

**Regulatory.** As IMP321 is being developed to treat life-threatening illnesses in their later stages, it may meet the requirements necessary for fast-track approval. The possibility of final approval is uncertain at this point as Prima has yet to accumulate a sufficient amount of clinical evidence.

**Competitive.** While Prima BioMed is focused on markets with high demand, there is abundant competition from other companies seeking to develop similar immunotherapy products. Immunotherapeutic agents for cancers other than the types that Prima BioMed is targeting may eventually become competitors. Many of these competing companies are also much larger and have greater financial resources for drug development and testing.

**Intellectual property.** IMP321, which became an internal asset with the acquisition of Immutep in 2014, is protected by multiple patent families that were either owned or licensed to Immutep. The latest of these patents expire in 2028. However, patent challenges could be successful in invalidating these patents and could significantly affect our valuation of the company.

**Financial.** PBMD is cash flow negative and, therefore, likely to require additional funding. We believe PBMD needs to raise cash in the capital markets before drug approval, which would dilute current shareholders and lower expected returns.

# Company Profile

Prima BioMed, Ltd. is an Australia-based global biopharmaceutical company with two Phase II clinical-stage cancer immunotherapeutic product candidates. The company's internal development pipeline is currently focused on IMP321, which is now in Phase I/II evaluation for metastatic breast cancer and metastatic melanoma. The company's ordinary shares are listed on the Australian Stock Exchange and the American Depository Receipts (ADRs) listed on the NASDAQ, at a ratio of 100 ordinary shares to 1 ADR.

# Annual Income Statement–Prima BioMed Ltd. (PBMD)

Fiscal year ends June 30					Jun-18	Jun-19	Jun-20	Jun-21	Jun-22	Jun-23	Jun-24	Jun-25	Jun-26	Jun-27	Jun-28
(in thousands AUD except share count and EPA*)	F2014A	F2015A	F2016A	F2017E	F2018E	F2019E	F2020E	F2021E	F2022E	F2023E	F2024E	F2025E	F2026E	F2027E	F2028E
Royalties	15.9	0.0	0.0	0.0	0.0	0.0	530.7	41,143.1	29,644.1	72,703.2	130,050.0	190,620.7	242,196.0	273,058.6	279,153.
Grant Income	2,004.2	1,335.5	1,589.8	1,621.6	1,750.0	2,000.0	2,000.0	2,000.0	2,000.0	2,000.0	2,000.0	2,000.0	2,000.0	2,000.0	2,000.
Gain (loss) on Foreign Exchange (F/X)	406.6	538.2	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.
Milestone, Licensing and Other Income	713.3	219.1	439.1	447.9	0.0	25,000.0	12,500.0	<u>0.0</u>	0.0	0.0	0.0	0.0	0.0	0.0	0.
Total Revenue	3,140.1	2,092.9	2,028.9	2,069.5	1,750.0	27,000.0	15,030.7	43,143.1	31,644.1	74,703.2	132,050.0	192,620.7	244,196.0	275,058.6	281,153.
Cost of Sales	0.0	0.0	0.0	0.0	0.0	0.0	37.1	2,880.0	2,075.1	5,089.2	9,103.5	13,343.4	16,953.7	19,114.1	19,540.
Gross Profit	3,140.1	2,092.9	2,028.9	2,069.5	1,750.0	27,000.0	14,993.5	40,263.1	29,569.1	69,614.0	122,946.5	179,277.2	227,242.3	255,944.5	261,612.
D&A	446.4	1.341.2	1.993.1	2.033.0	1,500.0	1,500.0	1,500.0	500.0	500.0	500.0	500.0	500.0	100.0	100.0	100.
R&D Expense	11.930.9	8.952.4	7.059.5	7,412.5	13,500.0	7,500.0	5,500.0	4.000.0	3.000.0	3.000.0	3.000.0	3.000.0	3.000.0	3.000.0	3.000.
SG&A Expense	4,092.6	5,723.1	6,982.6	7,331.8	7,551.7	7,778.3	8,011.6	8,252.0	8,499.5	8,754.5	9,017.1	9,287.7	9,566.3	9,853.3	10,148.
Operating Expenses	16,469.8	16,016.8	16,035.3	16,777.2	22,551.7	16,778.3	15,011.6	12,752.0	11,999.5	12,254.5	12,517.1	12,787.7	12,666.3	12,953.3	13,248.
Operating Profit (Loss)	(13,329.8)	(13,923.9)	(14,006.3)	(14,707.7)	(20,801.7)	10,221.7	(18.1)	27,511.1	17,569.5	57,359.5	110,429.4	166,489.6	214,576.0	242,991.2	248,363.
Finance Cost and Other	0.0	18.370.0	572.1	583.5	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.
Net Change in Fair Value of Financial Liability	0.0	0.0	(607.6)	(619.8)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.
Change in Fair Value of Derivatives	0.0	0.0	(49,154.3)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.
Pre-Tax Profit (Loss)	(13,329.8)	(32,293.9)	(63,196.2)	(14,671.5)	(20,801.7)	10,221.7	(18.1)	27,511.1	17,569.5	57,359.5	110,429.4	166,489.6	214,576.0	242,991.2	248,363.
Tax Benefit (Expense)	13.6	(142.2)	(1,181.0)	(1,204.6)	0.0	2,555.4	0.0	6,877.8	4,392.4	14,339.9	27,607.3	41,622.4	53,644.0	60,747.8	62,091.
Net Income before F/X	(13,343.4)	(32,151.7)	(62,015.2)	(13,466.8)	(20,801.7)	7,666.3	(18.1)	20,633.3	13,177.1	43,019.6	82,822.0	124,867.2	160,932.0	182,243.4	186,272.
F/X	(57.4)	(56.9)	307.0	313.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.
Net Income (Loss)	(13,400.8)	(32,208.6)	(61,708.2)	(13,153.7)	(20,801.7)	7,666.3	(18.1)	20,633.3	13,177.1	43,019.6	82,822.0	124,867.2	160,932.0	182,243.4	186,272.
EPA (*Earnings per ADR)	(1.10)	(2.02)	(2.76)	(0.53)	(0.71)	0.23	(0.00)	0.55	0.34	1.04	1.91	2.75	3.37	3.63	3.5
Weighted Average ADRs	12,201	15,911	22,363	24,779	29,412	33,955	34,150	37,430	39,299	41,261	43,321	45,485	47,756	50,141	52,64

Note: EPA (Earnings per ADR) for each period is adjusted for the AUD vs. USD spot exchange rates on June 30 and December 31.

Source: Company documents and FBR Research

# Semiannual Income Statement–Prima BioMed Ltd. (PBMD)

Fiscal year ends June 30		Dec-14	Jun-15		Dec-15	Jun-16		Dec-16	Jun-17	
(in thousands AUD except share count and EPA*)	F2014A	1H15A	2H15A	F2015A	1H16A	2H16A	F2016A	1H17E	2H17E	F2017E
Royalties	15.9	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Grant Income	2,004.2	1,169.9	165.6	1,335.5	1,264.7	325.2	1,589.8	1,290.0	331.7	1,621.6
Gain (loss) on Foreign Exchange (F/X)	406.6	624.5	(86.3)	538.2	0.0	0.0	0.0	0.0	0.0	0.0
Milestone, Licensing and Other Income	713.3	200.2	<u>18.9</u>	<u>219.1</u>	<u>164.7</u>	274.4	439.1	<u>168.0</u>	279.9	447.9
Total Revenue	3,140.1	1,994.7	98.2	2,092.9	1,429.3	599.6	2,028.9	1,457.9	611.6	2,069.5
Cost of Sales	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Gross Profit	3,140.1	1,994.7	98.2	2,092.9	1,429.3	599.6	2,028.9	1,457.9	611.6	2,069.5
D&A	446.4	216.7	1,124.6	1,341.2	1,026.4	966.7	1,993.1	1.046.9	986.1	2,033.0
R&D Expense	11,930.9	4,892.4	4,060.0	8,952.4	4,011.4	3,048.2	7,059.5	4,211.9	3,200.6	7,412.5
SG&A Expense	4,092.6	3,028.0	2,695.1	5,723.1	4,180.7	2,802.0	6,982.6	4,389.7	2,942.1	7,331.8
Operating Expenses	16,469.8	8,137.1	7,879.7	16,016.8	9,218.4	6,816.9	16,035.3	9,648.5	7,128.7	16,777.2
Operating Profit (Loss)	(13,329.8)	(6,142.4)	(7,781.5)	(13,923.9)	(7,789.1)	(6,217.2)	(14,006.3)	(8,190.6)	(6,517.1)	(14,707.7
Finance Cost and Other	0.0	204.6	18,165.4	18,370.0	505.9	66.2	572.1	516.0	67.5	583.5
Net Change in Fair Value of Financial Liability	0.0	54.1	(54.1)	0.0	(278.9)	(328.7)	(607.6)		(335.3)	(619.8
Change in Fair Value of Derivatives	0.0	0.0	0.0	0.0	(49,022.0)	(132.4)	(49,154.3)	0.0	0.0	0.0
Pre-Tax Profit (Loss)	(13,329.8)	(6,401.1)	(25,892.8)	(32,293.9)	(56,584.0)	(5,822.3)	(63,196.2)	(8,422.2)	(6,249.3)	(14,671.5
Tax Benefit (Expense)	13.6	0.0	(142.2)	(142.2)	(562.2)	(618.8)	(1,181.0)	(573.4)	(631.2)	(1,204.6
Net Income before F/X	(13,343.4)	(6,401.1)	(25,750.6)	(32,151.7)	(56,021.9)	(5,203.5)	(62,015.2)	(7,848.8)	(5,618.1)	(13,466.8
F/X	(57.4)	164.8	(221.7)	(56.9)	(269.0)	576.0	307.0	(274.4)	587.5	313.1
Net Income (Loss)	(13,400.8)	(6,236.3)	(25,972.3)	(32,208.6)	(56,290.9)	(4,627.5)	(61,708.2)	(8,123.1)	(5,030.5)	(13,153.7
EPA (*Earnings per ADR)	(1.10)	(0.50)	(1.52)	(2.02)	(2.87)	(0.22)	(2.76)	(0.36)	(0.21)	(0.53
Weighted Average ADRs	12,201	12,551	17,054	15,911	19,588	20,975	22,363	22,613	23,696	24,779

Source: Company documents and FBR Research

\*Closing price of last trading day immediately prior to the date of this publication unless otherwise indicated.

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Selling Covered Calls--Selling calls on long stock position. Risk is that the stock will be called away at strike, limiting investor profit to strike plus premium received.

Selling Uncovered Calls--Unlimited risk that investors may experience losses much greater than premium received.

Selling Uncovered Puts--Significant risk that investors will experience losses much greater than premium income received.

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Buying Calendar Spreads (different expiration months with short expiration earlier than long). Investors may lose the entire premium paid.

Selling Call or Put Vertical Spreads (Calls--short call and long call with higher strike; Puts--short put and long put with a lower strike, same expiration month for both options.) Investors risk the loss of the difference between the strike prices, reduced by the premium received.

Buying Straddle--Buying a put and a call with the same underlying strike and expiration. Investors risk loss of the entire premium paid.

Selling Straddle--Sale of call and put with the same underlying strike and expiration.) Unlimited risk that investors will experience losses much greater than the premium income received.

Buying Strangle--Long call and long put, both out of the money, with the same expiration and underlying security. Investors may lose the entire premium paid.

Selling Strangle--Short call and put, both out of the money, with the same expiration and underlying security. Unlimited risk of loss in excess premium collected.

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HOLD [Market Perform]	38.10%	17.76%
SELL [Underperform]	2.76%	0.00%

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