

Biotechnology

PBMD - NASDAQ November 3, 2017

Intraday Price 11/3/2017 **\$2.13**
 Rating: Buy
 12-Month Target Price: \$7.00
 52-Week Range: \$1.40 - \$3.26
 Market Cap (M): 50
 Shares O/S (M): 23.4
 Float: 0.0%
 Avg. Daily Volume (000): 137
 Debt (M): \$0.0
 Dividend: \$0.00
 Dividend Yield: 0.00%
 Risk Profile: Speculative
 Fiscal Year End: June

Total Expenses ('000)

	2017A	2018E	2019E
H1	3,716	6,437	6,759
H2	6,917	6,974	7,322
FY	10,633	13,411	14,081
Prior	8,716	12,362	12,981



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Prima Biomed Ltd.

Buy

IMP321 (LAG-3Ig): Heating up the T cell Response for Keytruda in Melanoma- New Data To Be Presented at SITC

Summary

- Prima Biomed reported FY17 (June) with revenue of \$3.2M and a net loss of \$7.1M, and updated its cash position as of Sept-30, reporting \$13M, which includes \$5M raised in July. We estimate there is sufficient runway into 2H18.
- New data from the ongoing P1 study of IMP321 + Keytruda in metastatic melanoma will be presented next week at SITC (Society for Immunotherapy of Cancer, Nov 9-12). The poster at SITC is titled: "Pushing the accelerator and releasing the break: Testing the soluble LAG-3 protein (IMP321), an antigen presenting cell activator, together with pembrolizumab in unresectable or metastatic melanoma." We expect that we will see data from the first two cohorts (N=12) and data from all three cohorts in 1H18.
- In melanoma, the majority of patients do not respond or have poor responses to checkpoint monotherapy. Several groups have demonstrated using DNA-based IL-12 turning cold tumors hot. However, IMP321 uses a different approach by acting as an activator of antigen presenting cells (APCs).
- APCs drive anti-tumor T cell production, thus IMP321 turns the immune system from cold to hot, driving more T cells for a checkpoint to take the breaks off of. Patients in the IMP321 study have had no response or poor responses to Keytruda immunotherapy.
- **Conclusion: While checkpoints have had success as monotherapies, the majority of patients are non-responders, thus the larger market opportunity has yet to be unlocked. We see LAG-3 as the next potential blockbuster checkpoint that could be used in combination with approved checkpoints. More data is coming at SITC.**

Details

IMP321 (Review/Update presented 10/31/17 at the World Immunotherapy Congress- [PRESENTATION LINK](#)): is Prima Biomed's lead LAG-3 candidate, and it is in development as an immune adjuvant or immune stimulator. IMP321 is a soluble dimeric recombinant form of LAG-3Ig, a fusion protein used to increase the immune response to tumors by stimulating dendritic cells through high affinity binding to MHC class II molecules on the dendritic cell surface. LAG-3 is one of two proteins shown to be able to properly condition dendritic cells (and monocytes) to undergo maturation and step up the stimulation of antigen targeting T cells (the other is CD40 ligand). What's important to note is that both LAG-3 and CD40 can do this without inflammation. IMP321 was developed by Dr. Frédéric Triebel in the late 1990s as a dendritic-cell activator. IMP321 has been shown to be highly efficacious as a vaccine adjuvant to inhibit tumor growth in a number of models of both cancer and infectious disease. The protein is safe and non-immunogenic, and has already shown efficacy in humans. When used at low doses, it can be used as a T-cell adjuvant for cancer vaccines. At higher doses, IMP321 can be combined with cancer chemotherapy to ramp up the immune response.

Large indications and the right partners. Novartis (NVS - \$83.43 - NR) has licensed IMP701 for development as a combination therapy with PD1 inhibitors in solid tumors. We believe that the ongoing phase I study will expand in its indications, taking a more aggressive timeline to approval. GlaxoSmithKline (GSK - \$36.08 - NR) is evaluating IMP731 in a phase I study in psoriasis (data are expected late 2017). Prima will receive single-digit royalties from each partnership. The lead in-house program, IMP321, an antigen-presenting cell (APC) activator that ramps up T-cell production following chemotherapy, already demonstrated POC in breast cancer and is currently in a phase IIb registration study. IMP321 could launch in 2020. A phase I study of an IMP321 combination with Keytruda in melanoma patients is also positive so far.

Income Statement (\$'000, USD)	July-Dec		Jan-Jun								
Prima Biomed LTD, I: YE June 30	1H-2017A	2H-2017A	2017A	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
Revenue (000's)											
Total Revenues	-	-	-	-	-	-	-	-	-	-	-
License revenue											
Miscellaneous income	173	443	616								
Grant Income	1,051	1,503	2,553								
Milestones and Royalties:											
IMP321 (Breast cancer)						11,767	28,427	46,857	68,917	87,027	96,059
IMP321 (Melanoma)						-	-	20,951	25,901	33,353	45,814
IMP731 (Psoriasis)				10,000	10,000	10,000	10,000	10,000	22,518	35,902	47,798
IMP701 (Solid tumors)				10,000	10,000	10,000	10,000	10,000	29,155	37,545	46,415
CVac					5,000	5,000	5,000	8,000	10,000	12,000	15,000
Total Revenues	1,224	1,945	3,169	20,000	25,000	36,767	53,427	95,808	156,491	205,827	251,085
Expenses											
Cost Of Goods Sold											
COGS % Sales											
Research & Development	2,086	3,499	5,585	5,864	6,157	6,465	6,788	7,128	7,484	7,858	8,251
R&D % Rev's											
General & Administrative Expense	1,630	1,717	3,347	7,547	7,924	8,321	8,737	9,173	9,632	10,114	10,619
SG&A %											
Depreciation and amortization		1,702	1,702								
Total expenses	3,716	6,917	10,633	13,411	14,081	14,785	15,525	16,301	17,116	17,972	18,870
Oper. Inc. (Loss)	(2,492)	(4,972)	(7,464)	6,589	10,919	21,981	37,902	79,507	139,375	187,855	232,215
Other income and expenses											
Interest income	49	31	80								
Loss on foreign exchange	(156)	490	333								
Finance cost											
Changes in fair value of comparability milestone											
Net Change in fair value of financial liability	(288)	(291)	(579)								
Loss on disposal of assets											
Exchange differences on the translation of foreign operations											
Total other income	(395)	521	(165)	-	-	-	-	-	-	-	-
Pre-tax income	(2,887)	(4,451)	(7,629)	6,589	10,919	21,981	37,902	79,507	139,375	187,855	232,215
Pretax Margin											
Taxes (or benefits)	425	313	738					3,975	13,937	28,178	41,799
Tax Rate								5%	10%	15%	18%
Exchange differences on the translation of foreign operations		209	209								
GAAP Net Income (loss)	(2,462)	(4,347)	(7,101)	6,589	10,919	21,981	37,902	75,531	125,437	159,677	190,416
Non GAAP Net Income (loss)	(2,462)	(4,347)	(7,101)	6,589	10,919	21,981	37,902	75,531	125,437	159,677	190,416
GAAP -EPS	(0.12)	(0.18)	(0.32)	0.26	0.41	0.77	1.25	2.49	4.13	5.24	6.24
Wgtd Avg Shrs (Bas) - '000s	20,637	23,585	22,111	25,120	26,672	28,475	30,284	30,345	30,405	30,466	30,527
Wgtd Avg Shrs (Dil) - '000s	20,637	23,585	22,111	25,120	26,672	28,475	30,284	30,345	30,405	30,466	30,527

Source: Company reports and Maxim

DISCLOSURES

Prima Biomed Ltd. Rating History as of 11/02/2017

powered by: BlueMatrix



Maxim Group LLC Ratings Distribution		As of: 11/02/17	
		% of Coverage Universe with Rating	% of Rating for which Firm Provided Banking Services in the Last 12 months
Buy	Fundamental metrics and/or identifiable catalysts exist such that we expect the stock to outperform its relevant index over the next 12 months.	80%	38%
Hold	Fundamental metrics are currently at, or approaching, industry averages. Therefore, we expect this stock to neither significantly outperform nor underperform its relevant index over the next 12 months.	17%	18%
Sell	Fundamental metrics and/or identifiable catalysts exist such that we expect the stock to underperform its relevant index over the next 12 months.	2%	25%

**See valuation section for company specific relevant indices*

I, Jason McCarthy, Ph.D., attest that the views expressed in this research report accurately reflect my personal views about the subject security and issuer. Furthermore, no part of my compensation was, is, or will be directly or indirectly related to the specific recommendation or views expressed in this research report.

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Maxim Group makes a market in Prima Biomed Ltd.

Maxim Group managed/co-managed/acted as placement agent for an offering of the securities for Prima Biomed Ltd. in the past 12 months.

Maxim Group received compensation for investment banking services from Prima Biomed Ltd. in the past 12 months.

Maxim Group expects to receive or intends to seek compensation for investment banking services from Prima Biomed Ltd. in the next 3 months.

PBMD: For Prima Biomed, we use the BTK (Biotechnology Index) as the relevant index.

Valuation Methods

PBMD: Our therapeutic model assumes a royalty structure for each LAG-3 product, initially with IMP701 and IMP321 in 2020 and followed by IMP731 in 2023. Our models assume risk adjustments for each product based on the stage(s) of development. Our therapeutic models assume a risk adjustment. We then apply a 30% discount to our free-cash-flow, discounted EPS, and sum-of-the-parts models, which are equally weighted to derive a price target.

Price Target and Investment Risks

PBMD: Aside from general market and other economic risks, risks particular to our price target and rating for Prima Biomed include: (1) Development—To date, LAG-3 checkpoint modulators have not been approved; (2) Regulatory—The company's ongoing and future studies may not be sufficient to gain approval; (3) Commercial—The company lacks commercial infrastructure to support a launch if approved; (4) Financial—The company is not yet profitable and may need to raise additional capital to fund operations.

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Risk ratings take into account both fundamental criteria and price volatility.

Speculative – Fundamental Criteria: This is a risk rating assigned to early-stage companies with minimal to no revenues, lack of earnings, balance sheet concerns, and/or a short operating history. Accordingly, fundamental risk is expected to be significantly above the industry. Price Volatility: Because of the inherent fundamental criteria of the companies falling within this risk category, the price volatility is expected to be significant with the possibility that the investment could eventually be worthless. Speculative stocks may not be suitable for a significant class of individual investors.

High – Fundamental Criteria: This is a risk rating assigned to companies having below-average revenue and earnings visibility, negative cash flow, and low market cap or public float. Accordingly, fundamental risk is expected to be above the industry. Price Volatility: The price volatility of companies falling within this category is expected to be above the industry. High-risk stocks may not be suitable for a significant class of individual investors.

Medium – Fundamental Criteria: This is a risk rating assigned to companies that may have average revenue and earnings visibility, positive cash flow, and is fairly liquid. Accordingly, both price volatility and fundamental risk are expected to approximate the industry average.

Low – Fundamental Criteria: This is a risk rating assigned to companies that may have above-average revenue and earnings visibility, positive cash flow, and is fairly liquid. Accordingly, both price volatility and fundamental risk are expected to be below the industry.

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