

COMPANY NOTE

Estimate Change

USA | Healthcare | Biotechnology

September 9, 2014

Jefferies

Immune Design (IMDZ) Q2 Earnings: CMB305 PI Trial Initiation On Track For Q1'15

Key Takeaway

With in-line Q2, we await the initiation of PIb trial of CMB305 in several types of solid tumors in Q1 2015. IMDZ plans to initiate the CMB305 PIb on assessing the topline data from G305 and LV305 PI studies expected in Q1 2015. Topline data from the G100 PI trial in MCC is expected in H1 2015.

CMB305 PI Trial Initiation In Q1 2015: CMB305, a combination therapy of NY-ESO-1 dendritic cell vaccine (LV305) and G305 a NY-ESO-1 protein fused TLR-4 agonist, will undergo evaluation in a PIb trial in solid tumors in Q1 2015 with preliminary data expected in H2 2015. Assuming positive data in PI, IMDZ plans to proceed to PII in NSCLC and synovial sarcoma. LV305 primes dendritic cells and has shown to eradicate lung tumors in a preclinical model. LV305 + immune booster G305 are synergistic and have shown to boost the number of tumor eradicating cytotoxic T cells in preclinical models. G305 and LV305 are currently undergoing PI evaluation in five solid tumors and IMDZ plans to initiate the CMB305 PIb on assessing the data observed from these studies. Topline data from PI studies of LV305 and G305 is expected in Q1 2015.

Topline data from G100 PI trial in MCC in H1 2015: In a preliminary PI analysis, G100, the TLR-4 agonist has shown encouraging efficacy with 20% ORR observed in 5 merkel cell carcinoma (MCC) pts. IMDZ plans to combine radiation therapy to G100 in the second phase of PI study to observe better response. The PI trial is enrolling 10 MCC pts with safety as EP and immunogenicity as secondary EP. Topline data from PI study is expected in H1 2015.

Q2 financials: IMDZ reported Q2 revenue of \$1.1M and GAAP EPS of (\$16.57) primarily on the company's pre-IPO share count. Cash and equivs were \$69.9M as of end of July 2014.

Valuation/Risks

Our \$15 PT is DCF-based. Risks to our thesis include clinical, regulatory and commercial risks.

USD	Prev.	2013A	Prev.	2014E	Prev.	2015E	Prev.	2016E
Rev. (MM)	--	1.6	0.8	1.5	--	2.0	--	2.0
EV/Rev		89.6x		95.6x		71.7x		71.7x
EPS								
Mar	--	--	(0.81)A	(22.25)A	--	--	--	--
Jun	--	--	(0.30)A	(16.57)A	--	--	--	--
Sep	--	--	--	(0.31)	--	--	--	--
Dec	--	--	--	(0.29)	--	--	--	--
FY Dec	--	(2.28)	(1.71)	(39.42)	--	(1.58)	--	(1.22)
FY P/E		NM		NM		NM		NM

BUY

Price target \$15.00

Price \$12.26

Financial Summary

Net Debt (MM):	(\$69.9)
Long-Term Debt (MM):	\$0.0
Cash & ST Invest. (MM):	\$69.9
Cash/Share:	\$4.01
Cash (MM):	\$69.9

Market Data

52 Week Range:	\$12.81 - \$11.51
Total Entprs. Value (MM):	\$143.4
Market Cap. (MM):	\$213.3
Shares Out. (MM):	17.4
Float (MM):	4.3
Avg. Daily Vol.:	NA

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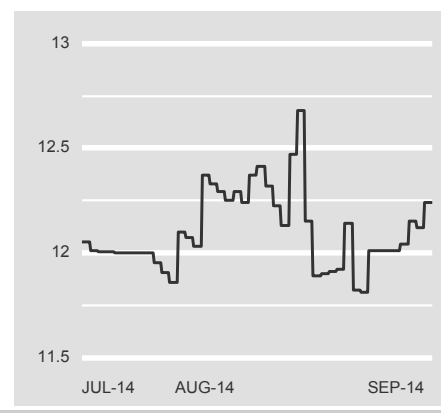
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Price Performance



Valuation

We arrive at our \$15 PT based on a DCF valuation model which assumes a WACC of 13%, patent expiry for CMB305 in 2032, and outstanding shares of 17.4 million. We estimate risk-adjusted peak U.S. CMB305 sales of \$360 million and risk-adjusted US G100 sales of \$30 million. We estimate US approval and launch of G100 and CMB305 in 2021 and 2022, respectively. We have not included EU sales of CMB305 or G100 or licensing royalties received from the infectious disease and allergy programs into our model and presents upside.

Exhibit 1: DCF sensitivity analysis

Disc Rate	Price/Share
9%	\$24.25
11%	\$19.05
13%	\$15.04
15%	\$11.95
0%	\$9.54

Source: Jefferies estimates

Risks

Clinical Failure: As with all companies in biotechnology that are investing in the development of preclinical/clinical programs, trial failures can lead to delays in projections for market entry or possibly discontinuation of programs.

Regulatory Failure: The FDA could determine the new drug application is inadequate for CMB305 and G100 and could delay approval. Any delays in approval timelines could impact our earnings estimates, price target, and/or rating.

Commercial Failure: We currently project U.S. sales of \$360 million (risk-adjusted) for CMB305 and \$30 million (risk-adjusted) for G100. Our estimates may rely on the success of the company/partners to receive drug reimbursement from private/public payors.

Financing Risks: We estimate IMDZ may need additional financing(s) in 2016-2017 to develop CMB305 and G100 and the pipeline and fund a potential U.S. launch of CMB305 and G100. The company may offset the need to raise additional capital by potentially licensing ex-U.S. rights to CMB305 and G100 and licensing royalties from infectious disease and allergy program. We currently have not modelled any potential upfront payments from a licensing collaboration.

Exhibit 2. Key IMDZ milestones

Product	Indication	Event	Date
G100	Merkel cell carcinoma	Preliminary efficacy data from PI trial	H2 2014
		Topline results for PI trial	H1 2015
		Topline PIII data	2020
		US regulatory filing and approval	2021
LV305	Solid tumors	Preliminary data from the PI trial in sarcoma, NSCLC, melanoma, ovarian and breast cancer	H2 2014
		Topline data from the PI trial	Q1 2015
G305	Solid tumors	Topline data from the PI trial in sarcoma, NSCLC, melanoma, ovarian, and breast cancer	Q1 2015
CMB305	Solid tumors	IND filing	H2 2014
		Initiation of Plb in sarcoma, NSCLC, melanoma and ovarian cancer	Q1 2015
		Preliminary efficacy data from Plb in solid tumors	2H 2015
		Topline data from the Plb in solid tumors	H1 2016
	NSCLC and synovial sarcoma	Initiation of PII trial	YE 2015/ early 2016
		Topline PIII data in 3rd/4th line NSCLC and synovial sarcoma	2021
		US regulatory filing and approval	2022

Source: Jefferies estimates, company data

Exhibit 3: IMDZ Income Statement

Immune Design

Quarterly Income Statement

(All values in \$MM except EPS and average shares)

	2012A	2013A	2014E					2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E
	FY	FY	1Q4	2Q4	3Q4	4Q4	FY	FY	FY	FY	FY	FY	FY	FY	FY	FY	FY	FY	FY
Revenue:																			
Product sales			0.0	0.1															
CMB305 - synovial sarcoma	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	10.3	211	32.6	33.6	37.0
CMB305 - NSCLC	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	13.5	85.1	19.3	156.6	181.0
G100 - MCC	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	12.1	14.8	17.7	19.9	212	22.6
License and collaboration revenues	3.0	1.6	0.0	1.0	0.3	0.3	1.5	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0
Total revenue, net	3.0	1.6	0.1	1.1	0.3	0.3	1.5	2.0	2.0	2.0	2.0	2.0	2.0	14.1	40.5	126.0	173.8	213.4	242.5
Costs and expenses:																			
Cost of goods sold	15	0.7	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	18	5.8	18.6	25.8	317	36.1
Research & development	8.6	116	4.1	3.9	4.2	3.9	16.1	26.8	25.0	25.0	19.3	20.3	20.9	215	22.1	22.8	23.5	24.0	24.4
Selling, general & administrative	3.7	4.4	1.4	1.9	1.4	1.4	5.6	2.6	2.8	3.0	3.3	3.4	3.6	13.7	14.1	14.6	15.0	15.4	15.9
Total operating expenses	13.8	16.7	5.5	5.8	5.6	5.3	21.7	29.4	27.8	28.0	22.6	23.7	24.5	37.0	42.1	56.0	64.3	71.1	76.4
Income (loss) from operations	(10.9)	(15.1)	(5.5)	(4.7)	(5.4)	(5.1)	(20.1)	(27.4)	(25.8)	(26.0)	(20.6)	(21.7)	(22.5)	(23.0)	(1.5)	70.0	109.5	142.3	166.1
Other income (expense):																			
Miscellaneous (expense) income	0.0	(10)	(2.7)	(14)	0.0	0.0	(4.2)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Interest income	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Interest expense	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net profit (loss) before income taxes	(10.8)	(16.0)	(8.2)	(6.1)	(5.4)	(5.1)	(20.1)	(27.4)	(25.8)	(26.0)	(20.6)	(21.7)	(22.5)	(23.0)	(1.5)	70.0	109.5	142.3	166.1
Income tax expense (benefit)			0.0	0.0	0.0	0.0	0.0			0.0	0.0	0.0	0.0	0.0	0.0	7.0	110	14.2	16.6
Income tax (%)										0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	10.0%	10.0%	10.0%	10.0%
Net Income (GAAP)	(10.8)	(16.0)	(8.2)	(6.1)	(5.4)	(5.1)	(20.1)	(27.4)	(25.8)	(26.0)	(20.6)	(21.7)	(22.5)	(23.0)	(1.5)	63.0	98.6	128.1	149.5
Adjusted Items (Non-GAAP)																			
Stock options	0.3	0.8	0.2	0.2	0.2	0.2	0.8	12	15	2.0	2.0	2.0	2.0	2.5	2.5	3.0	3.0	3.0	4.0
Depreciation and amortization expense	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net Income (Non-GAAP)	(10.5)	(15.2)	(8.0)	(5.9)	(5.2)	(4.9)	(19.3)	(26.2)	(24.3)	(24.0)	(18.6)	(19.7)	(20.5)	(20.5)	1.0	66.0	101.6	131.1	153.5
EPS, GAAP																			
Basic	(30.43)	(2.28)	(22.25)	(16.57)	(0.31)	(0.29)	(39.42)	(158)	(122)	(119)	(0.83)	(0.86)	(0.82)	(0.83)	(0.05)	2.22	3.44	4.42	5.11
Diluted	\$ (30.43)	\$ (2.28)	\$ (22.25)	\$ (16.57)	\$ (0.31)	\$ (0.29)	\$ (39.42)	\$ (158)	\$ (122)	\$ (119)	\$ (0.83)	\$ (0.86)	\$ (0.82)	\$ (0.82)	\$ (0.05)	\$ 2.16	\$ 3.31	\$ 4.21	\$ 4.82
Weighted average share- Basic	0.4	7.0	0.4	0.4	17.4	17.4	8.9	17.4	212	219	24.8	25.3	27.6	27.8	28.1	28.4	28.7	29.0	29.2
Weighted average share- Diluted	0.4	7.0	0.4	0.4	17.4	17.4	8.9	17.4	212	219	24.8	25.3	27.6	28.1	28.7	29.2	29.8	30.4	31.0

Source: Company data and Jefferies estimate

Source: Jefferies estimates, company data

Exhibit 4: IMDZ DCF analysis

Immune Design

Discounted Cash Flow Analysis

(All values in \$MM)	2012A	2013A	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E
Sales	3.0	1.6	1.5	2.0	2.0	2.0	2.0	2.0	2.0	14.1	40.5	126.0	173.8	213.4	242.5
Operating Expenses	13.8	16.7	21.7	29.4	27.8	28.0	22.6	23.7	24.5	37.0	42.1	56.0	64.3	71.1	76.4
EBIT	(10.9)	(15.1)	(20.1)	(27.4)	(25.8)	(26.0)	(20.6)	(21.7)	(22.5)	(23.0)	(1.5)	70.0	109.5	142.3	166.1
(-): Taxes	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	7.0	11.0	14.2	16.6
EBIAT	(10.9)	(15.1)	(20.1)	(27.4)	(25.8)	(26.0)	(20.6)	(21.7)	(22.5)	(23.0)	(1.5)	63.0	98.6	128.1	149.5
(+): Depreciation	0.5	0.4	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.0
(+): FAS-123 Options	0.3	0.8	0.8	1.2	1.5	2.0	2.0	2.0	2.0	2.5	2.5	3.0	3.0	3.0	4.0
(-): Capital expenditures	0.3	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.0
(-): Changes in working capital	1.9	0.2	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Unlevered free cash flow	(12.2)	(14.2)	(19.3)	(26.1)	(24.2)	(24.0)	(18.5)	(19.6)	(20.4)	(20.4)	1.1	66.1	101.6	131.2	153.5

Source: Jefferies estimates

Company Description

Immune Design Corp., a clinical-stage immunotherapy company, focuses on the development of novel immune-based therapies based on its DCVex and GLAAS discovery platforms for cancer and other chronic conditions. Its product candidates in Phase I clinical trials comprise LV305, CMB305, and G305 for the treatment of solid tumor types, such as breast cancer, melanoma, non-small cell lung cancer, ovarian cancer, or sarcoma; and G100 for the treatment of patients with merkel cell carcinoma. The company was founded in 2008 and is headquartered in Seattle, Washington.

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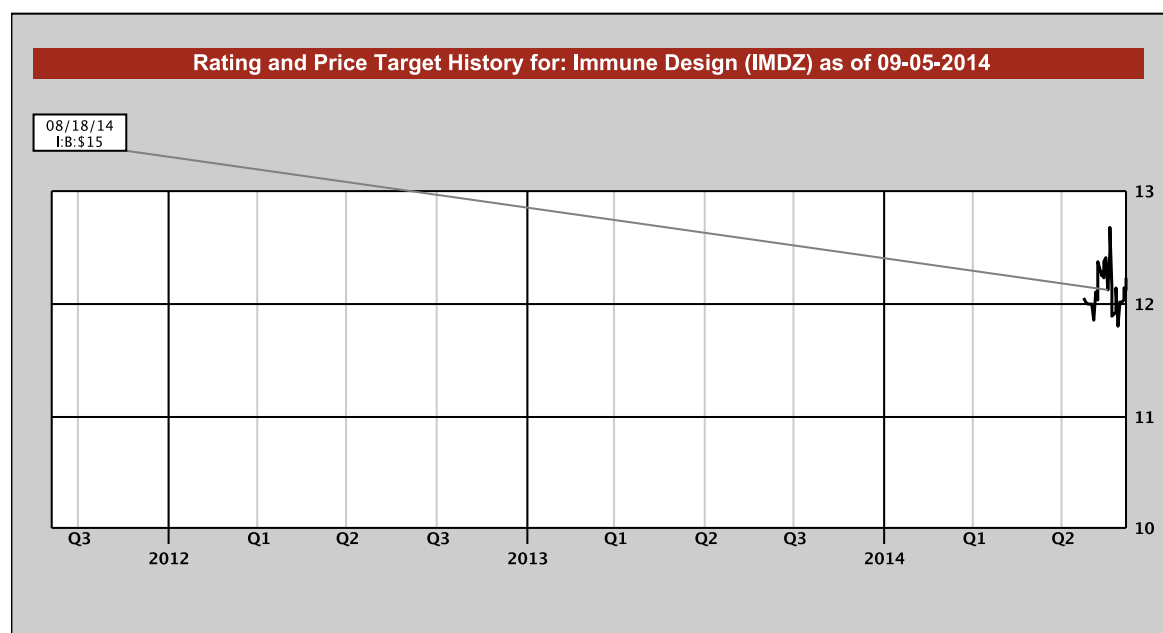
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