May 15, 2015

**OUTPERFORM** 

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Reason for report: **EARNINGS** 

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(NASDAQ:IMDZ)

#### IMMUNE DESIGN CORP.

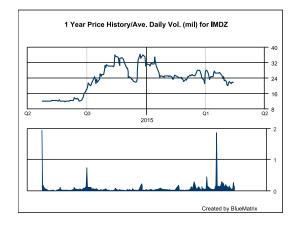
Complementary Immune Activation Supports Combo Approach; Sets Up 2H Catalysts

- Bottom Line: On its 1Q:15 earnings call yesterday, and in an additional press release subsequent to the publication of the ASCO abstracts on Wednesday (5/13), IMDZ reported detailed results from its three Phase I studies of LV305 (ZVex-NY-ESO-1 RNA; CD8+ T-cell activator), G305 (GLAAS + NY-ESO-1 protein; CD4+ T-cell activator), and G100 (intratumoral GLA monotherapy). We believe the immunological characterization provided yesterday for G305 and LV305 provided clear evidence of de-novo immune activation against the intended target NY-ESO-1 in a majority of patients, particularly at the higher dose levels as well as the complementary immune responses generated by IMDZ' two product platforms (dendritic cell targeting lentivirus and GLA adjuvant). We believe these new data provide mechanistic validation of IMDZ's combination approach with CMB305. We are encouraged by the additional data released yesterday and expect full details on immunological parameters at the upcoming ASCO presentations. We reiterate our OP rating with a price target of \$40.
- G305 induced NY-ESO-1-specific CD4+ T-cell and antibody immune responses. G305, a combination of purified NY-ESO-1 protein and a GLAAS TLR agonist, induced CD4+ T-cell responses in 5/11 evaluable patients, 4 of which were de-novo. Among the two higher dose groups, G305 induced CD4+ T-cells in a majority (5/8) of patients. An additional 4 patients had prior CD4+ T-cells reactive against NY-ESO-1, which were sustained upon G305 treatment. G305 also induced antibody responses against NY-ESO-1 in 9/12 evaluable patients, 3 of which were de-novo. 2 additional patients had pre-existing antibodies against NY-ESO-1 which were sustained after G305 treatment. Surprisingly, 2 out of 10 evaluable patients also saw de-novo induction of target-specific CD8 Tcells. Together, these data were clear evidence to us that G305 induced CD4+ T-cells against the intended target, and the observation of CD8+ T-cell induction was a welcome upside surprise in immunological activity. Management noted that 8/12 patients had stable disease as their best response, 4 of which remained ongoing.
- LV305 induced broad target-specific T-cell responses. In 11 evaluable patients each, LV305 (dendritic cell-targeting lentivirus carrying NY-ESO-1 RNA payload) induced strong target-specific CD4+ and CD8+ T-cell responses in 5 and 6 out of 11 patients, respectively. Among the two highest dose cohorts, CD8+ T-cell responses (the effect intended) were induced in 4 out of 5 evaluable patients, all of which were de-novo. In our view, this result provides strong validation of LV305's ability to induce NY-ESO-1-specific T-cell immunity and IMDZ's dendritic cell-targeting lentivirus platform as a whole. Of note, no antibody responses against NY-ESO-1 were induced, as expected.

S&P 600 Health	1,626.23			
Price:		\$21.29		
Price Target:		\$40.00		
Methodology:				
	DCF analysis and proba	ability-weighted sales		
52 Week High:		\$40.13		

**Key Stats:** 

	00.00
52 Week High:	\$40.13
52 Week Low:	\$11.51
Shares Outstanding (mil):	19.2
Market Capitalization (mil):	\$408.8
Cash Per Share:	\$6.74
Dividend (ann):	\$0.00
Dividend Yield:	0.0%



Dec Yr	1Q	2Q	3Q	4Q	FY Rev	1Q	2Q	3Q	4Q	FY EPS	P/E
2014A	0.0	\$1.1	\$3.5	\$1.8	\$6.4	(\$22.25)	(\$16.57)	(\$0.55)	(\$0.78)	(\$4.56)	NM
2015E - New	\$1.9A	\$1.6	\$1.6	\$1.6	\$6.8	(\$0.56)A	(\$0.57)	(\$0.57)	(\$0.56)	(\$2.20)	NM
2015E - Old	\$1.6	\$1.6	\$1.6	\$1.6	\$6.4	(\$0.75)	(\$0.75)	(\$0.74)	(\$0.74)	(\$2.91)	NM
2016E - New					\$6.8	İ				(\$2.86)	NM
2016E - Old					\$6.4	j				(\$3.70)	NM

Source: Company Information and Leerink Partners LLC Research

Revenues in millions. Quarterly EPS may not total to annual figure due to change in shares outstanding.



#### **INVESTMENT THESIS**

We rate IMDZ Outperform. IMDZ is a clinical-stage biotechnology company focused on immunotherapies for cancer and has two proprietary platforms, ZVex and GLAAS, for activating essential cells of the immune system to enable recognition and elimination of cancer cells. Immune activation and cytotoxic T cell generation likely will have a role in future immunotherapy for cancer. Immuno-oncology is emerging as a new pillar of cancer treatment due to the potential for durable response and functional cure. Despite the remarkable success of checkpoint inhibitors such as PD-1/PDL1 antibodies, currently only a minority of unselected patients with a few types of tumors achieve an objective response. Both the proportion of patients (about half) without tumorinfiltrating lymphocytes (TILs) as well as the adaptive tumor immune escape mechanism of PDL1 expression in response to TILs argue for the need for immune activation to generate tumorspecific cytotoxic T cells. Based on preclinical data, MEDACorp key opinion leaders (KOLs) believe vaccines are among the most important combinations to pursue for checkpoint inhibitors. IMDZ has developed a novel approach for activating immune cells against specific and endogenous tumor antigens. Issues of historical cancer vaccines included limited CD8+ T cell engagement and T cell sequestration associated with ex vivo peptide loading and mineral oil carriers. IMDZ's novel technology of in vivo targeting of antigens specifically to dendritic cells may overcome these limitations. In addition, the second platform, GLAAS, can further strengthen the response via the activation of CD4+ T cells and provide an opportunity for a unique combination. MEDACorp key opinion leaders (KOLs) see IMDZ as one of the strongest early-stage immunooncology companies. We received excellent feedback from KOLs on the ZVex platform and preclinical data, GLAAS as a potent adjuvant, as well as the creditability and credentials of the management. There were some questions about NY-ESO-1 as a target, but overall KOLs were enthusiastic about the story. In light of the potential upside in the platforms being applied broadly to other cancer antigens as well as established partnerships with AZN and SNY in infectious diseases and food allergy, we see the valuation of IMDZ as inexpensive in comparison to other IO stories. Clinical data starting in 1Q:15 and continuing throughout 2015 could provide near-term catalysts.

**LV305** induced broad target-specific T-cell responses. Management also indicated that although it does not yet have data to share on the magnitude of pre-existing or acquired antivector immunity, it is actively collecting these datapoints, and we look to a further data update at ASCO with great interest. While no tumor regressions were expected from LV305 monotherapy, IMDZ noted that 67% (8/12) patients achieved a best response of stable disease (SD). The progression-free rate was 67% at 3 months and 42% at 6 months, and these appear to compare favorably to 21% and 8%, respectively, for inactive agents based on a meta analysis cited by IMDZ, although there are obvious caveats for such a comparison.

**G100** demonstrates good evidence of activity in Merkel Cell Carcinoma. Eight patients have been enrolled on study thus far, and G100 continued to show good safety with only grade 1 or 2 AEs observed. In addition to the previously reported pathological complete response in one



patient with locoregional disease, IMDZ' slide deck noted that 50% (4/8) of patients experienced an objective response after G100 treatment followed by radiation and/or surgery. Management reiterated its plans for initiating a trial of G100 in combination with radiation therapy in NHL.

**Model update:** IMDZ reported 1Q revenues of \$1.9M, operating expenses of (\$11.3M) and EPS of (\$0.56), respectively. Cash and cash equivalents at quarter-end were \$60.2M. The company also announced having raised net proceeds of \$74.2M in its secondary stock offering in mid-April, for total cash and cash equivalents of \$134.4M at quarter-end on a pro-forma basis. Management had previously guided to FY2015 net use of cash in operating activities of \$33-37M, expecting to end the year with \$38-42M in cash and cash equivalents, which it believed to be sufficient to fund operations into 2017. We have updated our model to account for these changes.

#### Immunological Activities of G305 and LV305

## G305 Phase 1 Immunogenicity: Broad Ab/CD4 T cell Response

		Antibo	dy (9/12)	CD4 T	cell (5/11)	CD8 T	cell (2/10)	Clinical	
	Patient	Pre	Response	Pre	Response	Pre	Response	Follow Up*	
	1	+	=	+	=	-	-	162	
Cohort 1	2	+	++	+	=	-	-	305	
2 μg x 3	3	+	++	N/E	N/E	N/E	N/E	355+	
Cohort 2	4	+	++	+	++	-	++	161	
Conort 2 5 μg x 3	5	-	++	-	-	-	-	299+	
- 1.0	6	-	++	-	++	-	-	70	
	7	-	-	-	-	-	-	62	
Cohort 3 10 µg x 3	8	-	++	-	++	-	-	70	
το με λο	9	+	++	+	=	N/E	N/E	70	
	10	+	++	-	++	-	++	191	
	11	+	++	-	++	-	-	211+	
	12	+	=	+	= /	+	=	216+	

<sup>+ +</sup> Ab: 4-fold rise or newly positive, =: High pre, no boost, N/E: not evaluable; + + T cell: Elispot >50 spots & >2-fold rise, ICS >2-fold rise; \* A '+' indicates stable disease as of 7 April 2015



### LV305 Phase1 Immunogenicity: Broad T-cell Responses

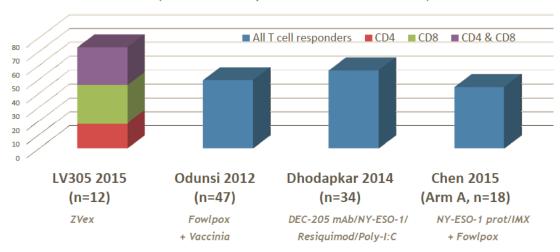
		Antibody (0/12)		CD4 T	cell (5/11)	CD8 T	cell (6/11)	Clinical
	Patient	Pre	Response	Pre	Response	Pre	Response	Follow Up**
	1	+	=	+	++	+	++	312+
Cohort 1 10 <sup>8</sup> vg x 3	2*	+	=	-	++	-	++	291+
10 Vg X 3	3*	-	-	-	-	-	-	61
5 1 1 1 1 1	4*	+	=	-	++	-	-	231+
Cohort 1A 10 <sup>8</sup> vg x 4	5	+	=	+	++	-	-	215+
20 Vg X 1	6	-	-	-	-	-	-	27
Cohort 2	7	-	-	-	-	-	++	140
10 <sup>9</sup> vg x 4	8	+	=	-	-	-	++	179+
_	9	+	=	N/E	N/E	N/E	N/E	168+
Cohort 3 10 <sup>10</sup> vg x 4	10	-	-	-	++	] -	++	139+
	<b>11</b>	+	=	-	-	-	-	134+
'6'''	12	•	-	-	-		++	134+

++ Ab: 4-fold rise or newly positive, =: High pre, no boost, N/E: not evaluable; ++ T cell: Elispot >50 spots & >2-fold rise, ICS >2-fold rise; \* Pre-existing T cells by in-house Elispot. \*\* A '+' indicates stable disease as of 7 April 2015



## Comparison of LV305-induced NY-ESO-1 T-cell Responses with Published Studies

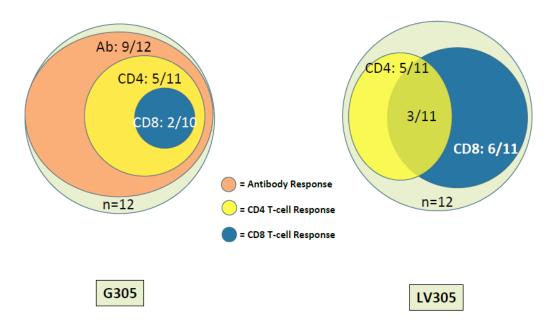
NY-ESO-1-specific T-cell responses (CD4 and CD8, ELISPOT/ICS/Tetramer)



Odunsi, et al (2012) Efficacy of vaccination with vaccinia and fowlpox vectors expressing NY-ESO-1, PNAS 109:5797 Dhodapkar, et al (2014) Immunity with a Vaccine Targeting NY-ESO-1 to DEC-205, Sci Transl Med 6:232ra51 Chen, et al (2015) Immune responses with NY-ESO-1 in ISCOMATRIX and NY-ESO-1 fowlpox, Int J Cancer 136:E590



# NY-ESO-1 Immunogenicity Biomarker differs by drug treatment



Source: IMDZ



#### **IMDZ Upcoming Catalysts**

Drug	Timing	Description
C100 (CLA)	5/30/2015	Data from Phase I Merkel cell carcinoma trial (n=10)
<b>G100</b> (GLA)	5/30/2015	presented at ASCO
	2015	Initiate Phase I trial in combo w/radiation in NHL (n=30)
	2015	IST in combo w/radiation in Sarcoma (n=12) continues
<b>G305</b> (GLAAS + NY-ESO1 protein)	5/30/2015	Data from dose escalation (n=12) presented at ASCO
LV305 (Zvex + NY-ESO1 RNA)	5/30/2015	Data from dose-escalation (n=12) presented at ASCO
	2015	Continue enrolling Phase I Expansion (n=32)
	2H:15	Data from expansion (n=32)
+ anti-PD-1	2015	Initiate Phase I in PD-1 NR melanoma (n=20)
CMB305 (LV305 + G305)	2015	Continue to enroll Phase I Dose-escalation (n=6 to 12)
	2015	Initiate Phase I Expansion (n=32)
	2H:15	Data from dose-escalation
	2H:15	Initial data from expansion
	2H:15	Initiate Randomized Phase II
+ checkpoint inhibitor	2H:15	Initiate Randomized Phase II in high incidence tumors
	2H:15	Initiate Randomized Phase II in sarcoma

Source: Company Reports and Leerink Partners

#### **IMDZ** Pipeline

Store of Development	Commant Status / Unacusing David annuants
Stage of Development	Current Status/Upcoming Developments
<b>G100</b> (GLA)	
Phase I	Data from Phase I MCC trial (n=10) to be presented at ASCO
G305 (GLAAS + NY-ESO1 protein)	
Phase I	Data from Phase I dose escalation (n=12) to be presented at ASCO
LV305 (Zvex + NY-ESO1 RNA)	
Phase I	Data from Phase I dose escalation (n=12) to be presented at ASCO
CMB305 (LV305 + G305)	
Preclinical	Phase I Dose-escalation ongoing

Source: Company Reports and Leerink Partners



#### **VALUATION**

Our price target is \$40 a share based on a DCF analysis and probability-weighted sales for G100 in Merkel cell carcinoma and low-grade non-Hodgkin's lymphoma (10-30% probability), and for CMB305 in synovial sarcoma (20% probability), melanoma (10% probability), NSCLC (15% probability), and ovarian cancer (10% probability) with a 10% discount rate. We believe this discount rate is appropriate as we use probability-weighted sales for the products. In addition, we also assigned \$100M (increased from \$50M due to recent expansions of collaborations) to partnered programs but no value for potential products beyond NY-ESO-1.

#### **RISKS TO VALUATION**

- Early stage of development with uncertainties in efficacy and safety;
- Unknown future landscape in immunotherapy for cancer;
- Initial target (NY-ESO-1) remains to be validated;
- Ability to scale up and manufacture lentivirus as a product;
- Lack of manufacturing capability and reliance on third-party manufacturers;
- Competition from immunotherapeutic approaches.

Immune Design													
(In '000s, except per share items)													
	0040	0040	20444					00455	22425	00475	22425	00105	22225
	2012	2013	2014A	1QA	2QE	3QE	4QE	2015E	2016E	2017E	2018E	2019E	2020E
REVENUE:				IQA	242	JQL	746						
LV305 (POS adjusted sales)	_	_	0	_	_	_	_	_	_	_	_	3,165	23,577
CMB305 (POS adjusted sales)	_	_	_ `	_	_	_	_	_	-	_	_	-	13,468
G100 (POS adjusted sales)	_	_	_	_	_	_	_	_	_	_	11,723	22,628	25,923
Other Product Sales	1,877	870	881	89	220	220	220	750	750	750	750	750	750
Product Development and Licensing Agreements	876	729	4,500	-	1.125	1,125	1.125	3,375	3.375	3.375	3,375	3,375	3,375
Contracts and Grants			,		.,	.,	.,	-,	-,	-,	-	-,	
Product Royalties			_					_	_	_	_		_
Milestone payments			_					_	_	_	_	_	_
Other, net	207		1,052	1,849	263	263	263	2,638	2,638	2,638	2,638	2,638	2,638
Total Revenue	2.960	1,599	6,433	1.938	1.608	1.608	1.608	6,763	6,763	6.763	18,486	29,391	46,154
	_,,,,,	1,000	2,122	1,000	1,000	1,000	1,000				10,100		,
OPERATING EXPENSES:													
Cost of product Sales	1,518	669	638	79							3,697	5,878	9,231
Research and Development	8,604	11,554	22,746	7,463	7,500	7,538	7,576	30,077	42,107	63,161	82,109	86,215	90,52
Sales General and Adminstrative	3,713	4,433	12,927	3,802	3,821	3,840	3,859	15,322	15,629	55,629	89,006	121,048	133,153
Royalties	-												
Amortization of Acquired Intangible Assets	40.005	40.050	00.044	44.044	44.004	44.070	44 405	45.000	F7 700	440.700	474.040	040.444	000.000
Total Operating Expense	13,835	16,656	36,311	11,344	11,321	11,378	11,435	45,399	57,736	118,790	174,813	213,141	232,909
Operating Loss	(10,875)	(15,057)	(29,878)	(9,406)	(9,713)	(9,770)	(9,827)	(38,715)	(50,973)	(112,027)	(156,327)	(183,751)	(186,756
Investment, Interest and Other Income, Net	35	37	4	0									
Change in fair value of convertible preferred stock wa	,	(955)	(4,277)	0 (0.400)	(0.740)	(0.770)	(0.007)	(00.745)	(50.070)	(440.007)	(450.007)	(400 754)	(400 75)
Net Income before Taxes	(10,840)	(15,975)	(34,151)	(9,406)	(9,713)	(9,770)	(9,827)	(38,715)	(50,973)	(112,027)	(156,327)	(183,751)	(186,756
Income tax rate% Income Tax													
Net Loss	(10,840)	(15,975)	(34,151)	(9,406)	(9,713)	(9,770)	(9,827)	(38,715)	(50,973)	(112,027)	(156,327)	(183,751)	(186,756
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Earnings per share		(43.48)	(4.56)	(0.56)	(0.57)	(0.57)	(0.56)	(2.20)	(2.86)	(3.74)	(3.70)	(3.49)	(3.51
Shares Used in Calculating Basic and Diluted Net		367	7,495	16,945	17,114	17,285	17,458	17,633	17,809	161,987	307,607	430,683	434,990
Loss per Share (actual)		001	.,.50	. 5,5 . 5	,	,200	,	,550	,000	,	00.,001	,	.5 .,500
. ,													
Shares Used in Calculating Basic and Diluted Net		7.008	7.495	16.945	17.114	17.285	17.458	17.633	17.809	29.987	42.287	52.710	53.23
. ,		7,008 7,008	7,495 9,402	16,945 18,974	17,114 19,163	17,285 19,355	17,458 19,548	17,633 19,744	17,809 19,941	29,987 20,141	42,287 32,342	52,710 42,666	53,237 43,092



### Disclosures Appendix Analyst Certification

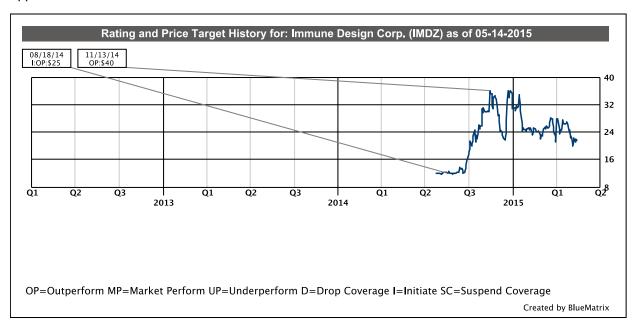
I, Howard Liang, Ph.D., certify that the views expressed in this report accurately reflect my views and that no part of my compensation was, is, or will be directly related to the specific recommendation or views contained in this report.

#### **Valuation**

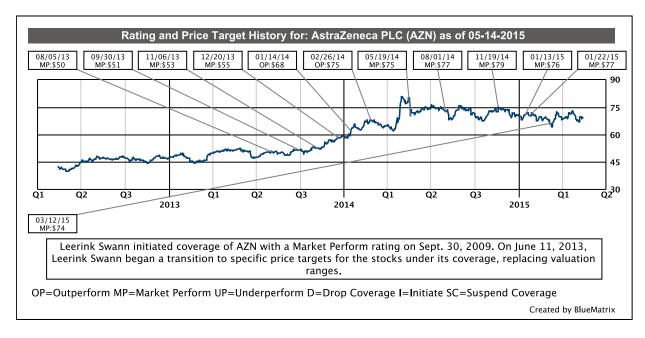
Our price target is \$40 a share based on a DCF analysis and probability-weighted sales for G100 in Merkel cell carcinoma and low-grade non-Hodgkin's lymphoma (10-30% probability), and for CMB305 in synovial sarcoma (20% probability), melanoma (10% probability), NSCLC (15% probability), and ovarian cancer (10% probability) with a 10% discount rate. We believe this discount rate is appropriate as we use probability-weighted sales for the products. In addition, we also assigned \$100M (increased from \$50M due to recent expansions of collaborations) to partnered programs but no value for potential products beyond NY-ESO-1.

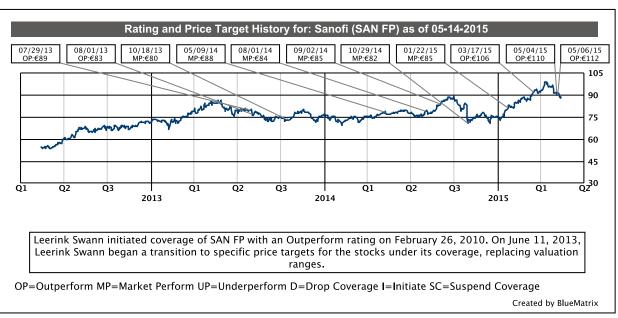
#### Risks to Valuation

Early stage of development with uncertainties in efficacy and safety; Unknown future landscape in immunotherapy for cancer; Initial target (NY-ESO-1) remains to be validated; Ability to scale up and manufacture lentivirus as a product; Lack of manufacturing capability and reliance on third-party manufacturers; Competition from immunotherapeutic approaches.











	Distribution of Ratings/Investment Bank	ing Services (I	,	erv./Past 12 Mos.
Rating	Count	Percent	Count	Percent
BUY [OP]	151	70.20	55	36.00
HOLD [MP]	64	29.80	2	3.00
SELL [UP]	0	0.00	0	0.00

#### **Explanation of Ratings**

Outperform (Buy): We expect this stock to outperform its benchmark over the next 12 months.

<u>Market Perform (Hold/Neutral):</u> We expect this stock to perform in line with its benchmark over the next 12 months.

<u>Underperform (Sell):</u> We expect this stock to underperform its benchmark over the next 12 months. The degree of outperformance or underperformance required to warrant an Outperform or an Underperform rating should be commensurate with the risk profile of the company.

For the purposes of these definitions the relevant benchmark will be the S&P 600® Health Care Index for issuers with a market capitalization of less than \$2 billion and the S&P 500® Health Care Index for issuers with a market capitalization over \$2 billion.



#### **Important Disclosures**

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In the past 12 months, the Firm has received compensation for providing investment banking services to Immune Design Corp. .

Leerink Partners LLC makes a market in Immune Design Corp.

Leerink Partners LLC is willing to sell to, or buy from, clients the common stock of AstraZeneca PLC and Sanofi on a principal basis.

Leerink Partners LLC has acted as the manager for a public offering of Immune Design Corp. in the past 12 months.

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