

Equity Research

Immune Design Corp.

IMDZ: We Are Initiating Coverage With An Outperform Rating

Outperform / V

Sector: Biotechnology

Market Weight

Initiation of Coverage

• **Summary:** We are initiating coverage of Immune Design with an Outperform rating and a \$17-18 valuation range. We believe IMDZ's differentiated platform has strong scientific merit for the treatment of cancers and believe shares will appreciate over time as the company's early-stage programs progress and potentially show activity. We see IMDZ as an attractive company that can become an important player longer term in the emerging immuno-oncology space. Our valuation range is based on a blend of discounted out-year EPS and sales multiples adjusted for probabilities of success in various solid tumor types. We estimate 2014E/2015E EPS of -\$2.24/- \$1.61

• **We believe IMDZ's immune-targeted platforms have strong scientific rationale and differentiated features.** The company's "ZVex" technology utilizes gene therapy specifically targeted to dendritic cells, in order to generate cytotoxic T-lymphocytes against specific tumor antigens. We believe both preclinical models testing ZVex, as well as early clinical data from other approaches such as CAR-T, demonstrate the clear promise of using activated T-cells to fight cancer. IMDZ's platform may also have some differentiating advantages, including more physiologic immune up-regulation, potential generation of immune memory capable of keeping cancers at bay, and utilization of GLA (through IMDZ's GLAAS platform) to further enhance immune responses.

• **Based on this scientific foundation, we see a good probability that IMDZ's clinical candidates will show immune activation and antitumor effects in humans.** IMDZ is currently exploring LV305 (lentivirus) and G305 (TLR4 agonist) to generate immune responses against the tumor antigen NY-ESO-1, with initial ph. I safety and immunogenicity data in Q1 2015; management plans to combine the two in a "prime boost" strategy (CMB305) later this year. Though exact measures of immune activity may be difficult to benchmark, we expect, based on the science and preclinical evidence, that the study will likely show signals of antigen-specific immune response that would speak to the technology's potential in cancer. We also believe that NY-ESO-1 as the initial target to study makes sense given its likely safety and good validation.

• **We see broad applicability for IMDZ's technology across multiple cancer types, with a large future market opportunity.** We agree with IMDZ's strategy of moving its programs forward in rare cancers, soft tissue sarcomas, which have high NY-ESO-1 expression and could enable a more rapid approval path, as well as 1-2 more common cancers like NSCLC and/or ovarian cancer, which could provide greater long-term revenue opportunity. We believe \$1.3B in worldwide sales of CMB305 could be achievable upon success in those solid tumors by 2023 and note that demonstration of efficacy in other cancer types, or utilization of the ZVex technology against other tumor antigens, could further increase the long-term revenue potential for IMDZ.

Valuation Range: \$17.00 to \$18.00 from NE to NE

Our valuation is based on a blend of 30x of probability-adjusted 2023E EPS and 5x of 2023E probability-adjusted sales. Risks include ZVex's failure to show clinical efficacy, a safety signal, competition, and manufacturing.

Investment Thesis:

We believe IMDZ is undervalued based on the promise of ZVex/GLAAS as novel immunotherapy platforms for cancers.

Please see page 7 for rating definitions, important disclosures and required analyst certifications

All estimates/forecasts are as of 08/18/14 unless otherwise stated.

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	2013A	2014E	2015E		
EPS		Curr.	Prior	Curr.	Prior
Q1 (Mar.)	NE	(\$0.81) A	NC	NE	NE
Q2 (June)	NE	(0.60)	NE	NE	NE
Q3 (Sep.)	NE	(0.52)	NE	NE	NE
Q4 (Dec.)	NE	(0.40)	NE	NE	NE
FY	(\$2.28)	(\$2.24)	NE	(\$1.61)	NE
CY	(\$2.28)	(\$2.24)		(\$1.61)	
FY P/EPS	NM	NM		NM	
Rev.(MM)	\$2	\$0		\$0	

Source: Company Data, Wells Fargo Securities, LLC estimates, and Reuters
NA = Not Available, NC = No Change, NE = No Estimate, NM = Not Meaningful
V = Volatile, * = Company is on the Priority Stock List

Sum of quarterly EPS may not equal annual EPS due to the shares (basic vs. diluted) we use to calculate EPS

Ticker	IMDZ
Price (08/15/2014)	\$12.41
52-Week Range:	\$11-13
Shares Outstanding: (MM)	15.8
Market Cap.: (MM)	\$196.1
S&P 500:	1,955.06
Avg. Daily Vol.:	148,982
Dividend/Yield:	\$0.00/0.0%
LT Debt: (MM)	\$0.0
LT Debt/Total Cap.:	0.0%
ROE:	NM
3-5 Yr. Est. Growth Rate:	5.0%
CY 2014 Est. P/EPS-to-Growth:	NM
Last Reporting Date:	06/23/2014

Source: Company Data, Wells Fargo Securities, LLC estimates, and Reuters

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Together we'll go far



Company Description:

Immune Design Corporation (IMDZ) is a clinical stage biopharmaceutical company, headquartered in San Francisco, California and Seattle, Washington, developing novel immunotherapies for cancer and infectious diseases. IMDZ is developing an in vivo targeting approach to specifically target key regulatory immune cells called dendritic cells to enable the body's own immune system to fight cancer and other diseases. IMDZ's technology platform consists of two main components, IMDZVex ("ZVex") and GLAAS. ZVex is a virus-based cell targeting vector that specifically delivers tumor (or other immunogen) antigen of interest to DCs such that robust induction of cytotoxic T-cells in effect fights the disease. There are several pipeline products under clinical development: LV305 (ZVex-NY-ESO-1) and G305 (GLAAS-NY-ESO-1) in phase I study for solid tumors, CMB305 (ZVex-NY-ESO-1 plus GLAAS) expected to enter the clinic end-2014, and G100 (GLAAS) in phase I study in Merkel cell carcinoma.

For more details, please see our full-length report, to be published shortly.

Investment Thesis

We are initiating coverage of IMDZ with an Outperform rating and a \$17-18 valuation range. We believe Immune Design's differentiated immunotherapy platform has strong scientific merit for the treatment of cancers, and we expect shares to appreciate over time as the early-stage programs progress in the clinic and potentially demonstrate activity. We see Immune Design as an attractive idea in the emerging immuno-oncology space.

We believe IMDZ's immune-targeted ZVex and GLAAS platforms have strong scientific rationale and differentiated features. ZVex utilizes gene therapy specifically targeted to dendritic cells in order to generate cytotoxic T-lymphocytes (CTLs), which are designed to then attack tumor cells expressing the antigen of interest. Tumor antigens are any antigens that are expressed in greater amounts in tumors compared to normal tissues, and which can be targets for immune recognition of cancer. Though Immune Design's technology has not yet been proven effective in humans, we believe other companies' CAR-T platforms, which have shown good initial clinical responses in cancer patients, provide good validation of the concept of activating T cells against specific tumor antigens. Additionally, ZVex may even offer some potential advantages by virtue of its differentiated dendritic cell targeting, including more physiologic immune up-regulation, greater versatility for use against intracellular targets, less cumbersome preparation and administration, and induction of immune memory that could lead to persistent antitumor effects. In animal models, ZVex substantially increased the numbers of activated T cells, supporting the mechanistic approach, and showed tumor inhibitory effects in several animal models, providing some proof of principle, though with the caveat that animal models in cancer do not always translate well to humans. CTL generation by ZVex was boosted by IMDZ's second platform, GLAAS, a TLR4 agonist that less specifically stimulates the immune system. While TLR agonists have been used as adjuvants by others in the past, we believe its use in combination with ZVex – as it is planned to be tested in the future – could provide a novel "prime boost" strategy to maximize generation of a tumor-specific immune response and optimize potential anticancer benefits.

Based on this strong scientific foundation, we believe IMDZ's clinical candidates, while early stage, have a good likelihood of showing immune activation and ultimately, anticancer activity, in humans. IMDZ is testing LV305, a ZVex with a NY-ESO-1 tumor antigen payload, in phase I for various types of advanced solid tumors, with initial immunogenicity data expected in Q1 2015. The company subsequently plans to combine it with TLR4 agonist G305 (GLAAS + NY-ESO-1), also currently in phase I, in a combination termed CMB305. We believe the choice of NY-ESO-1 as a tumor antigen to study first makes sense: the antigen has minimal expression in normal tissues compared to tumors, minimizing safety risk of an autoimmune response, and it has been validated as an immunotherapy target in studies showing antitumor activity of NY-ESO-1 specific T-cells generated by other means. While exact measures of immune activity observed in the phase I may be difficult to benchmark, due to small patient numbers, a heterogeneous population, and limited historical comparators, we believe, based on the science and preclinical evidence, that the study will show signals of antigen-specific immune up-regulation (if not signals of clinical activity), which would speak to the promise of the technology in treating cancer.

We see broad potential applicability for IMDZ's technology across multiple cancer types, with a market opportunity of about \$1.3 billion by 2023. Following the phase I, IMDZ will likely study CMB305 in a common tumor type such as non-small cell lung cancer (NSCLC) or ovarian cancer, as well as in soft-tissue sarcomas. We believe this strategy makes sense. While larger tumors could provide a greater long-term revenue opportunity, soft tissue sarcomas, given their rarity and high rate of NY-ESO-1 expression, could potentially provide a more rapid path to approval, possibly enabling CMB305 to reach the market as early as 2018 if data are compelling. The development landscape in solid tumors is very crowded, and CMB305 would

Upcoming Milestones and Product Pipeline**Exhibit 2. Upcoming milestones**

Product	Event	Timeline
LV305	Ph.I safety and immunogenicity data	1Q15
G305	Ph.I safety and immunogenicity data	1Q15
CMB305	IND filing	2H14
	Initiate ph.I study	end-2014
	Ph.I safety and immunogenicity data	2H15
	Initiate ph.II study	2H15
G100	Complete Merkel cell carcinoma study	1Q15

Source: Company reports and Wells Fargo Securities, LLC estimates

Exhibit 3. Product pipeline

Product (partner)	Indication/mechanism	Status
LV305	Soft tissue sarcomas, melanoma, ovarian cancer, NSCLC, breast cancer	Phase I
G305	Soft tissue sarcomas, melanoma, ovarian cancer, NSCLC, breast cancer	Phase I
CMB305	Soft tissue sarcomas, melanoma, ovarian cancer, NSCLC	Preclinical
G100	Merkel cell carcinoma	Phase I
GLA (AZN/MedImmune)	Three infectious disease indications (MEDI7510 - RSV)	Phase I
GLA (Medicago)	Pandemic influenza	Phase I
GLS (Sanofi)	Allergy	Preclinical

Source: Company reports and Wells Fargo Securities, LLC

Key Risks

- **Clinical risk.** While there is a significant amount of preclinical data supporting ZVex's potential as a differentiated platform in immunotherapy, IMDZ's products remain very early stage, and there is no clinical data yet to corroborate that the platform will translate to humans. ZVex's ability to target DC cells has been well demonstrated in animal models and in human DCs in vitro, but we believe it will be key to show that ZVex targeting of human DC is sufficiently high enough and able to stimulate CTL response in humans, and that this translates to a clinical antitumor response. If ZVex-mediated antigen expression in DC is not achievable in humans in vivo and/or it is unable to induce sufficient CTL response, IMDZ's platform would likely be deemed less differentiated compared with other immunotherapy platforms, and may not ultimately succeed clinically. Although NY-ESO-1 is a well-characterized tumor antigen, it has never been tested in the ZVex system. As such, it is difficult to determine whether a robust CTL response could be generated to induce tumor killing. Additionally, it is possible that immune tolerance could be broken by ZVex such that an anti-ESO-1 immune response could lead to unforeseen autoimmune side effect.
- **Regulatory risk.** ZVex platform utilizes lentiviral vectors to stimulate the immune system, similar to gene therapy approaches. The food and Drug Administration (FDA) has never reviewed or approved a drug using viral vectors, which we believe adds regulatory uncertainty. We believe there could be a higher bar for safety as this novel therapeutic modality has a relatively limited safety record. Additionally, given that there are several immunotherapies with some overlapping features, any setbacks associated with other modalities might negatively affect the regulatory standards for the whole class.
- **Commercial risk.** ZVex-NY-ESO-1-based therapy is to be targeted to patients with tumors that express the target antigen. While a significant number of tumors that IMDZ is targeting express a meaningful level of NY-ESO-1, it is possible that even smaller subset of these patients might respond to treatment, which could further limit the addressable market. Additionally, given that the company is still in the early development phase, it is difficult to predict the competitive landscape when a ZVex-based therapy reaches the market. As there are several other competing immunotherapies in the same class (e.g., monoclonal TCRs and CAR-Ts) and separate classes, the target market could be significantly more crowded, leading to a potential lower end-market share.
- **Manufacturing risk.** Because the gene therapy field is still in a relatively nascent stage of development and there are no FDA-approved commercial products yet available, industrial-scale manufacturing technology and capacity remain limited to only a few specialized manufacturers. Due to the limited number of available suppliers, any disruption in the supply chain could significantly delay clinical development, regulatory approval, and/or commercial supply. Cost of goods is also likely to be more expensive than more traditional therapies such as small molecules.

Financials**Exhibit 4. Simplified Balance Sheet (Pro Forma, as of March 31, 2014, estimated)**

Assets	
Cash and cash equivalents	\$78,262
Other assets	\$814
Total assets	\$79,076
Liabilities and Stockholders' Equity	
Current Liabilities	\$2,172
Deferred Revenue	\$0
Other liabilities	\$87
Stockholders' equity	\$76,817
Total liabilities and stockholders' equity	\$79,076

(in thousands of dollars)

Source: Company Reports and Wells Fargo Securities, LLC

Exhibit 5. Income Statement

Immune Design (IMDZ)
Statement of Operations (Income Statement)

(in thousands except per share amounts)

	2012A	2013A	10A	20E	30E	4QE	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E
Revenues																
Licensing revenues (1)	\$876	\$729	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Product sales / royalties (2)	1,877	870	25	100	100	100	325	368	383	433	476	523	576	633	697	766
Other, net (3)	207	-	-	-	-	-	-	-	-	-	10,000	10,000	35,000	35,000	10,000	10,000
U.S. sales of CMB305 (prob-adjusted)	-	-	-	-	-	-	-	-	-	-	2,039	6,481	28,632	58,949	99,247	153,828
Royalties on ex-U.S. sales of CMB305 (prob-adjusted)	-	-	-	-	-	-	-	-	-	-	-	576	1,831	4,728	12,410	22,394
Total revenues	\$2,960	1,599	25	100	100	100	325	358	383	433	12,515	17,580	66,039	99,310	122,354	186,986
Expenses																
Cost of products sold	1,518	669	14	75	75	75	239	268	295	324	683	1,429	5,013	9,317	15,410	23,649
Research and development	8,604	11,554	4,078	4,160	4,243	4,328	16,808	17,648	26,472	29,120	32,032	32,993	33,982	35,002	36,052	37,134
Selling, general and administrative	3,713	4,433	1,446	1,952	2,030	2,111	7,540	8,671	9,017	12,624	25,249	40,398	60,597	66,657	69,323	72,096
Total operating expenses	13,835	16,656	5,538	6,187	6,348	6,514	24,587	26,587	35,785	42,069	57,964	74,820	99,593	110,976	120,785	132,878
Operating income/loss	(10,875)	(15,057)	(5,513)	(6,087)	(6,248)	(6,414)	(24,262)	(26,230)	(35,392)	(41,636)	(45,449)	(57,240)	(33,554)	(11,666)	1,569	54,108
Interest and other income	35	37	1	3	6	9	20	46	40	52	78	67	49	54	39	57
Change in fair value of convertible preferred stock warrant	-	(955)	(2,711)	-	-	-	(2,711)	-	-	-	-	-	-	-	-	-
(Loss) income before benefit from income taxes	(10,840)	(15,975)	(8,223)	(6,083)	(6,242)	(6,405)	(26,953)	(26,183)	(35,351)	(41,584)	(45,370)	(57,173)	(33,504)	(11,612)	1,608	54,165
Benefit (expense) from income taxes	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Net (loss) income	(10,840)	(15,975)	(8,223)	(6,083)	(6,242)	(6,405)	(26,953)	(26,183)	(35,351)	(41,584)	(45,370)	(57,173)	(33,504)	(11,612)	1,608	54,165
Earnings Per Share (GAAP)	(\$30.43)	(\$2.28)	(\$0.81)	(\$0.60)	(\$0.52)	(\$0.40)	(\$2.24)	(\$1.61)	(\$1.85)	(\$1.89)	(\$2.02)	(\$2.50)	(\$1.28)	(\$0.44)	\$0.06	\$1.86
Shares Outstanding (Basic)	356	7,008	10,139	10,139	11,906	15,839	12,006	16,239	19,139	22,039	22,439	22,839	26,239	26,639	27,039	27,439
Shares Outstanding (Diluted)	356	7,008	10,139	10,139	11,906	17,589	13,756	17,989	20,889	23,789	24,189	24,589	27,989	28,389	28,789	29,189

Source: Company reports and Wells Fargo Securities, LLC estimates

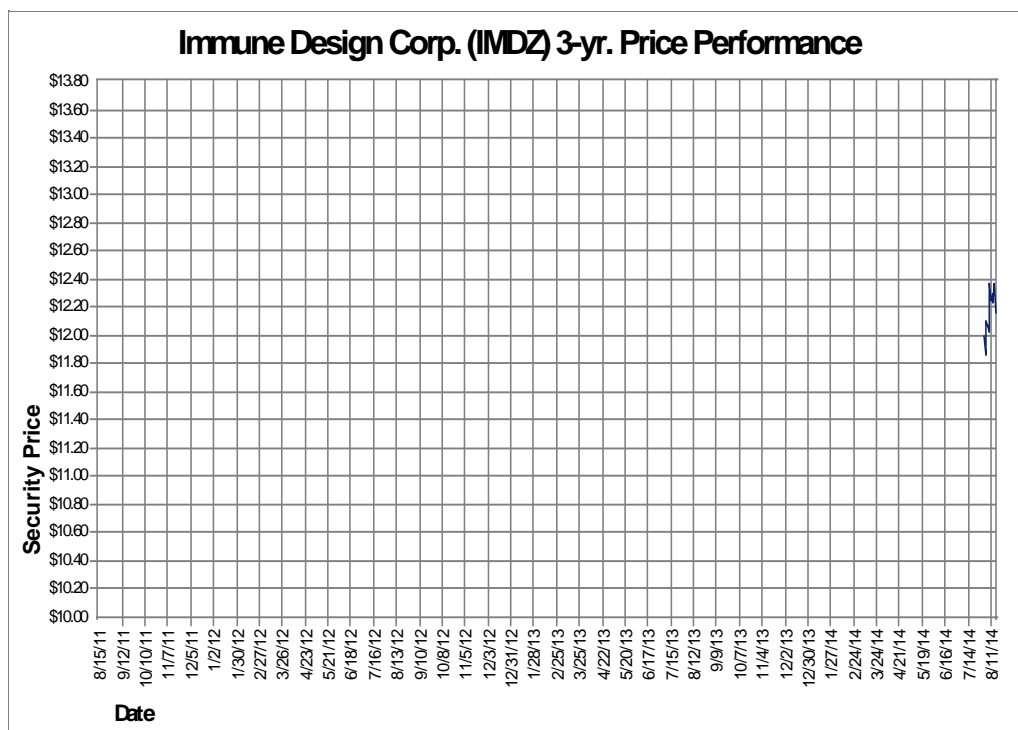
Note: 2014 quarterly EPS do not equal annual EPS due to calculation of EPS based on diluted vs. basic shares

(1) related to Medimmune collaboration

(2) Reflects sales of GLAAS to collaborators

(3) Includes amortization of potential upfront for ex-U.S. CMB305 partnership, potential milestones

Required Disclosures



	Date	Publication Price (\$)	Rating Code	Val. Rng. Low	Val. Rng. High	Close Price (\$)

Source: Wells Fargo Securities, LLC estimates and Reuters data

Symbol Key

- ▼ Rating Downgrade
- ▲ Rating Upgrade
- Valuation Range Change
- ◆ Initiation, Resumption, Drop or Suspend
- Analyst Change
- Split Adjustment

Rating Code Key

- 1 Outperform/Buy
- 2 Market Perform/Hold
- 3 Underperform/Sell
- SR Suspended
- NR Not Rated
- NE No Estimate

Additional Information Available Upon Request

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IMDZ: Risks include ZVex's failure to show clinical efficacy, a safety signal, competition, and manufacturing.

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As of: August 17, 2014

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