March 12, 2015

**OUTPERFORM**

Reason for report:

**COMPANY UPDATE**

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LEERINK

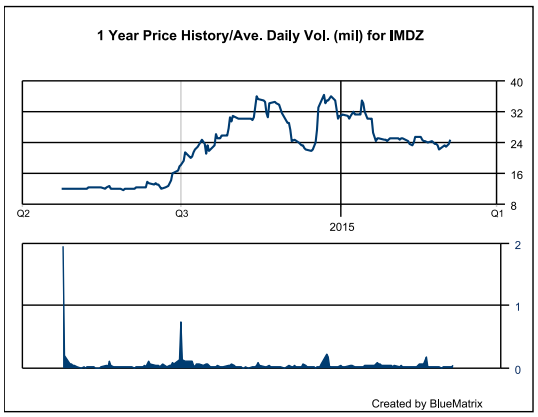
# IMMUNE DESIGN CORP.

## Beyond Litigation, Robust News Flow Provides Catalysts

• **Bottom Line:** Although the litigation with TheraVectys (TVS) stemming from the use by IMDZ of an outside manufacturer that had an exclusive contract with TVS would not seem a major conflict, the aggressive demands made by TVS make the trial outcome relevant, therefore the court's rejection of TVS' motion for preliminary injunction is a meaningful development. While an unfavorable ruling in the court trial (potentially in 3Q) remains possible, it would appear unlikely to have a major impact on IMDZ' development programs. We continue to expect robust news flow for IMDZ in 2015 including ASCO data on all three ongoing Phase I trials of LV305, G305 and G100 (potential top-line release in March/April), first CMB305 combination data in 2H:15, and dose expansion data for LV305 and LV305 + PD1 antibody combination data in 2H:15. We continue to believe that the need for technologies that generate cytotoxic T cells such as IMDZ' is supported by the lack of tumor-infiltrating lymphocytes (TILs) in approximately half of the melanoma and non-small cell lung cancer (NSCLC) patients as well as robust efficacy seen with ex vivo expanded TILs and chimeric antigen receptor T cells (CAR-T). In light of the increasingly large number of PD1/PDL1 antibodies in development, the combination partner could become the differentiating factor, therefore we believe that the clinical demonstration of proof of principle for IMDZ' platform, potentially in 2015, could be associated with a large upside. Our price target remains $40.

• **Court opinion provides some insight into the relative merits of each of TheraVectys' claims.** The court analyzed the evidence for the allegation that IMDZ improperly interfered with TheraVectys' contract by dividing it between the period before and after September 11, 2013 (when IMDZ first learned that TheraVectys was suing Henogen). The court opinion stated that TheraVectys had failed to establish that IMDZ had knowledge of Henogen's contractual obligations prior to this date, but had established a "reasonable probability" of proving tortious interference based on IMDZ' conduct after this. This stems from IMDZ procuring an additional batch of lentiviral vectors from Henogen through an agreement that was classified as an "addendum" to the original contract. While the court noted that IMDZ presumably could have taken steps to enforce the existing contract even in light of TheraVectys' contractual claims, expanding on the agreement "would appear improper." The misappropriation of trade secrets claim is similarly broken down by these time periods; however, these allegations do not appear as strong, with the opinion stating, "at this point, the record is not clear enough to determine with confidence that [TheraVectys] has a reasonable probability of success." The court opinion noted that even showing a reasonable probability of success still falls below that necessary to secure post-trial final relief.

| **Key Stats:** | **(NASDAQ:IMDZ)** |
|---|---|
| **S&P 600 Health Care Index:** | **1,573.40** |
| **Price:** | **$25.62** |
| Price Target: | $40.00 |
| Methodology: | DCF analysis and probability-weighted sales |
| 52 Week High: | $40.13 |
| 52 Week Low: | $11.51 |
| Shares Outstanding (mil): | 12.3 |
| Market Capitalization (mil): | $315.1 |
| Cash Per Share: | $6.80 |
| Dividend (ann): | $0.00 |
| Dividend Yield: | 0.0% |




| Dec Yr | 1Q | 2Q | 3Q | 4Q | FY Rev | 1Q | 2Q | 3Q | 4Q | FY EPS | P/E |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **2013A** | -- | -- | -- | -- | $1.6 | -- | -- | -- | -- | ($2.28) | NM |
| **2014E** | 0.0A | $1.1A | $3.5A | 0.0 | $4.6 | ($0.81)A | ($0.46)A | ($0.55)A | ($0.83) | ($2.17) | NM |
| **2015E** | -- | -- | -- | -- | 0.0 | -- | -- | -- | -- | ($3.23) | NM |
| **2016E** | -- | -- | -- | -- | 0.0 | -- | -- | -- | -- | ($2.18) | NM |

*Source: Company Information and Leerink Partners LLC Research*
*Revenues in millions. 2014E quarterly EPS don't 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 immuno-therapies 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 tumor-infiltrating 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 tumor-specific 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 immuno-oncology 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 March/April and continuing throughout 2015 could provide near-term catalysts.

**Background of litigation between TheraVectys, Henogen, and IMDZ.** IMDZ previously used Henogen as the manufacturer of its lentiviral vectors for LV305. In September 2013, TheraVectys (which is developing lentiviral vector vaccines for the treatment of HIV) sued Henogen in Belgian court, alleging that it had breached the terms of the exclusivity contract between the two companies by producing the lentivirus for IMDZ. As a result of this, Henogen was temporarily enjoined from producing or delivering these vectors to IMDZ. In October 2013, Henogen sued TheraVectys in the Commercial Court of Paris, which determined in April 2014 that Henogen had indeed violated the terms of the contract and ordered it to comply with the exclusivity agreement. Henogen is currently appealing the judgment; however the court has ordered provisional enforcement of it in the meantime. While IMDZ was not named in either of these lawsuits, TheraVectys filed a complaint against it in the US District Court of Delaware, alleging tortious interference, unfair competition, and misappropriation of trade secrets. TheraVectys dropped this

case in April 2014, but filed a new complaint in July 2014 in Delaware Chancery Court alleging similar claims along with unjust enrichment. While IMDZ currently has a new manufacturer, it is using the lentiviral vectors produced by Henogen in its ongoing Phase I trials. TheraVectys demanded a preliminary injunction that would have prohibited IMDZ from using the vectors, enrolling patients in new clinical trials, or using the data from ongoing LV305 trials for the next three years. On Monday (3/9), the court denied the motion for preliminary injunction, and a trial is expected to occur before the end of 3Q:15.

**If TheraVectys were to prevail, the potential remedy remains unclear but appears unlikely to have a substantially negative impact on IMDZ**. In the conclusion of the opinion, the court stated that IMDZ's procurement of lentivirus post-September 11, 2013, likely facilitated progress in its clinical trials. TheraVectys claims this is causing ongoing harm through increased competition in the in vivo lentiviral vector vaccine space (although it has yet to begin development of its technology in oncology). Even if the court were to find in favor of TheraVectys, it is unclear what sort of remedy it would impose. However, given that IMDZ' actions do not seem particularly egregious to us and TheraVectys was not able to establish enough irreparable damage to secure a preliminary injunction, we do not believe that any final ruling would have a substantially negative impact on IMDZ.

**Phase I data from individual components of "Prime Boost" (LV305 and G305) have been submitted to ASCO.** IMDZ has submitted abstracts to ASCO from it two Phase I dose-expansion trials of LV305 (dendritic cell-targeting lentivirus vector [ZVex] encoding NY-ESO-1) and G305 (TLR4 agonist [GLAAS] combined with NY-ESO-1 protein). Management indicated that it may release limited top-line results in a press release in March/April prior to the conference if the data are deemed material. Both of these trials include 12 patients with sarcoma, melanoma, NSCLC, or ovarian cancer. While any signs of tumor responses would be exciting, we believe the important readout will be immune response in addition to safety, including quality and the quantity of CD8+ T cells, CD4+ T cell, Tregs, NK cells, and antibodies. Additional data include the fold induction of CD8+ T cells, and the different subsets (memory and effectors) of CD8+ T cells generated as a result of immunization.

**IMDZ plans to report additional Phase I data from G100 (intratumoral GLA monotherapy) in Merkel cell carcinoma (MCC) at ASCO.** The company previously reported data from three MCC patients, one of whom had a CR (the other two did not respond). Data from all 10 patients in the Phase I trial are expected at ASCO (with partial data available in the abstract). An ongoing IST in sarcoma (n=12) and a planned Phase I trial in non-Hodgkin's lymphoma (NHL) (n=30) are both investigating G100 in combination with local radiation. IMDZ hopes to show both elimination of the treated tumor and an abscopal effect on distal tumors.

**Data from combined "Prime-Boost" (CMB305) dose-escalation and expansion trial are likely in 2H:15:** This combination of IMDZ' ZVex and GLAAS platforms represents its likely go-forward product and, as such, full results from the dose escalation portion (n=6 to 12) and initial data from the expansion portion (n=32) would provide an important first look. Like the Phase I trials of the individual components, these trials will include sarcoma, melanoma, NSCLC, and

ovarian cancer patients, and both tumor and immune responses will be analyzed. The company also plans to begin randomized Phase II trials of CMB305 in combination with a checkpoint inhibitor in sarcoma and "high incidence" tumors in 2H:15.

**Additional data are expected in 2H:15 for LV305 expansion cohort and LV305/PD-1 inhibitor combination.** The company plans to initiate a 20-patient trial of LV305 plus a PD-1 inhibitor in melanoma in patients who are non-responders to previous anti-PD1 treatment. This study is planned in 1Q:15 with data expected in the latter half of the year. While the company is unlikely to take this combination forward, it could serve as an initial proof-of-concept for the CMB305 + checkpoint inhibitor combinations noted above. Additionally, data from the LV305 expansion cohort (n=32) are also expected in 2H:15.

**IMDZ Upcoming Catalysts**

| Drug | Timing | Description |
|---|---|---|
| **G100** (GLA) | 2Q:15 | Data from Phase I Merkel cell carcinoma trial (n=10) - submitted to ASCO |
| | 2Q:15 | Initiate Phase I trial in combo w/radiation in NHL (n=30) |
| | 2015 | IST in combo w/radiation in Sarcoma (n=12) continues |
| **G305** (GLAAS + NY-ESO1 protein) | 2Q:15 | Data from dose escalation (n=12) - submitted to ASCO |
| **LV305** (Zvex + NY-ESO1 RNA) | 1Q:15 | Initiate Phase I Expansion (n=32) |
| | 2Q:15 | Data from dose-escalation (n=12) - submitted to ASCO |
| | 2H:15 | Data from expansion (n=32) |
| + anti-PD-1 | 1Q:15 | Initiate Phase I in NR melanoma (n=20) |
| | 2H:15 | Data from NR melanoma study (n=20) |
| **CMB305** (LV305 + G305) | 1Q:15 | Initiate Phase I Dose-escalation (n=6 to 12) |
| | 2Q:15 | 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**

| Stage of Development | Current Status/Upcoming Developments |
|---|---|
| **G100** (GLA) | |
| Phase I | Data from Phase I MCC trial (n=10) expected at ASCO |
| **G305** (GLAAS + NY-ESO1 protein) | |
| Phase I | Data from Phase I dose escalation (n=12) expected at ASCO |
| **LV305** (Zvex + NY-ESO1 RNA) | |
| Phase I | Data from Phase I dose escalation (n=12) expected at ASCO |
| **CMB305** (LV305 + G305) | |
| Preclinical | Initiate Phase I Dose-escalation expected in 1Q:15 |

*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)

| | 1QA | 2QA | 3QA | 4QE | 2014E | 2015E | 2016E | 2017E | 2018E | 2019E | 2020E |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **REVENUE:** | | | | | | | | | | | |
| CMB305 (POS adjusted sales) | - | - | - | - | 0 | - | - | - | - | - | 13,468 |
| G100 (POS adjusted sales) | - | - | - | - | 0 | - | - | - | 11,723 | 22,628 | 25,923 |
| Other Product Sales | 25 | 64 | 44 | | 133 | | | | | | |
| Product Development and Licensing Agreements | | 1000 | 3500 | | 4500 | | | | | | |
| Contracts and Grants | | | | | 0 | | | | | | |
| Product Royalties | | | | | 0 | | | | | | |
| Milestone payments | | | | | 0 | | | | | | |
| Other, net | | | | | 0 | | | | | | |
| **Total Revenue** | **25** | **1,064** | **3,544** | **-** | **4,633** | **-** | **-** | **-** | **11,723** | **22,628** | **39,391** |
| | | | | | | | | | | | |
| **OPERATING EXPENSES:** | | | | | | | | | | | |
| Cost of product Sales | 14 | 18 | 31 | | | | | | 2,345 | 4,526 | 7,878 |
| Research and Development | 4,078 | 3,883 | 5,988 | 6,048 | 19,997 | 24,678 | 37,018 | 55,526 | 83,290 | 87,454 | 91,827 |
| Sales General and Adminstrative | 1,446 | 1,850 | 4,082 | 4,164 | 11,542 | 17,329 | 17,676 | 57,676 | 98,049 | 147,073 | 161,780 |
| Royalties | | | | | | | | | | | |
| Amortization of Acquired Intangible Assets | | | | | | | | | | | |
| **Total Operating Expense** | **5,538** | **5,751** | **10,101** | **10,212** | **31,539** | **42,007** | **54,693** | **113,202** | **181,338** | **234,527** | **253,607** |
| | | | | | | | | | | | |
| **Operating Loss** | **(5,513)** | **(4,687)** | **(6,557)** | **(10,212)** | **(26,906)** | **(42,007)** | **(54,693)** | **(113,202)** | **(169,615)** | **(211,899)** | **(214,216)** |
| | | | | | | | | | | | |
| Investment, Interest and Other Income, Net | 1 | | 2 | | | | | | | | |
| Change in fair value of convertible preferred stock warrant liability | (2,711) | | (127) | | | | | | | | |
| Net Income before Taxes | (8,223) | (4,687) | (6,682) | (10,212) | (26,906) | (42,007) | (54,693) | (113,202) | (169,615) | (211,899) | (214,216) |
| Income tax rate% | | | | | | | | | | | |
| Income Tax | | | | | | | | | | | |
| **Net Loss** | **(8,223)** | **(4,687)** | **(6,682)** | **(10,212)** | **(26,906)** | **(42,007)** | **(54,693)** | **(113,202)** | **(169,615)** | **(211,899)** | **(214,216)** |
| | | | | | | | | | | | |
| Earnings per share | (0.81) | (0.46) | (0.55) | (0.83) | (2.17) | (3.23) | (2.18) | (4.46) | (4.51) | (4.41) | (4.42) |
| Shares Used in Calculating Basic and Diluted Net Loss per Share(pro forma) | 10,139 | 10,240 | 12,129 | 12,250 | 12,373 | 13,004 | 25,134 | 25,385 | 37,639 | 48,015 | 48,495 |
| Dilutive shares | 10,139 | 10,240 | 12,129 | 12,250 | 12,373 | 13,004 | 25,134 | 25,385 | 37,639 | 48,015 | 48,495 |

Source: Company Reports and Leerink Partners Estimates

# 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

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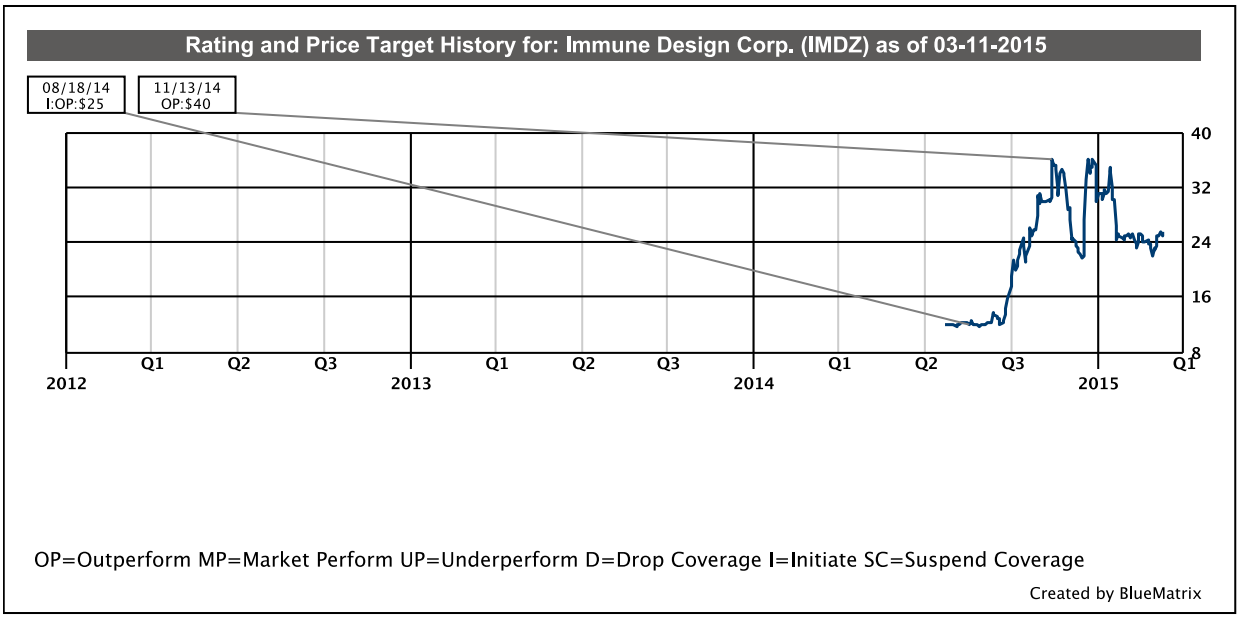
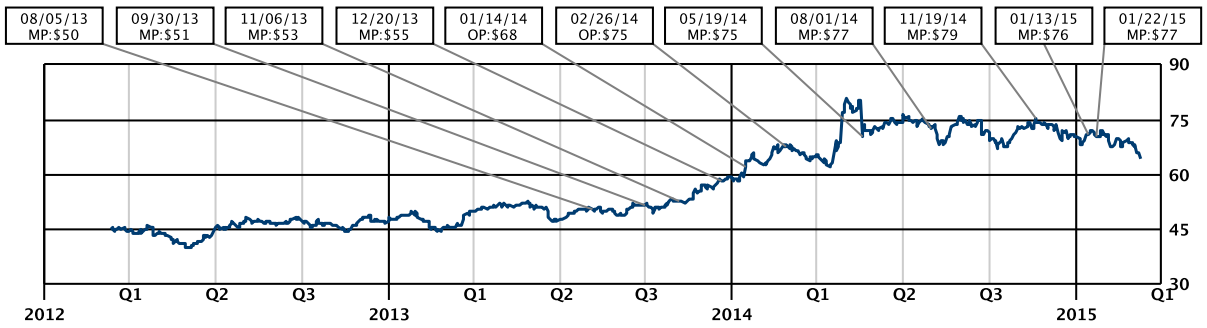


**Rating and Price Target History for: AstraZeneca PLC (AZN) as of 03-11-2015**

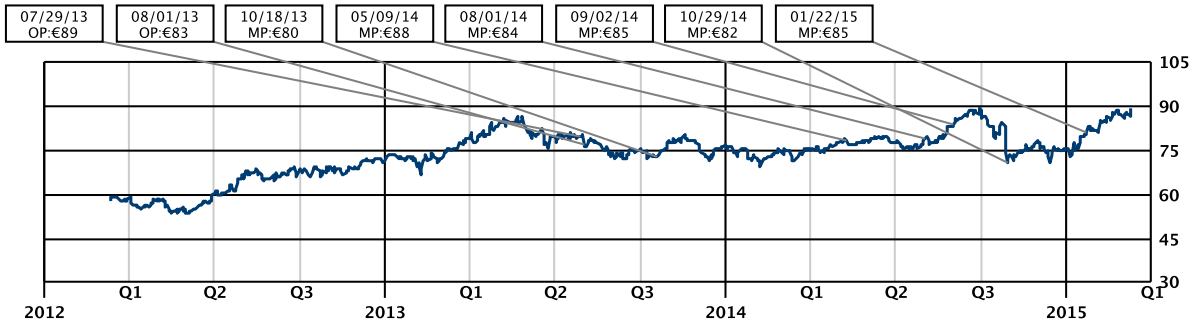



Leerink Swann initiated coverage of AZN with a Market Perform rating on Sept. 30, 2009. On June 11, 2013, Leerink Swann began a transition to specific price targets for the stocks under its coverage, replacing valuation ranges.

OP=Outperform MP=Market Perform UP=Underperform D=Drop Coverage I=Initiate SC=Suspend Coverage

Created by BlueMatrix

**Rating and Price Target History for: Sanofi (SAN FP) as of 03-11-2015**




Leerink Swann initiated coverage of SAN FP with an Outperform rating on February 26, 2010. On June 11, 2013, Leerink Swann began a transition to specific price targets for the stocks under its coverage, replacing valuation ranges.

OP=Outperform MP=Market Perform UP=Underperform D=Drop Coverage I=Initiate SC=Suspend Coverage

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| Distribution of Ratings/Investment Banking Services (IB) as of 12/31/14 | | | | |
|---|---|---|---|---|
| | | | IB Serv./Past 12 Mos. | |
| Rating | Count | Percent | Count | Percent |
| BUY [OP] | 150 | 70.00 | 60 | 40.00 |
| HOLD [MP] | 64 | 30.00 | 1 | 2.00 |
| 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.
**Market Perform (Hold/Neutral):** We expect this stock to perform in line with its benchmark over the next 12 months.
**Underperform (Sell):** 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

This information (including, but not limited to, prices, quotes and statistics) has been obtained from sources that we believe reliable, but we do not represent that it is accurate or complete and it should not be relied upon as such. All information is subject to change without notice. This is provided for information purposes only and should not be regarded as an offer to sell or as a solicitation of an offer to buy any product to which this information relates. The Firm, its officers, directors, employees, proprietary accounts and affiliates may have a position, long or short, in the securities referred to in this report, and/or other related securities, and from time to time may increase or decrease the position or express a view that is contrary to that contained in this report. The Firm's salespeople, traders and other professionals may provide oral or written market commentary or trading strategies that are contrary to opinions expressed in this report. The Firm's proprietary accounts may make investment decisions that are inconsistent with the opinions expressed in this report. The past performance of securities does not guarantee or predict future performance. Transaction strategies described herein may not be suitable for all investors. Additional information is available upon request by contacting the Editorial Department at One Federal Street, 37th Floor, Boston, MA 02110.

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MEDACorp is a network of healthcare professionals, attorneys, physicians, key opinion leaders and other specialists accessed by Leerink and it provides information used by its analysts in preparing research.

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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