Reason for report:

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### CAREDX, INC.

**PROPRIETARY - SURVEY** 

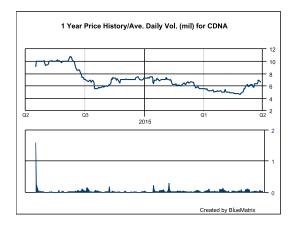
**Existing Business Plus Pipeline Should Drive Value Creation** 

- Bottom Line: Following recent due diligence, we continue to think CDNA is well-positioned to steadily increase product adoption and grow revenues, both organically and inorganically. We maintain our Outperform rating and \$10 price target on CDNA's stock.
- Patient stratification message/continued utility validation should drive steady AlloMap penetration. By focusing on AlloMap's utility in optimizing immunosuppressive therapy in patients with low probabilities of heart transplant rejection (as opposed to its utility as a substitution for biopsy in all transplant patients), CDNA ought to be able to increase clinician usage of its AlloMap test. CDNA intends to stratify patients by focusing on those for whom the AlloMap test shows to have a low probability of acute cellular rejection, which can inform treatment such as lowering the prescribed levels of immunosupressants. Moreover, increasing amounts of literature showing clinical utility coupled with continued growth in the Outcomes AlloMap Registry (OAR)clinical outcomes registry study should enhance the perceived clinical utility of the test. In a recent MEDACorp survey, roughly half of respondents cited a potential to increase AlloMap usage if they perceived the product had higher utility (see relevant section attached from recent LVAD survey).
- Execution in kidney will be key driver of stock; clinical validation trials begin. With the size of the kidney transplant surveillance market estimated at 8x that of heart transplant, successful execution on CDNA's cell free DNA (cfDNA) kidney transplant surveillance test will be a significant driver of stock performance. CDNA recently initiated clinical validation trials and we expect the company will have 6 centers enrolling patients by June end. CDNA plans to provide an interim data review in 1H16, and to begin clinical utility trials in 2H16 (contingent upon interim data). We believe it reasonable to expect revenue from the kidney test in 2017.
- Potential for inorganic growth opportunities. CDNA management is open to the idea of expanding its test menu/product offerings through inorganic growth. With the intent of growing/broadening its revenue base, CDNA would be focused on commercial stage tests in the transplantation/ infection market.

**Key Stats:** (NASDAQ:CDNA)

**Life Science Tools and Diagnostics** Sector: S&P 600 Health Care Index: Price: \$6.61 Price Target: \$10.00 Methodology: ~3.5x EV/TTM estimated revenue ending Dec 2016

52 Week High: \$10.89 52 Week Low: \$4.60 Shares Outstanding (mil): 11.8 Market Capitalization (mil): \$78.0 Book Value/Share: \$3.35 Cash Per Share: \$3.30 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	\$5.9	\$6.8	\$6.7	\$8.0	\$27.3	(\$0.21)	\$0.13	(\$0.01)	\$0.00	(\$0.05)	NM
2015E	\$7.2A	\$7.4	\$7.4	\$7.7	\$29.8	(\$0.21)A	(\$0.17)	(\$0.19)	(\$0.20)	(\$0.77)	NM
2016E					\$33.7	ļ				(\$0.73)	NM
2017E					\$42.0	l				(\$0.55)	NM

Source: Company Information and Leerink Partners LLC Research

Revenues in millions.

3Q14 excludes \$1.2m benefit from reversal of contingent consideration allowance for ImmuMetrix acquisition.



#### **INVESTMENT THESIS**

We rate Brisbane, California-based CareDx (CDNA) Outperform with a \$10 price target. CDNA markets a non-invasive molecular gene expression test (AlloMap) of 20 genes for heart transplant recipients to diagnose acute cellular rejection, reduce use of biopsy, and better tailor immunosuppression post-transplant to patient needs. Additionally, the company is developing products for post-transplant monitoring that use nextgen sequencing (NGS) to detect cell free DNA (cfDNA). We believe the company will continue to successfully expand its core AlloMap franchise while developing its cfDNA products, which could be marketed as early as 2017. We believe CDNA's pipeline opportunity is undervalued at current levels and thus our Outperform rating.

#### **VALUATION**

Our \$10 price target corresponds to an enterprise value (using projected levels of debt and cash) that is ~3.5x our revenue estimate for the twelve months ended Dec-16. This is a meaningful discount to the tools/diagnostics emerging growth peer group median multiple of ~5.5x, which we believe more than balances concerns over the size of CDNA's opportunity in heart transplant with its opportunities in kidney and other transplants.

#### **RISKS TO VALUATION**

CDNA's risks include, but are not limited to: the trajectory of the AlloMap revenue ramp, the ability to successfully develop and commercialize products using cfDNA for transplant surveillance, and the impact of a changing regulatory environment in the U.S. for diagnostics.



# LEFT VENTRICULAR ASSIST DEVICE (LVAD) IMPLANT VOLUMES

Respondent Distribution	
Specialty	Cardiothoracic surgery Heart failure specialists
Trends	LVAD Implant Volumes
Number of Respondents	24 Cardiothoracic Surgeons 14 Heart Failure Specialists
Respondent Distribution	United States
Survey Date	March 2015



Responses represent an average of the aggregate response (n=38) unless otherwise noted.

Screener 1: Which of the following best describes your specialty?

63.2%	Cardiothoracic surgery
36.8%	Heart failure specialists
0.0%	Other

1. Please estimate the average number of heart transplants you perform annually. (n=37)

	Mean	Median	Sum
Number of heart transplants I perform annually	23.4	25	864

2. Please estimate the average number of AlloMap tests you ordered / plan to order to monitor heart transplant recipients at the following time points and how you expect this number to change over the next two years.

#### 2014 (n=31)

	Mean	Median	Sum
1st year post transplant	13.9	10	430
2nd year post transplant	13.9	8	430
3-5 years post-transplant	13.9	5	432
>5 years post-transplant	13.7	5	425

#### 2015

	Mean	Median	Sum				
1st year post transplant	18.4	10	569				
2nd year post transplant	18.2	10	565				
3-5 years post-transplant	17.0	7	528				
>5 years post-transplant	16.8	5	522				

#### 2016

	Mean	Median	Sum
1st year post transplant	22.5	12	697
2nd year post transplant	21.1	12	655
3-5 years post-transplant	19.4	8	602
>5 years post-transplant	19.4	5	602

3. What would cause you to increase your use of AlloMap test, if anything?

See Appendix for a summary of responses



#### **Appendix: Summary of responses**

Question 3: What would cause you to increase your use of Allomap test, if anything?

2	Decrease rate and risk of biopsy
3	We do not trust AlloMap
4	Accurate and continuity
5	Less invasive than biopsy
6	We are not rely on AlloMap tests. We would rather to conventional biopsy.
9	Increased sensitization / PRA's
10	Cardiologists need convincing
12	Ease
15	Only if the test had a high sensitivity and specificity for correlation with the old ISHLT grade of 1B rejection and could
13	predict its occurrence
16	More consistent readings and fewer false positives
17	Increasing the number of transplants performed.
19	Lowered cost
20	Increasing number of rejection episodes
21	Better management of heart transplant
24	I don't foresee any changes in my use of AlloMap testing at the moment.
30	Guides immunosuppressive therapy
31	Cautious follow-up
32	Better fidelity and reproducibility
34	Less invasive procedures
35	Reimbursement
36	More data that it is effective
37	Better patient outcome
38	Cost

#### CareDx (CDNA)

Dan Leonard, 212-277-6116

\$28 - \$30M

													d@leerink.com	
Period Ended (\$ thousands)	2012	2013	Mar-14	Jun-14	Sep-14	Dec-14	2014	Mar-15	Jun-15e	Sep-15e	Dec-15e	2015e	2016e	2017e
Revenues														
Testing revenue	\$19,730	\$21,672	\$5,834	\$6,710	\$6,601	\$6,697	\$25,842	\$7,096	\$7,335	\$7,347	\$7,519	\$29,297	\$33,196	\$41,515
Other	<u>721</u>	<u>426</u>	<u>90</u>	<u>66</u>	<u>53</u>	1,255	<u>1,464</u>	<u>120</u>	<u>100</u>	<u>100</u>	<u>100</u>	<u>420</u>	<u>400</u>	<u>400</u>
Total revenues	20,451	22,099	5,924	6,776	6,654	7,952	27,306	7,216	7,435	7,447	7,619	29,717	33,596	41,915
Cost of service	<u>7,930</u>	9,078	2,162	2,403	<u>1,772</u>	2,204	<u>8,541</u>	<u>2,711</u>	2,528	2,532	2,591	<u>10,361</u>	11,423	14,251
Gross profit	12,521	13,021	3,762	4,373	4,882	5,748	18,765	4,505	4,907	4,915	5,029	19,356	22,173	27,664
SG&A	10,111	10,701	3,269	3,926	3,729	3,984	14,908	4,728	4,535	4,543	4,724	18,530	19,485	20,958
R&D	<u>4,752</u>	<u>3,176</u>	<u>720</u>	<u>792</u>	<u>1,036</u>	1,298	<u>3,846</u>	<u>1,421</u>	2,007	<u>2,160</u>	<u>2,210</u>	7,798	9,820	<u>11,736</u>
Operating income (loss)	(2,342)	(856)	(227)	(345)	117	466	11	(1,644)	(1,636)	(1,787)	(1,905)	(6,972)	(7,133)	(5,030)
Interest expense (income)	2,703	2,150	548	644	535	389	2,116	827	431	432	432	2,122	1,734	1,741
Other, net	<u>14</u>	<u>536</u>	<u>529</u>	(366)	(355)	<u>45</u> 32	(147)	<u>54</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>54</u>	<u>0</u>	<u>0</u>
Pretax income	(5,059)	(3,542)	(1,304)	(623)	(63)		(1,958)	(2,525)	(2,067)	(2,219)	(2,337)	(9,148)	(8,867)	(6,770)
Taxes	<u>0</u>	<u>0</u>	<u>0</u>	(1,500)	<u>0</u>	<u>0</u>	(1,500)	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>
Net income	(\$5,059)	(\$3,542)	(\$1,304)	\$877	(\$63)	\$32	(\$458)	(\$2,525)	(\$2,067)	(\$2,219)	(\$2,337)	(\$9,148)	(\$8,867)	(\$6,770)
Basic shares outstanding	6,913	6,923	6,172	1,013	9,280	11,802	5,816	11,814	11,864	11,914	11,964	11,889	12,089	12,289
Diluted shares outstanding	6,913	6,923	6,172	6,940	11,219	12,129	9,283	11,814	11,864	11,914	11,964	11,889	12,089	12,289
EPS diluted	(\$0.73)	(\$0.51)	(\$0.21)	\$0.13	(\$0.01) (1)	\$0.00	(\$0.05)	(\$0.21) (1)	(\$0.17)	(\$0.19)	(\$0.20)	(\$0.77)	(\$0.73)	(\$0.55)
EPS growth														
Revenue growth		9.8%	21.3%	25.8%	15.5%	15.1%	19.2%	21.6%	9.3%	11.3%	12.3%	13.4%	13.3%	25.1%
Volume (Ths)	8,337	10,064	2,792	3,019	3,024	3,095	11,930	3,111	3,411	3,417	3,497	13,437	15,440	16,984
Gross margin	61.2%	58.9%	63.5%	64.5%	73.4%	72.3%	68.7%	62.4%	66.0%	66.0%	66.0%	65.1%	66.0%	66.0%
SG&A % of revenue	49.4%	48.4%	55.2%	57.9%	56.0%	50.1%	54.6%	65.5%	61.0%	61.0%	62.0%	62.4%	58.0%	50.0%
R&D % of revenue	23.2%	14.4%	12.2%	11.7%	15.6%	16.3%	14.1%	19.7%	27.0%	29.0%	29.0%	26.2%	29.2%	28.0%
Operating margin	(11.5%)	(3.9%)	(3.8%)	(5.1%)	1.8%	5.9%	0.0%	(22.8%)	(22.0%)	(24.0%)	(25.0%)	(23.5%)	(21.2%)	(12.0%)
Tax rate	0.0%	0.0%	0.0%	240.8%	0.0%	0.0%	76.6%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
D&A expense	\$1,072	\$663	\$106	\$116	\$132	\$158	\$512	\$165	\$98	\$98	\$100	\$461	\$443	\$554
EBITDA	(\$1,270)	(\$193)	(\$121)	(\$229)	\$249	\$624	\$523	(\$1,479)	(\$1,538)	(\$1,689)	(\$1,805)	(\$6,511)	(\$6,690)	(\$4,476)
Free cash flow														
Operating cash flow	(\$1,776)	(\$546)	\$180	\$853	(\$3,661)	(\$722)	(\$3,350)	(\$1,014)			Γ	(\$8,141)	(\$7,896)	(\$5,543)
CapX	(141)	(98)	<u>(19)</u>	(145)	(169)	(400)	(733)	(364)				(491)	(743)	(1,117)
Free cash flow	(\$1,917)	(\$644)	\$161	\$708	(\$3,830)	(\$1,122)	(\$4,083)	(\$1,378)				(\$8.632)	(\$8,639)	(\$6,661)

Guidance Revenue

Notes:
Source: Company reports and Leerink Partners estimates
(1) Excludes change in fair value of Immumetrix consideration



# **Disclosures Appendix Analyst Certification**

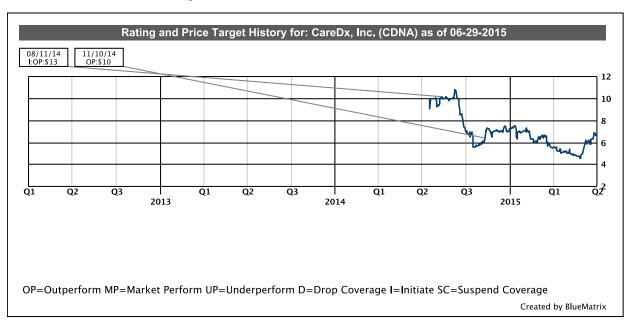
I, Dan Leonard, certify that the views expressed in this report accurately reflect my views and that no part of my compensation was, is, or will be directly related to the specific recommendation or views contained in this report.

#### **Valuation**

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Dis	stribution of Ratings/Investment Bank	king Services (IB)		rv./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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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 CareDx, Inc. .

Leerink Partners LLC makes a market in CareDx, Inc.

Leerink Partners LLC has acted as the manager for a public offering of CareDx, Inc. in the past 12 months.

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