#### **OUTPERFORM**

Dan Leonard (212) 277-6116

Dan.Leonard@Leerink.com

Kevin C. Chen (212) 277-6045

Kevin.Chen@leerink.com

Reason for report: **EARNINGS** 



## CAREDX, INC.

Business on Plan; cfDNA Interest Continues to Build

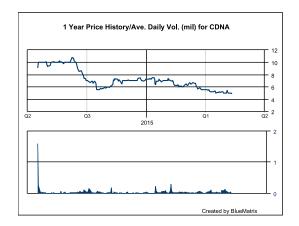
- Bottom Line: After a solid 1Q report, we maintain our Outperform rating and \$10 price target on CDNA's stock.
- Revenue beat, AlloMap volume in line. CDNA reported 1Q revenue of \$7.2M, which is 4.8% above our and the Street's ~\$6.8M expectation, beaten by strong AlloMap collections in the guarter. AlloMap volumes were ~3,100, up 11% y/y and in line with our forecast.
- AlloMap commercialization continues steadily. AlloMap is now used in 115/129 US transplant centers (up from 110 in Dec.), with 58 centers establishing a protocol (up from 48) and representing almost half of U.S. heart transplant centers. As of March 31st, the Outcomes AlloMap Registry (OAR) had 1,300 samples from 436 patients (up from 1,000+ samples and 364 patients in Dec.). Meanwhile, the cfDNA parallel registry study (D-OAR) of AlloMap launched in 5 more centers this guarter (total 8), with 118 samples from 64 patients.
- Interest in cell free DNA (cfDNA) continues to build. At the International Society for Heart and Lung Transplantation (ISHLT) meeting in April, CDNA presented three abstracts (all oral presentations) on the use of cfDNA as a marker in transplantation. Additionally, the company announced its presence in kidney transplant surveillance at the American Transplant Congress (ATC) last week.
- · DART study up and running. The DART trials, the two-phase cfDNA kidney trial in evaluating rejection in kidney transplants, enrolled the first of its 200 anticipated participants. The first data read-out is expected as planned in 1H16 and the initial results will determine the roll-out timing of the next phase, which will aim to establish clinical validity of cfDNA as a marker in kidney transplant surveillance.
- Collaboration with Diaxonhit (commercial partner in Europe) bearing fruit. CDNA continues to increase its presence in Europe, with the French Ministry of Health approving funding that will allow 15 transplant centers in France to use AlloMap to monitor their transplant patients.

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

S&P 600 Health Care Index: 1.606.69 Price: \$4.90 Price Target: \$10.00 Methodology: ~3.5x EV/TTM estimated revenue

ending Dec 2016

52 Week High: \$10.89 52 Week Low: \$4.88 Shares Outstanding (mil): 11.8 Market Capitalization (mil): \$57.8 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 - New	\$7.2A	\$7.4	\$7.4	\$7.7	\$29.8	(\$0.21)A	(\$0.17)	(\$0.19)	(\$0.20)	(\$0.77)	NM
2015E - Old	\$6.9	\$7.4	\$7.4	\$7.7	\$29.4	(\$0.19)	(\$0.20)	(\$0.20)	(\$0.21)	(\$0.81)	NM
2016E - New					\$33.7	İ				(\$0.73)	NM
2016E - Old					\$33.8	İ				(\$0.73)	NM
2017E					\$42.0					(\$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 ~6x, 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.

CareDx (CDNA)
Income statement

Dan Leonard, 212-277-6116

dan.leonard@leerink.co	n
------------------------	---

meetine statement												a continuo	
Period Ended (\$ thousands)	2013	Mar-14	Jun-14	Sep-14	Dec-14	2014	Mar-15	Jun-15e	Sep-15e	Dec-15e	2015e	2016e	2017e
Revenues													
Testing revenue	\$21,672	\$5,834	\$6,710	\$6,601	\$6,697	\$25,842	\$7,096	\$7,335	\$7,347	\$7,568	\$29,345	\$33,252	\$41,577
Other	<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	22,099	5,924	6,776	6,654	7,952	27,306	7,216	7,435	7,447	7,668	29,765	33,652	41,977
Cost of service	9,078	<u>2,162</u>	2,403	<u>1,772</u>	2,204	<u>8,541</u>	<u>2,711</u>	<u>2,528</u>	2,532	2,607	<u>10,378</u>	11,442	14,272
Gross profit	13,021	3,762	4,373	4,882	5,748	18,765	4,505	4,907	4,915	5,061	19,388	22,210	27,705
SG&A	10,701	3,269	3,926	3,729	3,984	14,908	4,728	4,535	4,543	4,754	18,560	19,518	20,988
R&D	<u>3,176</u>	<u>720</u>	<u>792</u>	<u>1,036</u>	<u>1,298</u>	<u>3,846</u>	<u>1,421</u>	2,007	<u>2,160</u>	2,224	<u>7,812</u>	<u>9,837</u>	<u>11,753</u>
Operating income (loss)	(856)	(227)	(345)	117	466	11	(1,644)	(1,636)	(1,787)	(1,917)	(6,984)	(7,144)	(5,037)
Interest expense (income)	2,150	548	644	535	389	2,116	827	431	432	432	2,122	1,734	1,741
Other, net	<u>536</u>	<u>529</u>	<u>(366)</u>	<u>(355)</u>	<u>45</u>	(147)	<u>54</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>54</u>	<u>0</u>	<u>0</u>
Pretax income	(3,542)	(1,304)	(623)	(63)	32	(1,958)	(2,525)	(2,067)	(2,219)	(2,349)	(9,160)	(8,878)	(6,778)
Taxes	<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	(\$3,542)	(\$1,304)	\$877	(\$63)	\$32	(\$458)	(\$2,525)	(\$2,067)	(\$2,219)	(\$2,349)	(\$9,160)	(\$8,878)	(\$6,778)
Basic shares outstanding	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	6,923	6,172	6,940	11,219	12,129	9,283	11,814	11,864	11,914	11,964	11,889	12,089	12,289
2 nation of the containing	0,020	0,2	0,0 .0	,	12,120	0,200	,	,	,	,	,000	.2,000	.2,200
EPS diluted EPS growth	(\$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)
Revenue growth	9.8%	21.3%	25.8%	15.5%	15.1%	19.2%	21.6%	9.3%	11.3%	13.0%	13.6%	13.3%	25.0%
Volume (Ths)	10.064	2,792	3,019	3,024	3,115	11,950	3,100	3,411	3,417	3,520	13,449	15.466	17,012
Gross margin	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	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	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	(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%	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	\$663	\$106	\$116	\$132	\$158	\$512	\$150	\$98	\$98	\$101	\$447	\$443	\$554
EBITDA	(\$193)	(\$121)	(\$229)	\$249	\$624	\$523	(\$1,494)	(\$1,538)	(\$1,689)	(\$1,816)	(\$6,537)	(\$6,701)	(\$4,483)
Free cash flow													
Operating cash flow	(\$546)	\$180	\$853	(\$3,661)	(\$722)	(\$3,350)				Г	(\$8,535)	(\$7,905)	(\$5,549)
CapX	(98)	(19)	(145)	(43,001)	(400)	(733)					(\$6,533) (241)	(746)	(1,120)
Free cash flow	(\$644)	\$161	\$708	(\$3,830)	(\$1,122)	(\$4,083)					(\$8,776)	(\$8,651)	(\$6,668)
		9101	9700	(ψυ,συσ)	(Ψ1,1ΖΖ)	(ψ+,003)					(ψο, / / ο)	(ψ0,001)	(ψ0,000)

Guidance

Revenue \$28 - \$30M

### Notes:

Source: Company reports and Leerink Partners estimates

(1) Excludes change in fair value of Immumetrix consideration



# Disclosures Appendix Analyst Certification

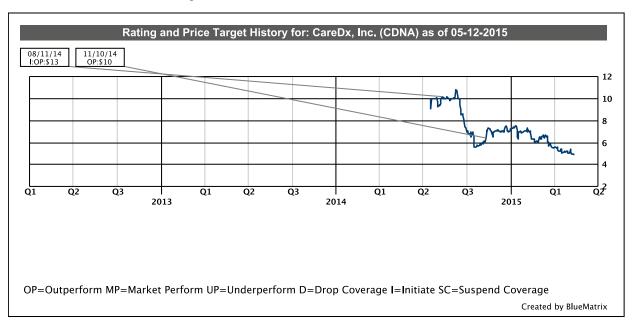
I, Dan Leonard, certify that the views expressed in this report accurately reflect my views and that no part of my compensation was, is, or will be directly related to the specific recommendation or views contained in this report.

### **Valuation**

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 ~6x, 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.





Di	Distribution of Ratings/Investment Banking Services (IB) as of 03/31/15 IB Serv./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**

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.

Like all Firm employees, analysts receive compensation that is impacted by, among other factors, overall firm profitability, which includes revenues from, among other business units, Institutional Equities, and Investment Banking. Analysts, however, are not compensated for a specific investment banking services transaction.

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.

©2015 Leerink Partners LLC. All rights reserved. This document may not be reproduced or circulated without our written authority.

Leerink Partners LLC Equity Research							
	Leernik Farmers L	Lo Equity Researc					
Director of Equity Research	John L. Sullivan, CFA	(617) 918-4875	john.sullivan@leerink.com				
Associate Director of Research	Alice C. Avanian, CFA	(617) 918-4544	alice.avanian@leerink.com				
	,	,					
Healthcare Strategy	John L. Sullivan, CFA	(617) 918-4875	john.sullivan@leerink.com				
	Alice C. Avanian, CFA	(617) 918-4544	alice.avanian@leerink.com				
Biotechnology	Howard Liang, Ph.D.	(617) 918-4857	howard.liang@leerink.com				
	Joseph P. Schwartz	(617) 918-4575	joseph.schwartz@leerink.com				
	Michael Schmidt, Ph.D.	(617) 918-4588	michael.schmidt@leerink.com				
	Gena Wang, Ph.D., CFA	(212) 277-6073	gena.wang@leerink.com				
	Paul Matteis	(617) 918-4585	paul.matteis@leerink.com				
	Jonathan Chang, Ph.D.	(617) 918-4015	jonathan.chang@leerink.com				
	Richard Goss	(617) 918-4059	richard.goss@leerink.com				
Life Science Tools	Dan Leonard	(212) 277-6116	dan.leonard@leerink.com				
& Diagnostics	Kevin C. Chen	(212) 277-6045	kevin.chen@leerink.com				
		(0.17) 0.10 10.11	, , , , , , , ,				
Pharmaceuticals/Major	Seamus Fernandez	(617) 918-4011	seamus.fernandez@leerink.com				
	Aneesh Kapur	(617) 918-4576	aneesh.kapur@leerink.com				
Specialty Pharmaceuticals	Jason M. Gerberry, JD	(617) 918-4549	jason.gerberry@leerink.com				
	Derek C. Archila	(617) 918-4851	derek.archila@leerink.com				
Medical Devices, Cardiology	Danielle Antalffy	(212) 277-6044	danielle.antalffy@leerink.com				
	Puneet Souda	(212) 277-6091	puneet.souda@leerink.com				
& Orthopedics	Richard Newitter	(212) 277-6088	richard.newitter@leerink.com				
	Ravi Misra	(212) 277-6049	ravi.misra@leerink.com				
Healthcare Services	Ana Gupte, Ph.D.	(212) 277 6040	ana.gupte@leerink.com				
Healthcare Services	Ana Gupte, Fil.D.	(212) 277-6040	ana.gupte@leenink.com				
Healthcare Technology	David Larsen, CFA	(617) 918-4502	david.larsen@leerink.com				
& Distribution	Christopher Abbott	(617) 918-4010	chris.abbott@leerink.com				
Digital Health	Steven Wardell	(617) 918-4097	steven.wardell@leerink.com				
Sr. Editor/Supervisory Analyst	Mary Ellen Eagan, CFA	(617) 918-4837	maryellen.eagan@leerink.com				
Supervisory Analysts	Randy Brougher		randy.brougher@leerink.com				
	Robert Egan		bob.egan@leerink.com				
	Amy N. Sonne		amy.sonne@leerink.com				

**New York** 299 Park Avenue, 21<sup>st</sup> floor New York, NY 10171 (888) 778-1653 Boston One Federal Street, 37<sup>th</sup> Floor Boston, MA 02110 (800) 808-7525 San Francisco 255 California Street, 12th Floor San Francisco, CA 94111 (415) 905-7200