November 10, 2014

**OUTPERFORM** 

Dan Leonard (212) 277-6116

Dan.Leonard@Leerink.com

**Justin Bowers, CFA** (212) 277-6066

Justin.Bowers@Leerink.com

Reason for report: **EARNINGS** 

Carmen Augustine

(212) 277-6012

Carmen.Augustine@Leerink.com



## CAREDX, INC.

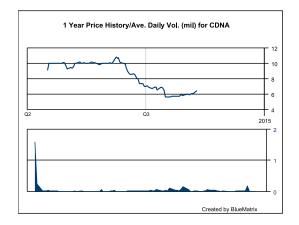
Another Steady Q, Look to 1H15 for Upcoming Catalysts; Reit. OP at \$10 PT

- **Bottom Line:** CareDx reported 3Q14 results after the close November 10. We reiterate our Outperform rating following the quarter while reducing our price target to \$10 from \$13 due to compression of the group multiple.
- Revenue beat and positive operating margin track with growth expectations. Revenue for the quarter came in at \$6.7M, above our \$6.6M estimate. AlloMap test volumes came in at >3,000, representing 16% YoY volume growth. Gross margin came in at 73.4%, above our estimate of 65%. Gross margin includes a \$550k one-time benefit from the reversal of an accrual related to the Roche settlement, the exclusion of which brings gross margin in line with our estimate. EBIT margin came in at 1.8%, above our (18.5%) estimate, driven primarily by lower-than-anticipated R&D expense. EBIT margin excludes a \$1.3M benefit in the quarter from the reversal of a contingent consideration owed to ImmuMetrix shareholders.
- AlloMap growth is tracking to expectations, with data discussion on the Outcomes AlloMap Registry (OAR) expected at the International Society for Heart & Lung Transplantation (ISHLT) in April 2015. AlloMap is used in 105 of 125 heart transplant centers (no change since 2Q14). 45 centers have now established official protocols while 28 are developing a protocol or utilization policy. OAR has ~750 patient results from 300 patients as of Sept. 30, up from 500 in June. Reimbursement collection remains steady at ~79% of AlloMap tests delivered in the 12 months ended March 31, 2014.
- Pipeline cell free DNA (cfDNA) products on track for upcoming data disclosures and cfDNA kidney trial launch in 1H15. Enrollment in the cfDNA outcomes registry (D-OAR) in heart is progressing on track, with abstracts submitted for data discussion at ISHLT 2015. cfDNA kidney development continues on track behind cfDNA heart, with initial validation data from the KARGO historical sample expected in 1H15. Management plans to commence a cfDNA kidney clinical study (KIDNA prospective study) in mid-2015 following positive validation data from the KARGO study.
- Our estimates remain largely unchanged aside from shifting R&D expense from 2014 to 2015-16 to account for timing of clinical trial costs. We lower our price target to \$10 from \$13 due to compression of the group multiple.

Key Stats:	(NASDAQ:CDNA)
SSD 600 Health Care Index:	4 260 47

Price: \$6.41
Price Target: \$10.00 from \$13.00
Methodology: ~3x EV/TTM estimated revenue ending
Sept 2016

52 Week High: \$10.89 52 Week Low: \$5.40 Shares Outstanding (mil): 12.0 Market Capitalization (mil): \$76.9 Book Value/Share: \$3.42 Cash Per Share: \$3.25 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	\$5.0	\$5.5	\$5.8	\$5.9	\$22.1	(\$0.19)	(\$0.12)	(\$0.12)	(\$0.08)	(\$0.51)	NM
2014E - New	\$5.9A	\$6.8A	\$6.7A	\$7.0	\$26.3	(\$0.21)A	\$0.13A	(\$0.01)A	(\$0.07)	(\$0.14)	NM
2014E - Old	\$5.9A	\$6.8A	\$6.6	\$7.0	\$26.2	(\$0.21)A	\$0.13A	(\$0.15)	(\$0.10)	(\$0.37)	NM
2015E - New					\$30.1			`		(\$0.49)	NM
2015E - Old					\$30.3					(\$0.43)	NM
2016E - New					\$40.1	i				(\$0.10)	NM
2016E - Old					\$40.3					(\$0.08)	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.

CAREDX, INC. November 10, 2014



## **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 1H15. 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 ~3x our revenue estimate for the twelve months ended Sept-16. This is in line with the tools/diagnostics peer group median multiple, which we believe adequately 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, INC. November 10, 2014

CareDx (CDNA)

Dan Leonard, 212-277-6116

Income statement								dan.leonard	@leerink.com
Period Ended (\$ thousands)	2012	2013	Mar-14	Jun-14	Sep-14	Dec-14e	2014e	2015e	2016e
Revenues									
Testing revenue	\$19,730	\$21,672	\$5,834	\$6,710	\$6,601	\$6,861	\$26,006	\$29,312	\$38,536
Other	<u>721</u>	<u>426</u>	<u>90</u>	<u>66</u>	<u>53</u>	<u>90</u>	<u>299</u>	800	1,600
Total revenues	20,451	22,099	5,924	6,776	6,654	6,951	26,305	30,112	40,136
Cost of service	<u>7,930</u>	<u>9,078</u>	<u>2,162</u>	<u>2,403</u>	<u>1,772</u>	2,433	<u>8,770</u>	10,539	<u>13,847</u>
Gross profit	12,521	13,021	3,762	4,373	4,882	4,518	17,535	19,573	26,289
SG&A	10,111	10,701	3,269	3,926	3,729	3,823	14,747	15,658	18,061
R&D	<u>4,752</u>	<u>3,176</u>	<u>720</u>	<u>792</u>	<u>1,036</u>	<u>1,112</u>	<u>3,660</u>	<u>8,431</u>	<u>8,027</u>
Operating income (loss)	(2,342)	(856)	(227)	(345)	117	(417)	(872)	(4,517)	201
Interest expense (income)	2,703	2,150	548	644	535	372	2,099	1,397	1,400
Other, net	<u>14</u>	<u>536</u>	<u>529</u>	(366)	<u>(355)</u>	<u>0</u>	(192)	<u>0</u>	<u>0</u>
Pretax income	(5,059)	(3,542)	(1,304)	(623)	(63)	(789)	(2,779)	(5,914)	(1,199)
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>
Net income	(\$5,059)	(\$3,542)	(\$1,304)	\$877	(\$63)	(\$789)	(\$1,279)	(\$5,914)	(\$1,199)
Basic shares outstanding	6,913	6,923	6,172	1,013	9,280	12,000	7,116	12,125	12,325
Diluted shares outstanding	6,913	6,923	6,172	6,940	11,219	12,000	9,083	12,125	12,325
EPS diluted	(\$0.73)	(\$0.51)	(\$0.21)	\$0.13	(\$0.01) (1)	(\$0.07)	(\$0.14)	(\$0.49)	(\$0.10)
EPS growth									
Revenue growth		9.8%	21.3%	25.8%	15.5%	18.0%	20.0%	12.7%	31.5%
Volume (Ths)	8,337	10,064	2,792	3,000	3,020	3,191	12,003	13,564	15,598
Gross margin	61.2%	58.9%	63.5%	64.5%	73.4%	65.0%	66.7%	65.0%	65.5%
SG&A % of revenue	49.4%	48.4%	55.2%	57.9%	56.0%	55.0%	56.1%	52.0%	45.0%
R&D % of revenue	23.2%	14.4%	12.2%	11.7%	15.6%	16.0%	13.9%	28.0%	20.0%
Operating margin	(11.5%)	(3.9%)	(3.8%)	(5.1%)	1.8%	(6.0%)	(3.3%)	(15.0%)	0.5%
Tax rate	0.0%	0.0%	0.0%	240.8%	0.0%	0.0%	54.0%	0.0%	0.0%
D&A expense	\$1,072	\$663	\$106	\$116	\$115	\$91	\$428	\$391	\$514
EBITDA	(\$1,270)	(\$193)	(\$121)	(\$229)	\$232	(\$326)	(\$444)	(\$4,126)	\$714
Free cash flow									
Operating cash flow	(\$1,776)	(\$546)	\$180	\$853			(\$7)	(\$4,910)	(\$36)
CapX	(141)	<u>(98)</u>	<u>(19)</u>	<u>(145)</u>			<u>(219)</u>	(669)	<u>(1,117)</u>
Free cash flow	(\$1,917)	(\$644)	\$1 <del>61</del>	\$708			(\$226)	(\$5,578)	(\$1,154)
	\ ' ' /	١٠ /	•			<u> </u>	١٠ - / ١	\· , -/	' ' - /

Guidance

Revenue \$26 - \$26.5M

#### Notes:

Source: Company reports and Leerink Partners estimates

<sup>(1)</sup> Excludes \$1.3M in benefit from change in fair value of Immumetrix consideration

CAREDX, INC. November 10, 2014

# CareDx (CDNA) Balance sheet

Balance sheet					
Period Ended (\$ thousands)	Dec-13	Mar-14	Jun-14	Sep-14	Dec-14e
Assets					_
Cash, equivalents, ST investments, restricted cash	\$5,128	\$4,837	\$7,872	\$39,048	\$37,136
Accounts receivable	2,270	2,093	1,725	1,749	2,285
Inventory	518	725	614	496	587
Prepaid expenses and other current assets	<u>255</u>	<u>1,825</u>	<u>3,319</u>	<u>718</u>	<u>556</u>
Total current assets	8,171	9,480	13,530	42,011	40,564
Property and equipment, net	1,553	1,466	1,665	2,049	1,830
Restricted cash / LT investments	147	147	147	147	147
Other assets	<u>2</u>	<u>2</u>	<u> 18,655</u>	<u> 18,655</u>	<u> 18,655</u>
Total assets	\$9,873	\$11,095	\$33,997	\$62,862	\$61,196
Liabilities and shareholders' equity					
Notes payable - current portion	\$4,461	\$5,485	\$10,434	\$5,798	\$4,200
Accounts payable	618	781	1,741	1,036	830
Accruals	2,434	4,247	8,365	3,611	2,780
Other liabilities	<u>80</u>	<u>65</u>	<u>674</u>	<u>673</u>	<u>673</u>
Total current liabilities	7,593	10,578	21,214	11,118	8,483
Notes payable - long-term portion	10,914	9,591	8,338	6,930	8,528
Other liabilities	<u>6,837</u>	<u>7,648</u>	<u>5,911</u>	<u>3,775</u>	<u>3,775</u>
Total liabilities	\$25,344	\$27,817	\$35,463	\$21,823	\$20,786
Convertible preferred stock	\$135,202	\$135,202	\$149,444	\$0	\$0
Shareholders' equity	(\$150,673)	(\$151,924)	(\$150,910)	\$41,039	\$40,409
Total liabilities and shareholders' equity	\$9,873	\$11,095	\$33,997	\$62,862	\$61,196

Source: Company reports and Leerink Partners estimates



## Disclosures Appendix Analyst Certification

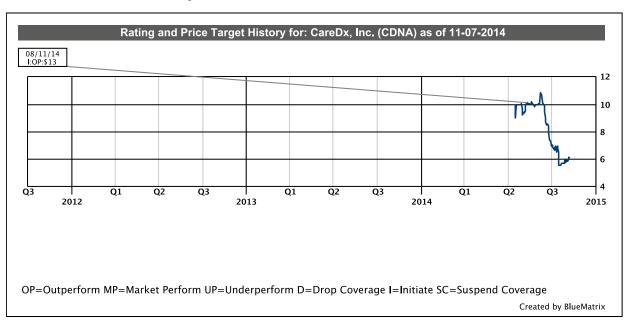
I, Dan Leonard, certify that the views expressed in this report accurately reflect my views and that no part of my compensation was, is, or will be directly related to the specific recommendation or views contained in this report.

## **Valuation**

Our \$10 price target corresponds to an enterprise value (using projected levels of debt and cash) that is ~3x our revenue estimate for the twelve months ended Sept-16. This is in line with the tools/diagnostics peer group median multiple, which we believe adequately 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.





Distribution of Ratings/Investment Banking Services (IB) as of 09/30/14 IB Serv./Past 13 Mos					
Rating	Count	Percent	Count	Percent	
BUY [OP]	138	69.30	51	37.00	
HOLD [MP]	61	30.70	2	3.30	
SELL [ŪP]	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.



©2014 Leerink Partners LLC. All rights reserved. This document may not be reproduced or circulated without our written authority.

Leerink Partners LLC Equity Research							
	Leerink Partners L	Lo Equity Resear	511				
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				
	7, 0.77	(011) 010 1011					
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				
and Diagnostics	Justin Bowers, CFA	(212) 277-6066	justin.bowers@leerink.com				
and Diagnooned	oddin Bowolo, Olivi	(212) 211 0000	jacan need cheer made n				
Pharmaceuticals/Major	Seamus Fernandez	(617) 918-4011	seamus.fernandez@leerink.com				
•	Ario Arabi	(617) 918-4568	ario.arabi@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				
O Outhouse Page	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				
nealtricare Services	Ana Gupte, Fil.D.	(212) 277-0040	ana.gupte@leennk.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	Robert Egan		bob.egan@leerink.com				
	Amy N. Sonne		amy.sonne@leerink.com				
Editorial	Cristina Diaz-Dickson	(617) 918-4548	cristina.diaz-dickson@leerink.com				
Research Associate	Carmen Augustine	(212) 277-6012	carmen.augustine@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 201 Spear Street, 16<sup>th</sup> Floor San Francisco, CA 94105 (800) 778-1164