

March 17, 2015

## OUTPERFORM

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Reason for report:

## EARNINGS

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## CAREDX, INC.

### Beat Driven by LabCorp Rev; Kidney Product Pushed Out

• **Bottom Line:** We have reduced our 2016-2017 revenue estimates for CDNA following disclosure that the development timeline for its kidney transplant monitoring product is elongated vs our prior expectation. Nonetheless, we reiterate our Outperform rating and \$10 price target.

• **Revenue beat driven by LabCorp payments.** CDNA reported 4Q revenue of \$8.0M, above our \$7.0M expectation due to a one-time \$1.1M payment from LH on a lupus project-related rights transfer. AlloMap volumes were ~3,100, up 13% YoY growth.

• **cfDNA in kidney timeline elongated; revenue pushed to 2017.** Mgmt announced a new two-phase cell-free (cf) DNA kidney trial, DART, replacing the KIDNA trial which was slated to begin in 2H15. The study will collect 18-month longitudinal samples from 200 patients in 10+ centers, with an early read-out after 6 months. The first phase of DART will establish clinical validity while the latter establishes utility. The original KARGO set of 300 samples included 222 qualified for analysis, but the data (from '04) had a number of limitations making it insufficient for a full clinical validation study. We expect DART enrollment to begin as early as 1H15, with the first data read-out in 9-12 months. We previously had assumed ~\$5M in kidney associated revenue in 2016E, but now push this expectation to 2017E.

• **cfDNA heart updates expected at ISHLT in April.** Enrollment in the D-OAR outcomes study continues on track, with 22 patients enrolled and 52 samples collected as of Dec. 31. Data from CARGO-2 were accepted as an abstract at ISHLT in addition to two other cfDNA abstracts. Two abstracts were accepted as presentations.

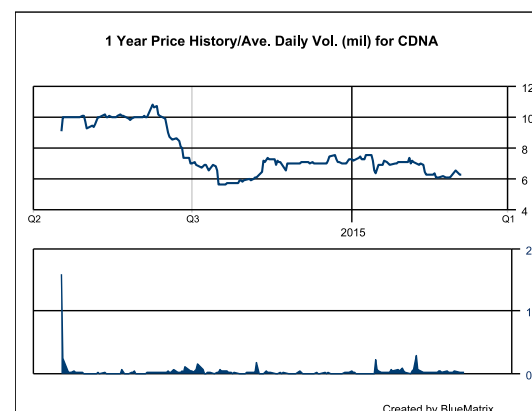
• **AlloMap commercialization tracks with expectations.** AlloMap is now used in 110/125 US transplant centers (up from 105 in Sept.), with 48 centers establishing a protocol (up from 45). As of Dec. 31, the Outcomes AlloMap Registry (OAR) had >1,000 samples from 364 patients, up from ~750 as of Sept. Encouragingly, data from the e-IMAGE study, a randomized study from Cedar Sinai Medical Center comparing AlloMap to biopsy, will be published in the journal *Circulation* soon, which could fuel commercialization efforts.

• **We've reduced estimates to account for changes in the kidney program and higher SG&A expense.**

### Key Stats:

(NASDAQ:CDNA)

<b>S&amp;P 600 Health Care Index:</b>	<b>1,612.47</b>
<b>Price:</b>	<b>\$6.64</b>
Price Target:	\$10.00
Methodology:	~3.5x EV/TTM estimated revenue ending Dec 2016
52 Week High:	\$10.89
52 Week Low:	\$5.40
Shares Outstanding (mil):	12.0
Market Capitalization (mil):	\$79.7
Book Value/Share:	\$3.42
Cash Per Share:	\$3.00
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	\$6.9	\$7.4	\$7.4	\$7.7	\$29.4	(\$0.19)	(\$0.20)	(\$0.20)	(\$0.21)	(\$0.81)	NM
2015E - Old	--	--	--	--	\$30.1	--	--	--	--	(\$0.49)	NM
2016E - New	--	--	--	--	\$33.8	--	--	--	--	(\$0.73)	NM
2016E - Old	--	--	--	--	\$40.1	--	--	--	--	(\$0.10)	NM

Source: Company Information and Leerink Partners LLC Research  
Revenues in millions.

3Q14 excludes \$1.2m benefit from reversal of contingent consideration allowance for ImmuMatrix 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 slight discount to the tools/diagnostics peer group median multiple of ~4x, 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 (CDNA)

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## Income statement

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Period Ended (\$ thousands)	2013	Mar-14	Jun-14	Sep-14	Dec-14	2014	Mar-15e	Jun-15e	Sep-15e	Dec-15e	2015e	2016e
Revenues												
Testing revenue	\$21,672	\$5,834	\$6,710	\$6,601	\$6,697	\$25,842	\$6,783	\$7,335	\$7,347	\$7,568	\$29,033	\$33,387
Other	426	90	66	53	1,255	1,464	100	100	100	100	400	400
Total revenues	22,099	5,924	6,776	6,654	7,952	27,306	6,883	7,435	7,447	7,668	29,433	33,787
Cost of service	9,078	2,162	2,403	1,772	2,204	8,541	2,340	2,528	2,532	2,607	10,007	11,488
Gross profit	13,021	3,762	4,373	4,882	5,748	18,765	4,543	4,907	4,915	5,061	19,425	22,300
SG&A	10,701	3,269	3,926	3,729	3,984	14,908	4,336	4,684	4,691	4,831	18,542	19,597
R&D	3,176	720	792	1,036	1,298	3,846	2,203	2,379	2,383	2,454	9,418	10,474
Operating income (loss)	(856)	(227)	(345)	117	466	11	(1,996)	(2,156)	(2,160)	(2,224)	(8,535)	(7,771)
Interest expense (income)	2,150	548	644	535	389	2,116	312	313	313	314	1,252	1,260
Other, net	536	529	(366)	(355)	45	(147)	0	0	0	0	0	0
Pretax income	(3,542)	(1,304)	(623)	(63)	32	(1,958)	(2,308)	(2,469)	(2,473)	(2,538)	(9,787)	(9,031)
Taxes	0	0	(1,500)	0	0	(1,500)	0	0	0	0	0	0
Net income	(\$3,542)	(\$1,304)	\$877	(\$63)	\$32	(\$458)	(\$2,308)	(\$2,469)	(\$2,473)	(\$2,538)	(\$9,787)	(\$9,031)
Basic shares outstanding	6,923	6,172	1,013	9,280	11,802	5,816	12,050	12,100	12,150	12,200	12,125	12,325
Diluted shares outstanding	6,923	6,172	6,940	11,219	12,129	9,283	12,050	12,100	12,150	12,200	12,125	12,325
EPS diluted	(\$0.51)	(\$0.21)	\$0.13	(\$0.01) (1)	\$0.00	(\$0.05)	(\$0.19)	(\$0.20)	(\$0.20)	(\$0.21)	(\$0.81)	(\$0.73)
EPS growth												
Revenue growth	9.8%	21.3%	25.8%	15.5%	15.1%	19.2%	16.3%	9.3%	11.3%	13.0%	12.3%	15.0%
Volume (Ths)	10,064	2,792	3,019	3,024	3,115	11,950	3,155	3,411	3,417	3,520	13,504	15,529
Gross margin	58.9%	63.5%	64.5%	73.4%	72.3%	68.7%	66.0%	66.0%	66.0%	66.0%	66.0%	66.0%
SG&A % of revenue	48.4%	55.2%	57.9%	56.0%	50.1%	54.6%	63.0%	63.0%	63.0%	63.0%	63.0%	58.0%
R&D % of revenue	14.4%	12.2%	11.7%	15.6%	16.3%	14.1%	32.0%	32.0%	32.0%	32.0%	32.0%	31.0%
Operating margin	(3.9%)	(3.8%)	(5.1%)	1.8%	5.9%	0.0%	(29.0%)	(29.0%)	(29.0%)	(29.0%)	(29.0%)	(23.0%)
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%
D&A expense	\$663	\$106	\$116	\$132	\$130	\$484	\$90	\$98	\$98	\$101	\$387	\$445
EBITDA	(\$193)	(\$121)	(\$229)	\$249	\$596	\$495	(\$1,906)	(\$2,058)	(\$2,062)	(\$2,123)	(\$8,148)	(\$7,326)
Free cash flow												
Operating cash flow	(\$546)	\$180	\$853	(\$3,661)		(\$4,128)					(\$9,398)	(\$8,055)
CapX	(98)	(19)	(145)	(169)		(493)					(437)	(748)
Free cash flow	(\$644)	\$161	\$708	(\$3,830)		(\$4,621)					(\$9,836)	(\$8,803)

## Guidance

Revenue

\$28 - \$30M

## Notes:

Source: Company reports and Leerink Partners estimates

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

**CareDx (CDNA)****Balance sheet**

Period Ended (\$ thousands)	Mar-14	Jun-14	Sep-14	Dec-14	Mar-15e	Jun-15e	Sep-15e	Dec-15e
x Assets								
Cash, equivalents, ST investments, restricted cash	\$4,837	\$7,872	\$39,048	\$36,431	\$33,985	\$31,800	\$29,673	\$27,455
Accounts receivable	2,093	1,725	1,749	2,687	2,263	2,444	2,448	2,521
Inventory	725	614	496	686	564	609	610	629
Prepaid expenses and other current assets	<u>1,825</u>	<u>3,319</u>	<u>718</u>	<u>542</u>	<u>551</u>	<u>595</u>	<u>596</u>	<u>613</u>
Total current assets	9,480	13,530	42,011	40,346	37,363	35,448	33,328	31,218
Property and equipment, net	1,466	1,665	2,049	1,968	1,809	1,956	1,959	2,018
Restricted cash / LT investments	147	147	147	147	147	147	147	147
Other assets	<u>2</u>	<u>18,655</u>	<u>18,655</u>	<u>18,680</u>	<u>18,680</u>	<u>18,680</u>	<u>18,680</u>	<u>18,680</u>
Total assets	\$11,095	\$33,997	\$62,862	\$61,141	\$57,999	\$56,231	\$54,114	\$52,063
x Liabilities and shareholders' equity								
Notes payable - current portion	\$5,485	\$10,434	\$5,798	\$5,961	\$3,766	\$3,766	\$3,766	\$3,766
Accounts payable	781	1,741	1,036	1,128	729	846	833	863
Accruals	4,247	8,365	3,611	3,541	2,753	2,974	2,979	3,067
Other liabilities	<u>65</u>	<u>674</u>	<u>673</u>	<u>505</u>	<u>505</u>	<u>505</u>	<u>505</u>	<u>505</u>
Total current liabilities	10,578	21,214	11,118	11,135	7,754	8,091	8,082	8,201
Notes payable - long-term portion	9,591	8,338	6,930	5,451	7,646	7,646	7,646	7,646
Other liabilities	<u>7,648</u>	<u>5,911</u>	<u>3,775</u>	<u>3,257</u>	<u>3,257</u>	<u>3,257</u>	<u>3,257</u>	<u>3,257</u>
Total liabilities	\$27,817	\$35,463	\$21,823	\$19,843	\$18,657	\$18,994	\$18,985	\$19,104
Convertible preferred stock	\$135,202	\$149,444	\$0	\$0	\$0	\$0	\$0	\$0
x Shareholders' equity	(\$151,924)	(\$150,910)	\$41,039	\$41,298	\$39,342	\$37,237	\$35,128	\$32,959
x Total liabilities and shareholders' equity	\$11,095	\$33,997	\$62,862	\$61,141	\$57,999	\$56,231	\$54,114	\$52,063

Source: Company reports and Leerink Partners estimates

## Disclosures Appendix

### Analyst Certification

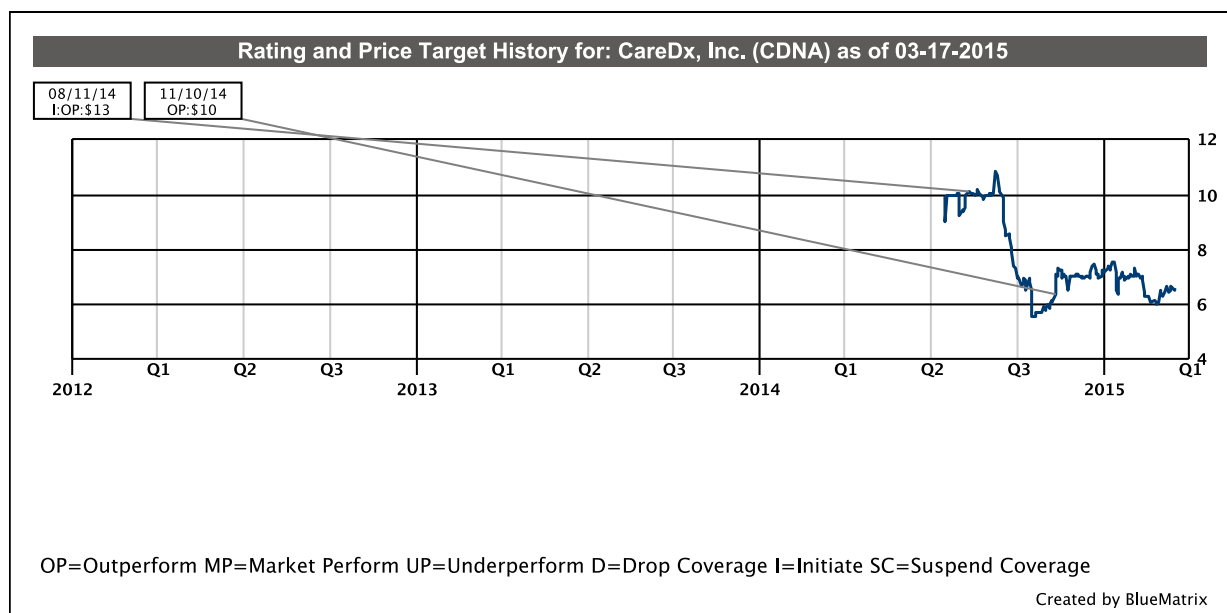
I, Dan Leonard, certify that the views expressed in this report accurately reflect my views and that no part of my compensation was, is, or will be directly related to the specific recommendation or views contained in this report.

### Valuation

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### Risks to Valuation

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Distribution of Ratings/Investment Banking Services (IB) as of 12/31/14				
Rating	Count	Percent	IB Serv./Past 12 Mos.	
			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

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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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