

CareDx, Inc. (CDNA)

Overweight

Incremental cfDNA Details Revealed At ISHLT; Remain Overweight

CONCLUSION

Management presented additional details on its fledgling dd-cfDNA (donor derived cell free DNA) assay for heart transplant rejection detection, with the 266 SNP assay expected to run on Illumina's MiSeq platform. Additionally, management described its cfDNA efforts as potentially yielding a universal transplant rejection assay (e.g. lung, liver, kidney), although management reiterated their focus on the largest opportunity initially (kidney, ~16.9K transplants annually, ~180K patient pool). Consistent with our initial perusal of ISHLT abstracts (see our note [here](#)), management highlighted the improved performance of its AlloMap heart assay when combined with dd-cfDNA, with AUC increasing to 0.78 (vs. 0.68 in AlloMap & dd-cfDNA alone).

- **Additional dd-cfDNA Details:** During the ongoing ISHLT meeting (Nice, France April 15-18), management held an investor update, providing incremental details on its dd-cfDNA test. As previously announced, CareDx' initial dd-cfDNA assay will target heart transplant rejection, with the assay evaluating 266 SNPs and designed to run on Illumina's MiSeq. Importantly, key opinion leader Dr. Jon Kobashigawa believes cfDNA may ultimately be a universal assay for transplant organ rejection detection, suggesting potential applications beyond heart and kidney (e.g. lung, liver). Management reiterated its intent to offer its dd-cfDNA assay as a no-cost add-on to its AlloMap assay, launching in April as a RUO offering, with an analytically validated assay expected to launch December 2015. Management suggested additional cfDNA data at the upcoming American Transplantation Congress meeting (Philadelphia, May 2-6, 2015), representing a potential catalyst for CDNA shares.
- **ISHLT Data Recap:** CDNA assessed 151 plasma and 132 biopsy samples (63 patients) from the CARGO II study, with cfDNA levels significantly higher ($p=0.017$) during biopsy-confirmed rejection events compared to stable patients (AUC: 0.68, 95% CI: 0.56-0.80). Additionally, out of 16 cases with >2 serial samples, 63% of cfDNA levels were elevated up to 25 days prior to rejection. The study's authors noted cfDNA levels and AlloMap scores (which also had an AUC of 0.68) were not correlated and combining the two tests (cfDNA + AlloMap score) increased AUC to 0.78 (95% CI 0.67-0.87) and detected rejection ($P<0.0001$). In a separate study, CDNA assessed 17 rejection-confirmed patients from the CARGO II trial who had consecutive blood samples taken from both treatment (initial rejection) and post-treatment (after rejection) visits. In 60% of grade 0R (i.e. quiescent) post-treatment biopsies, cfDNA levels decreased 1.8-fold, while 54% of patients without a significant decrease in cfDNA levels ($n=11$) experienced a 1R or 2R grade rejection within 30 days. We view the cfDNA data as encouraging and believe a cfDNA/AlloMap approach is unique, as a combined test may provide an incremental benefit vs. a single assay.

RISKS TO ACHIEVEMENT OF PRICE TARGET

Risks: weaker-than-expected AlloMap penetration, pipeline delays and competition.

COMPANY DESCRIPTION

CareDx develops novel tests for recipient organ transplant surveillance.

YEAR	REVENUE (US\$ m)						EARNINGS PER SHARE (US\$)					
	Mar	Jun	Sep	Dec	FY	FY RM	Mar	Jun	Sep	Dec	FY	FY P/E
2014A	5.9	6.8	6.7	8.0	27.3	2.4x	(0.21)	0.02	0.12	0.00	(0.08)	NM
2015E	6.8	7.1	7.4	7.7	29.0	2.2x	(0.18)	(0.19)	(0.18)	(0.16)	(0.72)	NM
2016E	8.2	8.7	9.2	9.7	35.8	1.8x	(0.15)	(0.13)	(0.12)	(0.12)	(0.51)	NM

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PRICE: US\$5.38

TARGET: US\$8.00

3.2x FY17E EV/Revenue discounted 25% to FY16E (FY17E Rev: \$43.4M, FY16E: 13.2M shares outstanding, \$0.02 in net debt/sh).

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Changes	Previous	Current
Rating	—	Overweight
Price Tgt	—	US\$8.00
FY15E Rev (mil)	—	US\$29.0
FY16E Rev (mil)	—	US\$35.8
FY15E EPS	—	US\$(0.72)
FY16E EPS	—	US\$(0.51)
52-Week High / Low	US\$10.89 / US\$5.02	
Shares Out (mil)	12.1	
Market Cap. (mil)	US\$65.1	
Avg Daily Vol (ooo)	37	
Book Value/Share	US\$3.40	
Net Cash Per Share	US\$2.06	
Debt to Total Capital	22%	
Yield	0.00%	
Fiscal Year End	Dec	

Price Performance - 1 Year

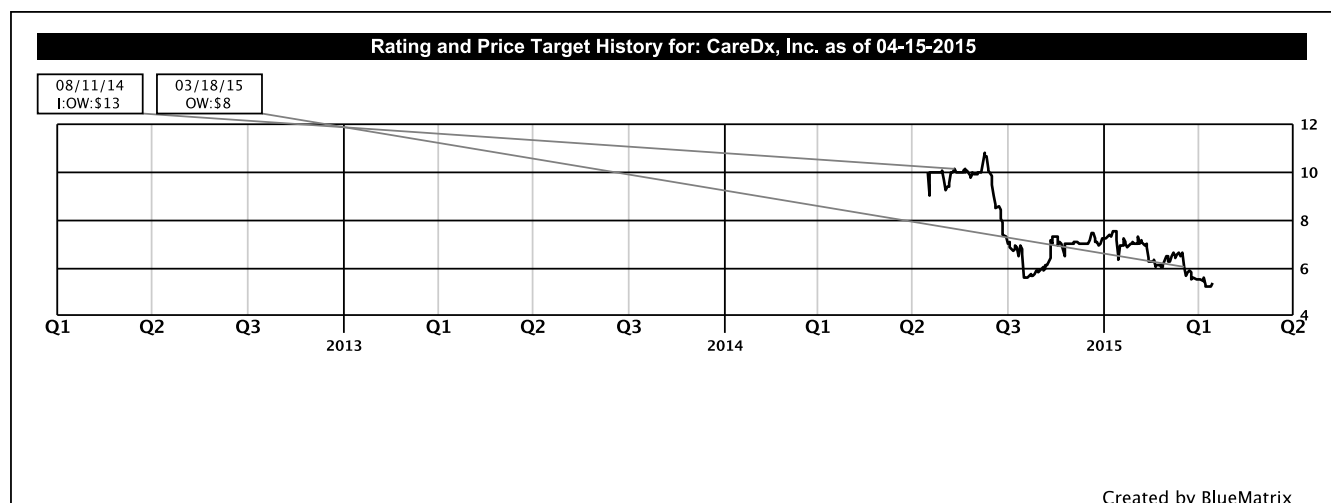


Source: Bloomberg

	2014A				2015E				2016E				Annual				
	Mar Qtr 1 A	Jun Qtr 2 A	Sep Qtr 3 A	Dec Qtr 4 A	Mar Qtr 1 E	Jun Qtr 2 E	Sep Qtr 3 E	Dec Qtr 4 E	Mar Qtr 1 E	Jun Qtr 2 E	Sep Qtr 3 E	Dec Qtr 4 E	2013A	2014A	2015E	2016E	2017E
Total Revenue	5,924	6,776	6,654	7,952	6,757	7,145	7,393	7,743	8,234	8,697	9,178	9,672	22,098	27,306	29,038	35,781	43,378
Cost of Product Revenue	2,162	2,403	1,772	2,204	2,262	2,343	2,356	2,406	2,519	2,612	3,055	3,409	9,078	8,541	9,368	11,595	15,417
Gross Profit	3,762	4,373	4,882	5,748	4,495	4,801	5,036	5,338	5,714	6,085	6,123	6,263	13,020	18,765	19,670	24,185	27,961
Operating Expenses:																	
Research & Development - Total	720	792	1,036	1,298	1,937	2,268	2,355	2,396	2,550	2,610	2,666	2,715	0	3,846	8,956	10,541	10,783
Research & Development - Core	720	792	961	1,198	1,824	2,143	2,218	2,246	2,388	2,435	2,478	2,515	3,176	3,671	8,431	9,816	9,733
RUO Heart	-	-	75	100	113	125	138	150	163	175	188	200	0	175	525	725	1,050
Sales & Marketing	1,474	1,610	1,753	1,635	2,335	2,510	2,535	2,560	2,690	2,740	2,645	2,695	5,891	6,472	9,940	10,770	11,555
General & Administrative	1,795	1,566	1,976	2,349	2,027	2,036	2,063	2,091	2,058	2,087	2,111	2,128	4,808	7,686	8,217	8,384	8,664
Other		750	(1,276)	37					110	110	110	110					
Total Operating Expense	3,989	4,718	3,489	5,319	6,299	6,815	6,953	7,046	7,409	7,547	7,531	7,648	13,875	17,515	27,113	30,135	31,442
Operating Income (Loss)	(227)	(345)	1,393	429	(1,804)	(2,013)	(1,917)	(1,709)	(1,694)	(1,463)	(1,408)	(1,385)	(855)	1,250	(7,443)	(5,950)	(3,480)
Interest & other income (expense), net	(1,077)	(278)	(69)	(434)	(404)	(382)	(380)	(360)	(310)	(291)	(267)	(251)	(2,686)	(1,858)	(1,526)	(1,119)	(782)
Pretax Income (Loss)	(1,304)	(623)	1,324	(5)	(2,209)	(2,395)	(2,296)	(2,069)	(2,004)	(1,754)	(1,675)	(1,635)	(3,540)	(608)	(8,969)	(7,069)	(4,263)
Provision for Income Taxes	0	(1,500)	0	0	0	0	0	0	0	0	0	0	0	(1,500)	0	0	0
Net Income (Loss) - Reported	(1,304)	877	1,324	(5)	(2,209)	(2,395)	(2,296)	(2,069)	(2,004)	(1,754)	(1,675)	(1,635)	(3,540)	892	(8,969)	(7,069)	(4,263)
SBC	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Non-Recurring	0	(750)	0	0	0	0	0	0	110	110	110	110	0	(750)	0	440	440
Net Income (Loss) - Ongoing (w/ SBC)	(1,304)	127	1,324	(5)	(2,209)	(2,395)	(2,296)	(2,069)	(1,894)	(1,644)	(1,565)	(1,525)	(3,540)	142	(8,969)	(6,629)	(3,823)
Net Income (Loss) - Non-GAAP	(1,304)	127	1,324	(5)	(2,209)	(2,395)	(2,296)	(2,069)	(1,894)	(1,644)	(1,565)	(1,525)	(3,540)	142	(8,969)	(6,629)	(3,823)
Net Income (assuming 40% Tax)																	
Diluted EPS (Reported)	(0.21)	0.13	0.12	(0.00)	(0.18)	(0.19)	(0.18)	(0.16)	(0.16)	(0.14)	(0.13)	(0.12)	(0.35)	0.03	(0.72)	(0.54)	(0.32)
Diluted EPS (Ongoing, w/ SBC)	(0.21)	0.02	0.12	(0.00)	(0.18)	(0.19)	(0.18)	(0.16)	(0.15)	(0.13)	(0.12)	(0.12)	(0.57)	(0.08)	(0.72)	(0.51)	(0.29)
Avg. Share Outstanding, Diluted	6,172	6,940	11,219	12,129	12,229	12,329	12,429	12,757	12,857	12,957	13,057	13,157	6,172	9,115	12,436	13,007	13,407
Expense Variables:																	
Cost of Revenue	36.5%	35.5%	26.6%	27.7%	33.5%	32.8%	31.9%	31.1%	30.6%	30.0%	33.3%	35.2%	41.1%	31.3%	32.3%	32.4%	35.5%
Research & Development - Total	12.2%	11.7%	15.6%	16.3%	28.7%	31.7%	31.9%	30.9%	31.0%	30.0%	29.0%	28.1%					
Research & Development - Core	12.2%	11.7%	14.4%	15.1%	27.0%	30.0%	30.0%	29.0%	29.0%	28.0%	27.0%	26.0%	14.4%	13.4%	29.0%	27.4%	22.4%
RUO Heart	0.0%	0.0%	1.1%	1.3%	1.7%	1.7%	1.9%	1.9%	2.0%	2.0%	2.0%	2.1%					
Sales & Marketing	24.9%	23.8%	26.3%	20.6%	34.6%	35.1%	34.3%	33.1%	32.7%	31.5%	28.8%	27.9%	26.7%	23.7%	34.2%	30.1%	26.6%
General & Administrative	30.3%	23.1%	29.7%	29.5%	30.0%	28.5%	27.9%	27.0%	25.0%	24.0%	23.0%	22.0%	21.8%	28.1%	28.3%	23.4%	20.0%
Total Operating Expenses	67.3%	69.6%	52.4%	66.9%	93.2%	95.4%	94.1%	91.0%	90.0%	86.8%	82.1%	79.1%	62.8%	64.1%	93.4%	84.2%	72.5%
Effective Interest Rate, cash	0.4%	0.4%	0.4%	0.4%	0.5%	0.5%	0.6%	0.6%	0.7%	0.7%	0.8%	0.8%	-52.4%	-5.1%	-6.7%	-10.0%	-11.0%
Effective Tax Rate	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM
Margin Analysis:																	
Gross Margin	63.5%	64.5%	73.4%	72.3%	66.5%	67.2%	68.1%	68.9%	69.4%	70.0%	66.7%	64.8%	58.9%	68.7%	67.7%	67.6%	64.5%
Incremental Gross Margin	96.0%	78.5%	186.0%	106.2%	88.0%	116.2%	20.9%	196.9%	82.6%	82.7%	60.9%	48.0%	77.6%	110.3%	52.2%	67.0%	49.7%
Operating Margin	NM	NM	20.9%	5.4%	NM	NM	NM	NM	NM	NM	NM	NM	NM	4.6%	NM	NM	NM
Incremental Operating Margin	58.4%	50.1%	52.8%	-2.1%	-189.4%	-452.6%	-448.1%	1026.5%	14.9%	42.6%	34.6%	22.5%	126.7%	40.4%	-501.9%	22.1%	32.5%
Pretax Margin	NM	NM	19.9%	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM
Net Income Margin	NM	12.9%	19.9%	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	3.3%	NM	NM	NM
YoY Growth Rates:																	
Total Revenues	18.9%	24.2%	14.6%	35.8%	14.1%	5.4%	11.1%	-2.6%	21.9%	21.7%	24.1%	24.9%	792.9%	23.6%	6.3%	23.2%	21.2%
Cost of Goods Sold (Product Sales)	1.8%	13.4%	-29.2%	-5.5%	4.6%	-2.5%	33.0%	9.2%	11.4%	11.5%	29.6%	41.7%	94.0%	-5.9%	9.7%	23.8%	33.0%
Research & Development	-6.1%	4.0%	20.7%	23.7%	58.4%	55.9%	44.6%	56.6%	15.2%	9.2%	4.3%	5.3%	-61.8%	15.6%	129.7%	16.4%	-0.8%
S, G & A	-28.1%	-6.4%	44.1%	81.2%	153.4%	170.6%	130.8%	87.4%	30.9%	13.6%	11.7%	12.0%	-26.3%	9.9%	53.6%	8.4%	7.3%
Operating Expenses	9.7%	31.3%	-4.0%	76.5%	57.9%	44.4%	99.3%	32.5%	17.6%	10.8%	8.3%	8.5%	-41.0%	26.2%	54.8%	11.1%	4.3%
Operating Income	NM	NM	NM	-16.0%	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM
Pretax Income	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM
Net Income (Reported)	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM
Net Income (Ongoing)	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM
EPS	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM
Other Data:																	
Days Sales Outstanding	33.6	25.7	23.8	25.5	30.4	23.5	23.4	23.1	22.5	19.7	18.3	16.7	37.5	35.9	25.1	16.0	19.1
Inventory Turns	13.9	14.4	12.8	14.9	15.0	17.5	16.0	16.0	16.0	16.0	16.0	16.0	NA	NA	32.6	16.9	16.1
EBITDA Per Share	(0.02)	(0.14)	0.14	0.06	(0.12)	(0.14)	(0.13)	(0.11)	(0.10)	(0.08)	(0.07)	(0.07)	(0.03)	0.13	(0.49)	(0.32)	(0.13)
Free Cash Flow Per Share	0.20	(0.08)	(0.39)	(0.07)	(0.00)	(0.16)	(0.14)	(0.13)	(0.13)	(0.07)	(0.12)	(0.06)	0.33	(0.54)	(0.44)	(0.38)	(0.27)
Net Debt (Cash) Per Share	1.66	1.57	(2.35)	(2.06)	(1.87)	(1.53)	(1.22)	(0.90)	(0.61)	(0.38)	(0.06)	0.02	(0.83)	(4.00)	(1.84)	(0.86)	(0.53)

Source: Company reports and Piper Jaffray & Co. Current disclosure information for this company is located at <http://www.piperjaffray.com/researchdisclosures>.

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Notes: The boxes on the Rating and Price Target History chart above indicate the date of the Research Note, the rating, and the price target. Each box represents a date on which an analyst made a change to a rating or price target, except for the first box, which may only represent the first Note written during the past three years.

Legend:

I: Initiating Coverage
R: Resuming Coverage
T: Transferring Coverage
D: Discontinuing Coverage
S: Suspending Coverage
OW: Overweight
N: Neutral
UW: Underweight
NA: Not Available
UR: Under Review

Distribution of Ratings/IB Services Piper Jaffray				
Rating	Count	Percent	IB Serv./Past 12 Mos.	
			Count	Percent
BUY [OW]	376	61.24	98	26.06
HOLD [N]	224	36.48	14	6.25
SELL [UW]	14	2.28	0	0.00

Note: Distribution of Ratings/IB Services shows the number of companies currently in each rating category from which Piper Jaffray and its affiliates received compensation for investment banking services within the past 12 months. FINRA rules require disclosure of which ratings most closely correspond with "buy," "hold," and "sell" recommendations. Piper Jaffray ratings are not the equivalent of buy, hold or sell, but instead represent recommended relative weightings. Nevertheless, Overweight corresponds most closely with buy, Neutral with hold and Underweight with sell. See Stock Rating definitions below.

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- **Overweight (OW):** Anticipated to outperform relative to the median of the group of stocks covered by the analyst.
- **Neutral (N):** Anticipated to perform in line relative to the median of the group of stocks covered by the analyst.
- **Underweight (UW):** Anticipated to underperform relative to the median of the group of stocks covered by the analyst.

Other Important Information