

CareDx, Inc. (CDNA)

Overweight

cfDNA ISHLT Data Preview; Mixed Coverage Update; Remain Overweight

CONCLUSION

We reviewed several CDNA cfDNA abstracts from the upcoming ISHLT conference (4/15-18), with data showing cfDNA levels correspond to rejection events ($p=0.017$) and elevated levels are present up to 25 days prior to rejection. Interestingly, CDNA combined its cfDNA and legacy Allomap test into one score, with the combined test offering a higher AUC (although not statistically different due to sample size) vs. a single assay (AUC: 0.78 vs 0.68). Separately, we updated our reimbursement database, discovering a negative coverage change (plus 1 positive decision). We believe the negative change is a one-off event, with the payer citing previously published data. We remain Overweight CDNA shares.

- ISHLT cfDNA Data Preview:** We recently reviewed 6 CDNA abstracts from the upcoming ISHLT conference (April 15-18, 2015), with 3 focused on cell-free DNA (cfDNA) in heart transplant recipients. Specifically, 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 (i.e. not rejecting) 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 (i.e. each test captured incremental information about rejection). Combining the two tests (cfDNA levels and Allomap score) increased AUC to 0.78 (95% CI 0.67-0.87) as well as 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. The study's authors conclude cfDNA levels typically decline when rejection resolves, although heightened levels long-term is a sign of persistent rejection. We view the new 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.

- Coverage Update:** Our latest private payer reimbursement database update found a positive coverage decision from BCBS of LA (~1.0M members), although BS of CA (~2.3M members) recently (2/2015) moved Allomap to investigational (was medically necessary, initial coverage 8/2011). We believe the unfavorable coverage change is a one-off event, with BS of CA citing previously published data in its medical policy.
- Please see page 2 for a preview of CareDx's 4Q14.**

RISKS TO ACHIEVEMENT OF PRICE TARGET

Risks for CareDx include 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
2014E	5.9A	6.8A	6.7A	6.7	26.1	2.9x	(0.21)A	0.02A	0.12A	(0.09)	(0.16)	NM
2015E	6.8	7.1	7.4	7.8	29.1	2.6x	(0.13)	(0.14)	(0.13)	(0.10)	(0.50)	NM
2016E	8.4	10.0	11.2	12.5	42.1	1.8x	(0.09)	(0.01)	0.04	0.10	0.04	NM

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PRICE: US\$6.67

TARGET: US\$13.00

3.2x FY17E EV/Revenue discounted 25% to FY16E (FY17E Rev: \$55.8M, FY16E: 12.3M shares outstanding, \$1.53 in net cash/sh).

William R. Quirk, CFA

Sr Research Analyst, Piper Jaffray & Co.
612 303-6858, william.r.quirk@pjc.com

David C. Clair, CFA

Research Analyst, Piper Jaffray & Co.
612 303-6747, david.c.clair@pjc.com

Alexander D. Nowak

Research Analyst, Piper Jaffray & Co.
612 303-5679, alexander.d.nowak@pjc.com

Changes	Previous	Current
Rating	—	Overweight
Price Tgt	—	US\$13.00
FY15E Rev (mil)	—	US\$29.1
FY16E Rev (mil)	—	US\$42.1
FY15E EPS	—	US\$(0.50)
FY16E EPS	—	US\$0.04

52-Week High / Low	US\$10.89 / US\$5.40
Shares Out (mil)	11.2
Market Cap. (mil)	US\$74.7
Avg Daily Vol (ooo)	32
Book Value/Share	US\$3.66
Net Cash Per Share	US\$2.35
Debt to Total Capital	24%
Yield	0.00%
Fiscal Year End	Dec

Price Performance - 1 Year



Source: Bloomberg

- Modeling Mixed 4Q14:** We anticipate revenue of \$6.7M (+15.0% yoy), just below Street expectations (\$6.9M), reflecting 2,996 Allomap tests (+8.9% yoy, flat qoq) processed in the quarter. Our model includes 590 bpts yoy improvement to gross margins, driving EPS of (\$0.09), just above Street consensus ((\$0.11)). For F2015, our \$29.1M (+11.7% yoy) revenue forecast includes 13,246 Allomap tests and \$0.1M in cfDNA revenue, with faster-than-expected cfDNA test development representing potential upside. All-in, we anticipate EPS of (\$0.50) (Street: (\$0.45)), reflecting increased costs for cfDNA studies. CDNA reports 4Q14 results on 3/17 at 4:30PM EST (dial-in: 855-420-0616, password: 73593758).

Exhibit 1

Managed Care Entity	Membership Est. (mm's)	Medical Policy			Effective Date	Comments
		Covered	Not Covered	NA		
Medicare/Medicaid	49.3	X			Feb-12	Meet Medicare reasonable and necessary criteria.
United	33.8		X			Medical policy unavailable for review.
Anthem	31.1	X			Jul-14	Medically necessary in heart transplant recipients between 1 and 5 years post transplant.
Aetna	19.6	X			Sep-14	AlloMap considered medically necessary for monitoring rejection in heart transplant recipients more than 1 year post heart transplant
Cigna	13.7	X			Feb-15	Considered medically necessary 6 months-5 years following transplant when several criteria are met.
HCSC	10.1		X		Oct-14	Considered experimental, investigational and unproven
Kaiser Permanente	7.1	X				Medical policy unavailable for review.
Humana	6.8	X			Feb-15	Members eligible for AlloMap for heart transplant recipients who are between 1 and 5 years post transplant.
Independence BC	5.7	X			Jul-11	AlloMap is medically necessary when the individual is at least 6 months post-heart transplant.
BCBS of Michigan	4.4			X		Medical policy unavailable for review.
Highmark	4.1	X			Jan-15	Considered medically necessary to rule out acute heart rejection (grade 2 or greater) in appropriate low-risk patients between 6 months and 5 years post-transplant.
Florida Blue	3.3		X		Jun-14	Considered experimental / investigational
BCBS of North Carolina	2.9		X		Apr-14	Considered investigational
Horizon BCBS of NJ	2.8		X		May-14	Considered investigational
EmblemHealth	2.6	X			Dec-13	Members eligible for AlloMap testing (every 1-3 months) to rule-out moderate-severe ACR (grade $\geq 2R$) when certain criteria are met.
CareFirst	2.6	X			Feb-14	Medically necessary for patients between 6 months and 5 years post transplant who are determined to be at low risk for organ rejection.
BCBS of Tennessee	2.3		X		Jun-14	Considered investigational
BCBS of Alabama	2.3		X		Apr-14	Considered investigational
BS of California	2.3		X		Feb-15	Considered Investigational (previously covered)
BCBS of Massachusetts	2.1		X		Jul-14	Considered investigational
BCBS of Minnesota	2.0		X		Mar-13	Considered investigational
Molina Healthcare	2.0			X		Policy unavailable for review
Regence	1.9		X		Aug-14	Considered investigational
Premera	1.4			X		Policy unavailable for review
Wellmark BCBS	1.4			X		Policy unavailable for review
Excellus BCBS	1.4			X		Policy unavailable for review
BCBS of South Carolina	1.3		X		Jan-15	Considered investigational
WellCare	1.2		X		Nov-13	Considered experimental and investigational
Medical Mutual of Ohio	1.2	X			Nov-14	Medically necessary for heart transplant recipients between one and five years post-transplant when endomyocardial biopsy is not planned.
Health Net	1.2	X			May-14	Members eligible for AlloMap testing (every 1-3 months) to rule-out moderate-severe ACR (grade $\geq 2R$) when certain criteria are met.
Medica	1.1			X		Policy unavailable for review
BCBS of Arizona	1.0		X		May-14	Considered experimental / investigational
BCBS of Louisiana	1.0	X			Nov-14	Eligible for coverage
Harvard Pilgrim	0.9			X		Policy unavailable for review
BCBS of Mississippi	0.8		X		Jun-14	Considered investigational
Arkansas BCBS	0.8			X		Policy unavailable for review
BCBS of Kansas City	0.8			X		Policy unavailable for review
Capital BC	0.8		X		Oct-14	Considered investigational
Tufts Health Plan	0.8		X		Dec-14	Considered investigational
BCBS of Kansas	0.7		X		Oct-13	Considered experimental / investigational
HMSA (BCBS of Hawaii)	0.6			X		Medical policy unavailable for review
BC of Idaho	0.5		X		Apr-13	Considered investigational
BCBS of Nebraska	0.5			X		Medical policy unavailable for review
BCBS of Oklahoma	0.5			X		Medical policy unavailable for review
Group Health Cooperative	0.5	X			Jan-15	Covered for heart transplant patients who can no longer undergo biopsy for the detection of allograft rejection.
BCBS of Rhode Island	0.5			X		Medical policy unavailable for review
BCBS of Western NY	0.5		X		Jul-14	Considered investigational
BC of NE Pennsylvania	0.4		X		Jul-14	Considered investigational
Centene	0.4			X		Policy unavailable for review
BCBS of North Dakota	0.4			X		Policy unavailable for review
BCBS of Montana	0.2		X		Oct-14	Considered experimental, investigational and unproven.
WPS	0.2			X		Policy unavailable for review
BS of NE NY	0.1		X		Jul-14	Considered investigational
BCBS of Vermont	0.1			X		Policy unavailable for review
BCBS of Wyoming	0.1			X		Policy unavailable for review

Source: Medical policy guidelines sourced from managed care websites and Piper Jaffray estimates

Source: Membership information sourced from managed care websites, SEC filings and Piper Jaffray estimates

Note: Excluding Palmetto, membership estimates have been adjusted based on Piper Jaffray estimates to exclude Medicare, MA and PDP enrollment figures wherever possible

	2014E				2015E				2016E				Annual				
	Mar	Jun	Sep	Dec	Mar	Jun	Sep	Dec	Mar	Jun	Sep	Dec	2013A	2014E	2015E	2016E	2017E
	Qtr 1 A	Qtr 2 A	Qtr 3 A	Qtr 4 E	Qtr 1 E	Qtr 2 E	Qtr 3 E	Qtr 4 E	Qtr 1 E	Qtr 2 E	Qtr 3 E	Qtr 4 E					
Total Revenue	5,924	6,776	6,654	6,733	6,757	7,147	7,410	7,816	8,447	10,012	11,153	12,456	22,098	26,087	29,131	42,068	55,832
Cost of Product Revenue	2,162	2,403	1,772	2,287	2,278	2,702	2,766	2,904	3,327	3,775	4,185	4,665	9,078	8,624	10,650	15,953	20,352
Gross Profit	3,762	4,373	4,882	4,446	4,479	4,445	4,644	4,912	5,120	6,237	6,968	7,791	13,020	17,463	18,481	26,115	35,480
Operating Expenses:																	
Research & Development - Total	720	792	1,036	1,200	1,937	2,055	2,064	2,026	2,063	2,077	2,195	2,193	0	3,748	8,082	8,528	8,556
Research & Development - Core	720	792	961	1,100	1,824	1,930	1,927	1,876	1,901	1,902	2,008	1,993	3,176	3,573	7,557	7,803	7,506
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	1,778	1,678	1,703	1,728	1,753	1,883	1,933	1,838	1,888	5,891	6,615	6,862	7,542	10,682
General & Administrative	1,795	1,566	1,976	1,985	1,960	1,965	1,964	1,954	1,985	2,052	2,175	2,242	4,808	7,322	7,843	8,454	9,411
Other		750	(1,276)						110	110	110	110					
Total Operating Expense	3,989	4,718	3,489	4,963	5,574	5,723	5,756	5,733	6,041	6,173	6,318	6,433	13,875	17,159	22,786	24,965	29,089
Operating Income (Loss)	(227)	(345)	1,393	(517)	(1,095)	(1,278)	(1,112)	(821)	(921)	64	650	1,358	(855)	304	(4,305)	1,151	6,392
Interest & other income (expense), net	(1,077)	(278)	(69)	(500)	(404)	(383)	(379)	(359)	(307)	(287)	(260)	(239)	(2,686)	(1,924)	(1,525)	(1,094)	(692)
Pretax Income (Loss)	(1,304)	(623)	1,324	(1,017)	(1,499)	(1,661)	(1,491)	(1,179)	(1,228)	(223)	389	1,118	(3,540)	(1,620)	(5,830)	57	5,700
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	(1,017)	(1,499)	(1,661)	(1,491)	(1,179)	(1,228)	(223)	389	1,118	(3,540)	(120)	(5,830)	57	5,700
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	(1,017)	(1,499)	(1,661)	(1,491)	(1,179)	(1,118)	(113)	499	1,228	(3,540)	(870)	(5,830)	497	6,140
Net Income (Loss) - Non-GAAP	(1,304)	127	1,324	(1,017)	(1,499)	(1,661)	(1,491)	(1,179)	(1,118)	(113)	499	1,228	(3,540)	(870)	(5,830)	497	6,140
Net Income (assuming 40% Tax)																	
Diluted EPS (Reported)	(0.21)	0.13	0.12	(0.09)	(0.13)	(0.14)	(0.13)	(0.10)	(0.10)	(0.02)	0.03	0.09	(0.35)	(0.06)	(0.50)	0.00	0.45
Diluted EPS (Ongoing, w/ SBC)	(0.21)	0.02	0.12	(0.09)	(0.13)	(0.14)	(0.13)	(0.10)	(0.09)	(0.01)	0.04	0.10	(0.57)	(0.16)	(0.50)	0.04	0.49
Avg. Share Outstanding, Diluted	6,172	6,940	11,219	11,319	11,419	11,519	11,619	11,947	12,047	12,147	12,247	12,347	6,172	8,913	11,626	12,197	12,597
Expense Variables:																	
Cost of Revenue	36.5%	35.5%	26.6%	34.0%	33.7%	37.8%	37.3%	37.2%	39.4%	37.7%	37.5%	37.5%	41.1%	33.1%	36.6%	37.9%	36.5%
Research & Development - Total	12.2%	11.7%	15.6%	17.8%	28.7%	28.7%	27.9%	25.9%	24.4%	20.7%	19.7%	17.6%					
Research & Development - Core	12.2%	11.7%	14.4%	16.3%	27.0%	27.0%	26.0%	24.0%	22.5%	19.0%	18.0%	16.0%	14.4%	13.7%	25.9%	18.5%	13.4%
RUO Heart	0.0%	0.0%	1.1%	1.5%	1.7%	1.7%	1.9%	1.9%	1.9%	1.7%	1.7%	1.6%					
Sales & Marketing	24.9%	23.8%	26.3%	26.4%	24.8%	23.8%	23.3%	22.4%	22.3%	19.3%	16.5%	15.2%	26.7%	25.4%	23.6%	17.9%	19.1%
General & Administrative	30.3%	23.1%	29.7%	29.5%	29.0%	27.5%	26.5%	25.0%	23.5%	20.5%	19.5%	18.0%	21.8%	28.1%	26.9%	20.1%	16.9%
Total Operating Expenses	67.3%	69.6%	52.4%	73.7%	82.5%	80.1%	77.7%	73.3%	71.5%	61.7%	56.6%	51.6%	62.8%	65.8%	78.2%	59.3%	52.1%
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%	-5.3%	-6.2%	-5.8%	-2.7%
Effective Tax Rate	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	0.0%	0.0%
Margin Analysis:																	
Gross Margin	63.5%	64.5%	73.4%	66.0%	66.3%	62.2%	62.7%	62.8%	60.6%	62.3%	62.5%	62.5%	58.9%	66.9%	63.4%	62.1%	63.5%
Incremental Gross Margin	96.0%	78.5%	186.0%	105.2%	86.1%	19.5%	-31.5%	43.1%	37.9%	62.5%	62.1%	62.0%	77.6%	111.4%	33.4%	59.0%	68.0%
Operating Margin	NM	NM	20.9%	NM	NM	NM	NM	NM	NM	0.6%	5.8%	10.9%	NM	1.2%	NM	2.7%	11.4%
Incremental Operating Margin	58.4%	50.1%	52.8%	-117.1%	-104.2%	-251.3%	-331.1%	-28.0%	16.8%	50.7%	50.0%	49.3%	126.7%	29.1%	-151.5%	42.2%	38.1%
Pretax Margin	NM	NM	19.9%	NM	NM	NM	NM	NM	NM	NM	3.5%	9.0%	NM	NM	NM	0.1%	10.2%
Net Income Margin	NM	12.9%	19.9%	NM	NM	NM	NM	NM	NM	NM	3.5%	9.0%	NM	NM	NM	0.1%	10.2%
YoY Growth Rates:																	
Total Revenues	18.9%	24.2%	14.6%	15.0%	14.1%	5.5%	11.4%	16.1%	25.0%	40.1%	50.5%	59.4%	792.9%	18.1%	11.7%	44.4%	32.7%
Cost of Goods Sold (Product Sales)	1.8%	13.4%	-29.2%	-2.0%	5.3%	12.4%	56.1%	27.0%	46.1%	39.7%	51.3%	60.7%	94.0%	-5.0%	23.5%	49.8%	27.6%
Research & Development	-6.1%	4.0%	20.7%	34.5%	13.8%	5.8%	-1.4%	-1.4%	12.2%	13.5%	6.4%	7.7%	-61.8%	12.5%	111.5%	3.3%	-3.8%
S, G & A	-28.1%	-6.4%	44.1%	66.4%	153.4%	143.7%	100.5%	70.5%	4.2%	-1.4%	4.2%	6.2%	-26.3%	12.3%	3.7%	9.9%	41.6%
Operating Expenses	9.7%	31.3%	-4.0%	64.7%	39.7%	21.3%	65.0%	15.5%	8.4%	7.9%	9.8%	12.2%	-41.0%	23.7%	32.8%	9.6%	16.5%
Operating Income	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	455.5%
Pretax Income	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	9900.0%
Net Income (Reported)	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	9900.0%
Net Income (Ongoing)	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	1135.4%
EPS	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	1174.4%
Other Data:																	
Days Sales Outstanding	33.6	25.7	23.8	24.0	24.3	23.5	23.4	23.1	22.5	19.7	18.3	16.7	37.5	25.1	25.5	20.0	16.8
Inventory Turns	13.9	14.4	12.8	18.0	17.0	17.5	16.0	16.0	16.0	16.0	16.0	16.0	NA	NA	28.3	16.2	15.5
EBITDA Per Share	(0.02)	(0.14)	0.14	(0.01)	(0.07)	(0.08)	(0.07)	(0.04)	(0.04)	0.04	0.09	0.14	(0.03)	0.03	(0.26)	0.23	0.64
Free Cash Flow Per Share	0.20	(0.08)	(0.39)	(0.02)	(0.07)	(0.10)	(0.07)	(0.07)	(0.08)	0.00	0.02	0.05	0.33	(0.37)	(0.31)	0.03	0.53
Net Debt (Cash) Per Share	1.66	1.57	(2.35)	(2.11)	(1.84)	(1.55)	(1.28)	(1.00)	(0.75)	(0.58)	(0.41)	(0.50)	(0.83)	(4.11)	(2.12)	(1.55)	(2.00)

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

IMPORTANT RESEARCH DISCLOSURES



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]	377	59.56	102	27.06
HOLD [N]	242	38.23	20	8.26
SELL [UW]	14	2.21	1	7.14

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.

Analyst Certification — William R. Quirk, CFA, Sr Research Analyst
— David C. Clair, CFA, Research Analyst
— Alexander D. Nowak, Research Analyst

The views expressed in this report accurately reflect my personal views about the subject company and the subject security. In addition, no part of my compensation was, is, or will be directly or indirectly related to the specific recommendations or views contained in this report.

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