CAREDX, INC.

FORM 8-K
(Current report filing)

Filed 09/26/17 for the Period Ending 09/26/17

Address	8000 MARINA BLVD 4TH FLOOR BRISBANE, CA, 94005
Telephone	415-287-2300
CIK	0001217234
Symbol	CDNA
SIC Code	8071 - Services-Medical Laboratories
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): September 26, 2017

CAREDX, INC.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**001-36536**	**94-3316839**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

3260 Bayshore Boulevard
Brisbane, California 94005
(Address of Principal Executive Offices) (Zip Code)

(415) 287-2300
Registrant's telephone number, including area code

N/A
(Former Name, or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Item 7.01. Regulation FD Disclosure.

On September 26, 2017, CareDx, Inc. (the "Company") issued a press release announcing that the Molecular Diagnostics Services (MolDX) Program developed by Palmetto GBA has set the AlloSure reimbursement rate. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

The information contained in this Item 7.01, including Exhibit 99.1 hereto, is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any registration statement or other filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference to such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release issued by CareDx, Inc. dated September 26, 2017.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: September 26, 2017

CAREDX, INC.

By: /s/ Michael Bell
Michael Bell
Chief Financial Officer

Exhibit 99.1

MolDX sets AlloSure reimbursement at 2017 AlloMap level

80% of kidney transplant patients will have coverage for a validated, non-invasive test that assesses organ health by directly measuring graft injury

For immediate release:

BRISBANE, Calif., September 26th, 2017 — CareDx, Inc. (NASDAQ:CDNA), a molecular diagnostics company focused on the discovery, development and commercialization of clinically differentiated, high-value diagnostic solutions for transplant patients, received notice that the Molecular Diagnostics Services (MolDX) Program developed by Palmetto GBA has set AlloSure reimbursement at $2,840.75, which is same reimbursement as AlloMap in 2017.

AlloSure will be reimbursed for kidney transplant patients covered by Medicare across the United States starting October 9, 2017, the effective date of the Palmetto local coverage determination. Approximately 80% of kidney transplant patients are covered by Medicare. Payments will be made by Noridian, which has implemented the MolDX Program and is the Medicare administrator in CareDx's jurisdiction.

Medicare reimbursement for AlloSure follows a rigorous technical assessment by the MolDX Program. Evidence in support of the AlloSure test included a clinical trial in 14 leading transplant centers and 400 patients with follow-up over 18 months. A prospective observational cohort study will begin in early 2018 to provide additional data on longer term outcomes, as part of a coverage under data development commitment.

A study of over 110,000 patients from the United States Renal Data System showed a 500% increase in cost burden for patients with renal transplant failure. Twenty percent of annual kidney transplants are re-transplants, so a test to accurately measure probability of rejection has been a major medical need. "We are pleased to see Medicare reimburse AlloSure at the same level as AlloMap, highlighting the value of advanced diagnostic tests to measure organ health for transplant recipients. AlloSure testing provides the precision medicine approach needed for individual transplant recipient clinical management," said Sasha King, Chief Commercial Officer at CareDx.

About CareDx

CareDx, Inc., headquartered in Brisbane, California, is a molecular diagnostics company focused on the discovery, development and commercialization of clinically differentiated, high-value solutions for transplant recipients. CareDx offers products across the transplant testing continuum, including AlloMap ® and AlloSure ® for post-transplant surveillance and Olerup SSP ® , Olerup QTYPE ® , and Olerup SBT™ for pre-transplant HLA testing.

For more information, please visit: www.CareDx.com.

Forward Looking Statements

This press release contains forward-looking statements about our business, research, development and commercialization efforts, including statements regarding our prospective observational cohort study. These forward-looking statements are based upon information that is currently available to us and our current expectations, speak only as of the date hereof, and are subject to numerous risks and uncertainties, including risks associated with successful research, development and planned commercialization of our technologies, that are described in our filings with the SEC, including the Annual Report on Form 10-K for the fiscal year ended December 31, 2016 filed by us with the SEC on April 21, 2017 and the periodic reports that we have subsequently filed with the SEC. Any of these may cause our actual results, performance or achievements to differ materially and adversely from those anticipated or implied by our forward-looking statements. We expressly disclaim any obligation, except as required by law, or undertaking to update or revise any such forward-looking statements.

CONTACTS:

CareDx, Inc.
Sasha King
Chief Commercial Officer
415-287-2393
sking@caredx.com

Investor Relations
David Clair
Integrated Corporate Relations, Inc.
646-277-1266
david.clair@icrinc.com