

**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): January 6, 2022

ORTHO CLINICAL DIAGNOSTICS HOLDINGS PLC

(Exact name of Registrant as Specified in Its Charter)

England and Wales
(State or Other Jurisdiction
of Incorporation)

001-39956
(Commission File Number)

98-1574150
(IRS Employer
Identification No.)

1001 Route 202, Raritan, New Jersey
(Address of Principal Executive Offices)

08869
(Zip Code)

Registrant's Telephone Number, Including Area Code: (908) 218-8000

Not Applicable
(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 (see General Instructions A.2. below):

- 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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Ordinary shares, \$0.00001 par value	OCDX	Nasdaq Global Select Market

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 2.02 Results of Operations and Financial Condition.

On January 6, 2022, Ortho Clinical Diagnostics Holdings plc (“Ortho Clinical Diagnostics”) issued a press release announcing its preliminary unaudited financial results for its fiscal fourth quarter and fiscal year ended January 2, 2022. A copy of the press release is furnished with this Current Report on Form 8-K as Exhibit 99.1.

The information contained in Item 2.02 of this Current Report on Form 8-K and Exhibit 99.1 shall not be deemed “filed” for 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 in any filing under the Securities Act of 1933, as amended, or the Exchange Act, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release issued by Ortho Clinical Diagnostics Holdings plc dated January 6, 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

ADDITIONAL INFORMATION AND WHERE TO FIND IT

This communication does not constitute an offer to sell or the solicitation of an offer to buy any securities or a solicitation of any vote or approval. The proposed business combination transaction among Ortho Clinical Diagnostics, Quidel Corporation (“Quidel”) and Coronado Topco, Inc. (“Topco”) will be submitted to the shareholders of Ortho Clinical Diagnostics and Quidel for their consideration. Ortho Clinical Diagnostics and Topco expect to file with the Securities and Exchange Commission (“SEC”) a registration statement on Form S-4 that will include a prospectus of Ortho Clinical Diagnostics and Topco and a proxy statement of Ortho Clinical Diagnostics. Ortho Clinical Diagnostics and Topco also plan to file other documents with the SEC regarding the proposed transaction. INVESTORS AND SECURITY HOLDERS OF ORTHO CLINICAL DIAGNOSTICS ARE URGED TO READ THE PROXY STATEMENT, PROSPECTUS AND OTHER RELEVANT DOCUMENTS THAT WILL BE FILED WITH THE SEC CAREFULLY AND IN THEIR ENTIRETY WHEN THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT THE PROPOSED TRANSACTION. Investors and security holders will be able to obtain free copies of the proxy statement, prospectus and other documents containing important information about Ortho Clinical Diagnostics, Quidel and Topco, once such documents are filed with the SEC, through the website maintained by the SEC at <http://www.sec.gov>. Copies of the documents filed with the SEC by Ortho Clinical Diagnostics, when and if available, can be obtained free of charge on Ortho Clinical Diagnostics’ website at <https://www.orthoclinicaldiagnostics.com/en-us/home/> or by directing a written request to OrthoCareTechnicalSolutions@orthoclinicaldiagnostics.com.

Ortho Clinical Diagnostics and certain of its respective directors, executive officers and certain members of management may be deemed to be participants in the solicitation of proxies from the shareholders of Ortho Clinical Diagnostics in connection with the proposed transaction. Information about the directors and executive officers of Ortho Clinical Diagnostics is set forth in its annual report on Form 10-K, which was filed with the SEC on March 19, 2021. Other information regarding the participants in the proxy solicitation and a description of their direct and indirect interests, by security holdings or otherwise, will be contained in the prospectus and proxy statement and other relevant materials when and if filed with the SEC in connection with the proposed transaction.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This document includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements may be identified by words such as “may,” “will,” “expect,” “intend,” “anticipate,” “believe,” “estimate,” “plan,” “project,” “could,” “should,” “would,” “continue,” “seek,” “intend,” “target,” “guidance,” “outlook,” “forecast” and other similar words. These forward-looking statements are based on Ortho Clinical Diagnostics’ current objectives, beliefs and expectations, and they are subject to significant risks and uncertainties that may cause actual results and financial position and timing of certain events to differ materially from the information in the forward-looking statements. The following factors, among others, could cause actual results and financial position and timing of certain events to differ materially from those described in the forward-looking statements: failure of a proposed transaction to be implemented; the challenges and costs of closing, integrating, restructuring and achieving anticipated synergies; the ability to retain key employees; and other economic, business, competitive, and/or regulatory factors affecting the businesses of Ortho Clinical Diagnostics and Quidel generally, including those set forth in Ortho Clinical Diagnostics’ filings with the SEC, especially in the “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of

Operations” section of its annual report on Form 10-K and quarterly report on Form 10-Q, its current reports on Form 8-K and other SEC filings, including the proxy statement and prospectus. Any forward-looking statements speak only as of the date hereof or as of the dates indicated in the statements. Ortho Clinical Diagnostics assumes no obligation to publicly update or supplement any forward-looking statement to reflect actual results, changes in assumptions or changes in other factors affecting these forward-looking statements except as required by law.

Ortho Clinical Diagnostics Announces Preliminary Financial Results for Fourth Quarter and Fiscal Year 2021

**Expects 4Q Reported and Constant Currency Core Revenue Growth of ~4%
Fiscal Year Reported and Constant Currency Core Revenue Growth of ~16% and ~15%,
respectively**

RARITAN, N.J., January 06, 2022 -- Ortho Clinical Diagnostics Holdings plc (Nasdaq: OCDX) (the "Company"), one of the world's largest pure-play in vitro diagnostics (IVD) companies, today announced preliminary unaudited revenue results for the fourth quarter and fiscal year ended January 2, 2022. The Company is providing these updates in advance of its presentation at the J.P. Morgan Healthcare Conference on January 11, 2022.

Selected Preliminary Fourth Quarter and Fiscal Year 2021 Financial Results (Unaudited):

- Fourth quarter Core revenue excluding CoV-2 assay sales is expected to increase approximately 7% to a range of \$508 million to \$510 million, or approximately 8% in Constant Currency
- Fourth quarter Reported and Constant Currency Core revenue is expected to increase approximately 4% to a range of \$518 million to \$520 million
- Fourth quarter total revenue is expected to increase approximately 1% to a range of \$520 million to \$522 million, or approximately 2% in Constant Currency

"We concluded the year with another excellent quarter, bringing our preliminary FY 2021 Constant Currency Core revenue growth rate to approximately 15%," said Chris Smith, Chairman and Chief Executive Officer of Ortho Clinical Diagnostics. "This was highlighted by profitable growth across all major geographic regions, and in both our Clinical Laboratories and Transfusion Medicine businesses, demonstrating the strength and stability of our recurring revenue business model."

"We are excited about the definitive agreement we entered into with Quidel Corporation. By joining Quidel's point-of-care and molecular diagnostics with Ortho's global sales force of more than 2,300 people in 130 countries, we believe there is a substantial opportunity to capitalize on the cross-sale opportunities and move into attractive adjacent markets. I believe that these actions, combined with our strong foundation, position us well for 2022 and beyond," Smith continued.

Preliminary revenues for the fourth quarter ended January 2, 2022 are as follows:

\$ in millions	Quarter Ended		Change	
	January 2, 2022	January 3, 2021	As Reported	Constant Currency
Core	\$518-\$520	\$501	4%	4%
Core, excluding CoV-2 assay sales	\$508-\$510	\$475	7%	8%
Non-Core ¹	\$2	\$16	(87%)	(87%)
Total Revenue	\$520-\$522	\$517	1%	2%

Note: Changes presented in the table above have been calculated using actual, non-rounded amounts and may not recalculate. 1. Non-core revenue is comprised of contract manufacturing and licensing revenue.

Preliminary revenues for the fiscal year ended January 2, 2022 are as follows:

\$ in millions	Year Ended		Change	
	January 2, 2022	January 3, 2021	As Reported	Constant Currency
Core	\$2,014-\$2,016	\$1,735	16%	15%
Core, excluding CoV-2 assay sales	\$1,946-\$1,948	\$1,661	17%	16%
Non-Core ¹	\$28	\$31	(10%)	(10%)
Total Revenue	\$2,042-\$2,044	\$1,766	16%	14%

Note: Changes presented in the table above have been calculated using actual, non-rounded amounts and may not recalculate. 1. Non-core revenue is comprised of contract manufacturing and licensing revenue.

The Company expects to report its full fourth quarter and fiscal year 2021 financial results after the market close on Wednesday, February 16, 2022. The preliminary financial results ranges described herein have not been audited and are subject to adjustment based on the Company's completion of year-end financial close processes.

Conference Call Information

Ortho Clinical Diagnostics will hold a conference call on Wednesday, February 16, 2022, at 5:00 pm ET to discuss the full financial results of the fourth quarter and fiscal year ended January 2, 2022. Interested parties can access the call and accompanying presentation on the "Investors" portion of the Company's website at <https://ir.orthoclinicaldiagnostics.com/>. Presentation materials will also be posted to the "Investors" portion of the website at the time of the call. Those unable to access the webcast may join the call via phone by dialing 833-362-0203 (domestic) or 914-987-7672 (international) and entering Conference ID number 8289754.

A replay of the conference call will be available a few hours after the event on the “Investors” portion of the Company’s website, under the “Events” section.

About Ortho Clinical Diagnostics

Ortho Clinical Diagnostics Holdings plc (Nasdaq: OCDX) is one of the world’s largest pure-play in vitro diagnostics (IVD) companies dedicated to transforming patient care.

More than 800,000 patients across the world are impacted by Ortho’s tests each day. *Because Every Test Is A Life™*, Ortho provides hospitals, hospital networks, clinical laboratories and blood banks around the world with innovative technology and tools to ensure test results are fast, accurate, and reliable. Ortho’s customized solutions enhance clinical outcomes, improve efficiency, overcome lab staffing challenges and reduce costs.

From launching the first product to determine Rh+ or Rh- blood type, developing the world’s first tests for the detection of antibodies against HIV and hepatitis C, introducing patented dry-slide technology and marketing the first U.S. Food and Drug Administration-authorized high-volume antibody and antigen tests for COVID-19, Ortho has been a pioneering leader in the IVD space for over 80 years.

The company is powered by Ortho Care®, an award-winning, holistic service and support program that ensures best-in-class technical, field and remote service and inventory support to laboratories in more than 130 countries and territories around the globe.

For more information, visit [Ortho’s website](#) or social media channels: [LinkedIn](#), [Twitter](#), [Facebook](#) and [YouTube](#).

Forward Looking Statements

This Press Release contains “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements include, among others, statements concerning (i) the Company’s unaudited preliminary financial information for the fiscal fourth quarter and the fiscal year ended January 2, 2022 and (ii) the benefits of the business combination transaction involving Quidel and the Company, including the combined company’s future financial and operating results, plans, objectives, expectations and intentions and other statements that are not historical facts. The preliminary financial information set forth in this press release is subject to the completion of the Company’s audit process and is subject to change. The estimated preliminary results included in this press release should not be viewed as a substitute for the Company’s annual financial statements prepared in accordance with U.S. generally accepted accounting principles (“GAAP”). There can be no assurance that the estimated preliminary results will be realized, and you are cautioned not to place undue reliance on the preliminary financial information, which reflects management’s current expectations and anticipated results of operations, all of which are subject to known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements, market trends, or industry results to differ materially from those expressed or implied by such forward-looking statements. Therefore, any statements contained herein that are not statements of historical fact may be forward-looking statements and should be evaluated as such. Without limiting the foregoing, the words as “anticipate,” “expect,” “suggest,” “plan,” “believe,” “intend,” “project,” “forecast,” “estimates,” “targets,” “projections,” “should,” “could,” “would,” “may,” “might,” “will,” and the negative thereof and similar words and expressions are intended to identify

forward-looking statements. Factors that might materially affect such forward looking statements include: the ongoing global coronavirus (COVID-19) pandemic; risks related to the proposed acquisition of us by Quidel Corporation, including (i) failure to complete the proposed transaction on the proposed terms or on the anticipated timeline, or at all, (ii) risks and uncertainties related to securing the necessary regulatory and shareholder approvals, the sanction of the High Court of Justice of England and Wales and satisfaction of other closing conditions to consummate the proposed transaction; (iii) the occurrence of any event, change or other circumstance that could give rise to the termination of the definitive transaction agreement relating to the proposed transaction; (iv) the challenges and costs of closing, integrating, restructuring and achieving anticipated synergies; and (v) the ability to retain key employees; increased competition; manufacturing problems or delays or failure to develop and market new or enhanced products or services; adverse developments in global market, economic and political conditions; our ability to obtain additional capital on commercially reasonable terms may be limited or non-existent; our inability to implement our strategies for improving growth or to realize the anticipated benefits of any acquisitions and divestitures, including as a result of difficulties integrating acquired businesses with, or disposing of divested businesses from, our current operations; a need to recognize impairment charges related to goodwill, identified intangible assets and fixed assets; inability to achieve some or all of the operational cost improvements and other benefits that we expect to realize; our ability to operate according to our business strategy should our collaboration partners fail to fulfill their obligations; risk that the insurance we maintain may not fully cover all potential exposures; product recalls or negative publicity may harm our reputation or market acceptance of our products; decreases in the number of surgical procedures performed, and the resulting decrease in blood demand; fluctuations in our cash flows as a result of our reagent rental model; terrorist acts, conflicts, wars and natural disasters that may materially adversely affect our business, financial condition and results of operations; the outcome of legal proceedings instituted against us and/or others; risks associated with our non-U.S. operations, including currency translation risks, the impact of possible new tariffs and compliance with applicable trade embargoes; the effect of the United Kingdom's withdrawal from the European Union; our inability to deliver products and services that meet customers' needs and expectations; failure to maintain a high level of confidence in our products; significant changes in the healthcare industry and related industries that we serve, in an effort to reduce costs; reductions in government funding and reimbursement to our customers; price increases or interruptions in the supply of raw materials, components for our products, and products and services provided to us by certain key suppliers and manufacturers; our ability to recruit and retain the experienced and skilled personnel we need to compete; work stoppages, union negotiations, labor disputes and other matters associated with our labor force; consolidation of our customer base and the formation of group purchasing organizations; unexpected payments to any pension plans applicable to our employees; our inability to obtain required clearances or approvals for our products; failure to comply with applicable regulations, which may result in significant costs or the suspension or withdrawal of previously obtained clearances or approvals; the inability of government agencies to hire, retain or deploy personnel or otherwise prevent new or modified products from being developed, cleared or approved or commercialized in a timely manner; disruptions resulting from President Biden's invocation of the Defense Production Act; results of clinical studies, which may be delayed or fail to demonstrate the safety and effectiveness of our products; costs to comply with environmental and health and safety requirements, or costs related to liability for contamination or other potential environmental harm; healthcare fraud and abuse regulations that could result in liability, require us to change our business practices and restrict our operations in the future; failure to comply with the anti-corruption laws of the United States and various international jurisdictions; failure to comply with

anti-terrorism laws and regulations and applicable trade embargoes; failure to comply with the requirements of federal, state and international laws pertaining to the privacy and security of health information; our inability to maintain our data management and information technology systems; data corruption, cyber-based attacks, security breaches and privacy violations; our inability to protect and enforce our intellectual property rights or defend against intellectual property infringement suits against us by third parties; risks related to changes in income tax laws and regulations; risks related to our substantial indebtedness; our ability to generate cash flow to service our substantial debt obligations; difficulties complying with Nasdaq rules regarding the composition of our Board of Directors and certain committees now that we are no longer a “controlled company”; risks related to the ownership of our ordinary shares; and other factors beyond our control. Unless legally required, we assume no obligation to update any such forward-looking information to reflect actual results or changes in the factors affecting such forward-looking information.

Non-GAAP Financial Measures

This press release contains financial measures, such as constant currency growth rate and Core revenue, excluding CoV-2 assay sales, which are considered non-GAAP financial measures under applicable U.S. Securities and Exchange Commission rules and regulations. These non-GAAP financial measures should be considered supplemental to, and not a substitute for, financial information prepared in accordance with GAAP. The Company's definition of these non-GAAP measures may differ from similarly titled measures used by others. The Company generally uses these non-GAAP financial measure to facilitate management's financial and operational decision-making, including evaluation of the Company's historical operating results, comparison to competitors' operating results and determination of management incentive compensation. These non-GAAP financial measures reflect an additional way of viewing aspects of the Company's operations that, when viewed with GAAP results and the reconciliations to corresponding GAAP financial measures, may provide a more complete understanding of factors and trends affecting the Company's business. Because non-GAAP financial measures exclude the effect of items that will increase or decrease the Company's reported results of operations, management strongly encourages investors to review the Company's consolidated financial statements and publicly filed reports in their entirety. A reconciliation of the non-GAAP financial measures to the most directly comparable GAAP financial measure is included in the tables accompanying this release. For example, such reconciling items include the impact of unrealized foreign currency exchange gains or losses. We cannot estimate or project these items and they may have a substantial and unpredictable impact on our results presented in accordance with GAAP.

Some columns and rows within tables may not add due to rounding. Percentages have been calculated using actual, non-rounded figures.

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ORTHO CLINICAL DIAGNOSTICS HOLDINGS PLC
Reconciliation of GAAP to Non-GAAP Results
Core and Non-Core Revenue and Core Revenue, excluding CoV-2 assays
(Unaudited)

(Dollars in millions)	Fiscal Quarter Ended		Percent Change	Currency Impact	Constant Currency Growth Rate ^(a)
	January 2, 2022	January 3, 2021			
Core Revenue	\$518 – \$520	\$ 501	4 %	(1 %)	4 %
Non-Core Revenue	2	16	(87 %)	–	(87 %)
Net Revenue	\$520 – \$522	\$ 517	1 %	(1 %)	2 %

(Dollars in millions)	Fiscal Year ended		Percent Change	Currency Impact	Constant Currency Growth Rate ^(a)
	January 2, 2022	January 3, 2021			
Core Revenue	\$2,014 – \$2,016	\$ 1,735	16 %	1 %	15 %
Non-Core Revenue	28	31	(10 %)	–	(10 %)
Net Revenue	\$2,042 – \$2,044	\$ 1,766	16 %	2 %	14 %

(Dollars in millions)	Fiscal Quarter Ended		Percent Change	Currency Impact	Constant Currency Growth Rate ^(a)
	January 2, 2022	January 3, 2021			
Core Revenue	\$518 – \$520	\$ 501	4 %	(1 %)	4 %
CoV-2 assays	(10)	(26)	(63 %)	–	(63 %)
Core, excluding CoV-2 assays	\$508 – \$510	\$ 527	7 %	(1 %)	8 %

(Dollars in millions)	Fiscal Year ended		Percent Change	Currency Impact	Constant Currency Growth Rate ^(a)
	January 2, 2022	January 3, 2021			
Core Revenue	\$2,014 – \$2,016	\$ 1,735	16 %	1 %	15 %
CoV-2 assays	(68)	(74)	(9 %)	–	(9 %)
Core, excluding CoV-2 assays	\$1,946 – \$1,948	\$ 1,661	17 %	1 %	16 %

(a) The term “constant currency” means we have translated local currency revenues for all reporting periods to U.S. dollars using internally-derived currency exchange rates held constant for each year. This additional non-GAAP financial information is not meant to be considered in isolation from or as substitute for financial information prepared in accordance with GAAP.

