

Ortho Clinical Diagnostics

Ortho Clinical Diagnostics Reports First Quarter 2021 Results

May 5, 2021

First Quarter Revenue Growth Exceeds Company's Expectations at 24.2%, Supporting Increase in 2021 Guidance

RARITAN, N.J., May 05, 2021 (GLOBE NEWSWIRE) -- Ortho Clinical Diagnostics Holdings plc (Nasdaq: OCDX), one of the world's largest pure-play in-vitro diagnostics (IVD) companies, today announced financial results for the first quarter ended April 4, 2021.

Highlights

- First quarter revenue increased 24.2% to \$506.8 million, or 21.8% in constant currency
- Core revenue grew 23.5% to \$499.3 million for the quarter, or 21.1% in constant currency basis
- Operating Income increased 382% to \$57.4 million from \$11.9 million last year
- Net loss was \$39.1 million, or (\$0.19) per diluted share, while Adjusted net income was \$54.9 million, or \$0.26 per diluted share in the first quarter of 2021
- First quarter Adjusted EBITDA rose 49% to \$152.4 million and Adjusted free cash flow rose 54% to (\$13.1) million year over year
- Company raised 2021 guidance to 9% to 11% Core revenue growth in constant currency and Adjusted EBITDA growth to 14.0% to 16.5%

First Quarter 2021 Financial Highlights

"We started off the year strong with continued momentum in our base business that was supplemented by our COVID-19 testing solutions," said Chris Smith, chairman and chief executive officer, Ortho Clinical Diagnostics. "Our Core revenue excluding our COVID-assay products was up 14%, as our commercial excellence programs continue to show strong returns and as many of our geographies are seeing an accelerating recovery from the impact of the global pandemic. We're confident in our ability to carry this momentum forward for the rest of the year, and beyond while executing against our strategic priorities. As a result, we've increased our 2021 outlook for both the top and bottom lines."

\$ in millions, other than per share amounts	Quarter Ended		Change	
	April 4, 2021	March 29, 2020	as reported	constant currency
Revenue	\$506.8	\$407.9	24.2%	21.8%
Core Revenue	\$499.3	\$404.3	23.5%	21.1%
Gross Profit Margin	51.0%	47.7%	330 bps	-
Income from Operations	\$57.4	\$11.9	382.4%	-
EPS (GAAP)	(\$0.19)	(\$0.69)	72.5%	-
Adjusted Diluted EPS	\$0.26	(\$0.01)	n/a	-
Adjusted Free Cash Flow	(\$13.1)	(\$28.4)	53.9%	-
Adjusted EBITDA	\$152.4	\$102.0	49.4%	-

- **Core revenue**, which excludes contract manufacturing and other licensing revenue, increased to \$499.3 million dollars in the first quarter of 2021, compared with \$404.3 million in the similar period last year, or a 21.1% increase on constant currency terms
- **Net loss** for the first quarter was (\$39.1) million, or (\$0.19) per share, compared with net loss of (\$101.2) million, or (\$0.69) per share, in the first quarter of 2020
- **Adjusted EBITDA** for the first quarter was \$152.4 million, an increase of 49.4% as compared to \$102.0 million in the prior year period
- **Adjusted free cash flow** for the first quarter was (\$13.1) million, compared with (\$28.4) million in the prior year period

Results by Segment

"During the quarter, we experienced top-line growth across each of our geographies and saw particular strength in our largest segment, Americas, which was up nearly 29% for the period," said Smith. "This was driven by pronounced growth in both Clinical Labs and Transfusion Medicine. Growth in our other three segments gained momentum throughout the quarter, and China had a particularly strong rebound with 11% top-line growth on a

constant currency basis.”

Revenues by segment were as follows:

\$ millions	Quarter Ended		Change	
	April 4, 2021	March 29, 2020	as reported	constant currency
Americas	\$321.4	\$250.5	28.3%	28.8%
EMEA	\$68.5	\$58.7	16.8%	8.2%
Greater China	\$55.0	\$46.3	18.7%	10.6%
Other	\$61.9	\$52.4	18.2%	15.1%
Total Revenue	\$506.8	\$407.9	24.2%	21.8%

Balance Sheet and Liquidity

As of April 4, 2021, the Company had \$153.8 million of cash and cash equivalents, compared to \$132.8 million of cash and cash equivalents on January 3, 2021. Total debt at April 4, 2021 was \$2.4 billion, a 36% decrease compared with \$3.7 billion on January 3, 2021.

During the first quarter:

- The Company completed its IPO in early February 2021, including full exercise of the over-allotment option by the underwriters, and raised approximately \$1.4 billion in net proceeds that were used primarily for debt reduction.
- Ortho created additional financial flexibility by amending its revolving credit facility in February 2021 to upsize from \$350 million to \$500 million and extend the maturity date to 2026.
- The Company received credit ratings upgrades by both Moody's and S&P Global after reducing debt with the IPO proceeds.

Fiscal Year 2021 Outlook

The Company today raised financial guidance for the fiscal year 2021 as follows:

	Fiscal Year 2021	Prior Guidance FY 2021
Core Revenue	\$1.93 - \$1.96 billion	\$1.86 - \$1.9 billion
Constant Currency Core Revenue Growth	9% – 11%	7% – 9%
Adjusted EBITDA	\$520 - \$532 million	\$504 - \$517 million
Adjusted EBITDA Growth	14% -16.5%	10% - 13%
Adjusted Diluted EPS	\$0.64 - \$0.69	\$0.57 - \$0.63

“We closed the first quarter very strong, and we are pleased to raise our outlook for all of our key performance indicators in 2021,” said Joseph Busky, chief financial officer, Ortho Clinical Diagnostics. “Our successful initial public offering and sustained annual cash flow generation are allowing us to strengthen our balance sheet and explore expansion opportunities within our current markets as well as through entry into additional high-growth markets that would complement our current businesses. We have the right strategy and the right team to drive long-term shareholder value and remain focused on driving further product innovation, commercial excellence and operational efficiency across our organization. We look forward to continuing to execute at a high level throughout fiscal year 2021.”

Conference Call Information

Ortho Clinical Diagnostics will hold a conference call to discuss its first quarter 2021 results today, at 5:00pm ET.

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 1883187.

A replay of the conference call will be available a few hours after the event on the investor relations section of the Company’s website, under the events section.

About Ortho Clinical Diagnostics

Ortho Clinical Diagnostics (Nasdaq: OCDX) is one of the world’s largest pure-play in vitro diagnostics (IVD) companies.

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 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 may contain "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. Such forward-looking statements reflect, among other things, our 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; 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; our ability to operate according to our business strategy should our collaboration partners fail to fulfill their obligations; risk that the insurance we will 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 former President Trump's invocation of the Defense Production Act; 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; and risks related to the ownership of our ordinary shares, including the fact that we are a "controlled company" within the meaning of the corporate governance standards of Nasdaq. 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, adjusted EBITDA, adjusted net income, adjusted diluted EPS and adjusted free cash flow, 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 U.S. generally accepted accounting principles (GAAP). Adjusted EBITDA, adjusted net income, adjusted diluted EPS and adjusted free cash flow eliminate impacts of certain non-cash, unusual or other items that that we do not consider indicative of our ongoing operating performance. The Company's definitions of these non-GAAP measures may differ from similarly titled measures used by others. The Company generally uses these non-GAAP financial measures 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. Reconciliations of the non-GAAP financial measures to the most directly comparable GAAP financial measures are included in the tables accompanying this release. For example, such reconciling items include the impact of unrealized foreign currency exchange gains or losses, gains or losses that are unusual or nonrecurring in nature, as well as discrete taxable events. 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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(In millions, except per share data)

	Fiscal First Quarter Ended	
	April 4, 2021	March 29, 2020
Net revenue	\$ 506.8	\$ 407.9
Cost of revenue, excluding amortization of intangible assets	248.2	213.2
Gross profit	258.6	194.7
Selling, marketing and administrative expenses	131.5	117.4
Research and development expense	28.9	23.6
Amortization of intangible assets	33.4	33.0
Other operating expense, net	7.4	8.8
Income from operations	57.4	11.9
Interest expense, net	43.4	52.2
Tax indemnification income, net	(0.2)	(2.5)
Other expense, net	50.0	59.3
Loss before provision for income taxes	(35.8)	(97.1)
Provision for income taxes	3.3	4.1
Net loss	<u>\$ (39.1)</u>	<u>\$ (101.2)</u>
Basic and diluted net loss per common share	\$ (0.19)	\$ (0.69)
Basic and diluted weighted-average common shares outstanding	206.2	146.3

ORTHO CLINICAL DIAGNOSTICS HOLDINGS PLC

Consolidated Balance Sheets

(Unaudited)

(In millions)

	April 4, 2021	January 3, 2021
Cash and cash equivalents	\$ 153.8	\$ 132.8
Accounts receivable	324.1	318.7
Inventories	291.1	278.7
Other current assets	150.8	127.0
Property, plant and equipment, net	805.6	832.0
Goodwill	576.1	580.1
Intangible assets, net	983.4	1,016.7
Deferred income taxes	7.8	8.0
Other assets	99.8	107.5
Total assets	<u>\$ 3,392.5</u>	<u>\$ 3,401.5</u>
Accounts payable	\$ 130.3	\$ 146.2
Accrued liabilities	260.9	284.7
Deferred revenue	34.3	35.5
Current portion of borrowings	139.4	160.0
Long-term borrowings	2,240.3	3,558.5
Employee-related obligations	38.9	39.3
Other liabilities	103.8	120.8
Deferred income taxes	68.0	67.3
Total liabilities	<u>3,015.9</u>	<u>4,412.3</u>
Total stockholders' equity (deficit)	<u>376.6</u>	<u>(1,010.8)</u>
Total liabilities and stockholders' equity (deficit)	<u>\$ 3,392.5</u>	<u>\$ 3,401.5</u>

ORTHO CLINICAL DIAGNOSTICS HOLDINGS PLC

Consolidated Statements of Cash Flows

(Unaudited)

(In millions)

	Fiscal First Quarter Ended	
	April 4, 2021	March 29, 2020
Cash used in operating activities	\$ (9.9)	\$ (17.5)
Cash used in investing activities	(10.7)	(18.3)

Cash provided by financing activities	41.1	316.2
Effect of exchange rate changes on cash	(0.2)	(2.5)
Increase in cash	20.3	277.9
Cash, cash equivalents and restricted cash at beginning of period	144.2	84.0
Cash, cash equivalents and restricted cash at end of period	\$ 164.5	\$ 361.9

	April 4, 2021	March 29, 2020
Reconciliation to amounts within the consolidated balance sheets:		
Cash and cash equivalents	\$ 153.8	\$ 349.8
Restricted cash included in Other assets	10.7	12.1
Cash, cash equivalents and restricted cash	\$ 164.5	\$ 361.9

ORTHO CLINICAL DIAGNOSTICS HOLDINGS PLC
Reconciliation of GAAP to non-GAAP results
(Unaudited)

(Dollars in millions)	Fiscal First Quarter Ended	
	April 4, 2021	March 29, 2020
Net loss	\$ (39.1)	\$ (101.2)
Interest expense, net	43.4	52.2
Provision for income taxes	3.3	4.1
Depreciation and amortization	82.7	79.8
Loss on extinguishment of debt	50.5	10.0
Stock-based compensation	3.5	1.6
Restructuring and severance related costs (a)	1.3	2.4
Tax indemnification income, net	(0.2)	(2.5)
Foreign currency exchange losses (b)	-	49.3
Other adjustments (c)	6.9	6.3
Adjusted EBITDA	\$ 152.4	\$ 102.0

(Dollars in millions)	Fiscal First Quarter Ended	
	April 4, 2021	March 29, 2020
Net loss	\$ (39.1)	\$ (101.2)
Intangible amortization	33.4	33.0
Loss on extinguishment of debt	50.5	10.0
Stock-based compensation	3.5	1.6
Restructuring and severance related costs (a)	1.3	2.4
Foreign currency exchange losses (b)	-	49.3
Other adjustments (c)	6.9	6.3
Total adjustments	95.6	102.6
Tax effect of reconciling items (d)	(2.0)	(3.3)
Discrete tax items (e)	0.3	-
Adjusted net income (loss)	\$ 54.9	\$ (1.9)
Adjusted basic EPS	\$ 0.27	\$ (0.01)
Adjusted diluted EPS	\$ 0.26	\$ (0.01)

(a) Represents restructuring and severance costs related to several discrete initiatives intended to strengthen operational performance and to support building our commercial capabilities including a project announced in fiscal year ended January 3, 2016 to outsource equipment manufacturing operations in Rochester, New York and a project announced in fiscal year ended December 30, 2018 to transfer certain production lines among facilities.

(b) For fiscal quarter ended March 29, 2020, this represents non-cash unrealized gains and losses resulting from the remeasurement of transactions denominated in foreign currencies primarily related to intercompany loans. In fiscal year 2021, the Company initiated programs to mitigate the impact of foreign currencies related to intercompany loans in our results and, as a result, such non-cash net unrealized losses were approximately \$22 million for the fiscal quarter ended April 4, 2021. Given we expect these programs to continue to mitigate the impact in future periods, we will not be adjusting our Adjusted EBITDA and Adjusted Net Income for non-cash unrealized gains and losses resulting from the remeasurement of transactions denominated in foreign currencies starting in the first quarter of fiscal 2021.

(c) Represents miscellaneous other adjustments related to unusual items impacting our results including the elimination of management fees, non-cash derivative mark-to-market (gain) loss and certain asset write-downs. See information below:

Fiscal First Quarter Ended

(\$ in millions)	April 4, 2021	March 29, 2020
EU medical device regulation transition costs	\$ 0.9	\$ 1.1
Principal shareholder management fee	0.8	0.8
Derivative mark-to-market loss	0.6	1.0
Other	4.6	3.4
Total other adjustments	<u>\$ 6.9</u>	<u>\$ 6.3</u>

(d) Non-GAAP adjustments were tax effected based on the nature of the expense and related jurisdiction, many of which are impacted by valuation allowances resulting in little to no tax impact.

(e) We exclude deferred tax resulting from changes in tax law and expiration of statutes, adjustments for uncertain tax positions, and other unusual items not related to current operating results.

(\$ in millions)	Fiscal First Quarter Ended	
	April 4, 2021	March 29, 2020
Net cash used in operating activities - GAAP	\$ (9.9)	\$ (17.5)
Adjustments:		
Net cash used in investing activities - GAAP	(10.7)	(18.3)
Unusual or non-recurring payments	7.5	7.4
Adjusted free cash flow (f)	<u>\$ (13.1)</u>	<u>\$ (28.4)</u>

(f) The Company defines free cash flow as net cash flow from operations accounted for under GAAP less net cash used in investing activities accounted for under GAAP plus or minus any unusual or non-recurring payments.

ORTHO CLINICAL DIAGNOSTICS HOLDINGS PLC
Reconciliation of GAAP to non-GAAP results
Core and Non-Core Revenue and Revenue by Segment
(Unaudited)

	Fiscal first quarter ended				Constant Currency Growth Rate ^(a)
	April 4, 2021	March 29, 2020	Percent Change	Currency Impact	
Core Revenue	\$ 499.3	\$ 404.3	23.5 %	\$ 9.2	21.1 %
Non-Core Revenue	7.5	3.6	106.4 %	-	106.4 %
Net Revenue	<u>\$ 506.8</u>	<u>\$ 407.9</u>	<u>24.2 %</u>	<u>\$ 9.2</u>	<u>21.8 %</u>
Segment net revenue					
Americas	\$ 321.4	\$ 250.5	28.3 %	\$ (0.7)	28.8 %
EMEA	68.5	58.7	16.8 %	4.8	8.2 %
Greater China	55.0	46.3	18.7 %	3.7	10.6 %
Other	61.9	52.4	18.2 %	1.6	15.1 %
Net revenue	<u>\$ 506.8</u>	<u>\$ 407.9</u>	<u>24.2 %</u>	<u>\$ 9.2</u>	<u>21.8 %</u>

(a) The term "constant currency" means we have translated local currency revenues for all reporting periods into U.S. dollars using the same comparable foreign currency exchange rates. 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.