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

FORM 10-Q

(Mark One)

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

For the quarterly period ended October 3, 2021

OR

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

Commission File Number: 001-39956

Ortho Clinical Diagnostics Holdings plc
(Exact name of registrant as specified in its charter)

England and Wales	**98-1574150**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
1001 Route 202 Raritan, New Jersey	**08869**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: 908-218-8000

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 per ordinary share	OCDX	Nasdaq Global Select Market

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☐
		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. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of October 29, 2021, the registrant had 236,889,470 ordinary shares outstanding ($0.00001 par value per share).

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Item 1. Financial Statements.

Ortho Clinical Diagnostics Holdings plc
Consolidated Statements of Operations
(Unaudited)
(In millions, except per share data)

	Fiscal Quarter Ended		Fiscal Nine Months Ended	
	October 3, 2021	September 27, 2020	October 3, 2021	September 27, 2020
Net revenue	$ 522.5	$ 451.1	$ 1,521.8	$ 1,249.6
Cost of revenue, excluding amortization of intangible assets	252.4	234.1	748.7	650.2
Gross profit	270.1	217.0	773.1	599.4
Selling, marketing and administrative expenses	140.9	121.0	411.0	347.9
Research and development expense	32.1	32.7	91.3	82.1
Amortization of intangible assets	33.3	33.1	100.3	98.7
Other operating expense, net	9.8	9.5	27.7	22.8
Income from operations	54.0	20.7	142.8	47.9
Interest expense, net	36.1	48.9	112.5	148.6
Tax indemnification (income) expense, net	(0.2)	16.5	(0.6)	11.6
Other (income) expense, net	(2.6)	(5.9)	50.8	61.1
Income (loss) before income taxes	20.7	(38.8)	(20.0)	(173.4)
Provision for (benefit from) income taxes	6.0	(10.3)	24.4	(2.4)
Net income (loss)	$ 14.7	$ (28.5)	$ (44.4)	$ (171.0)
Basic net income (loss) per ordinary share	$ 0.06	$ (0.20)	$ (0.20)	$ (1.17)
Basic weighted-average ordinary shares outstanding	235.6	146.4	225.4	146.4
Diluted net income (loss) per ordinary share	$ 0.06	$ (0.20)	$ (0.20)	$ (1.17)
Diluted weighted-average ordinary shares outstanding	242.8	146.4	225.4	146.4

The accompanying notes are an integral part of these unaudited consolidated financial statements.

Ortho Clinical Diagnostics Holdings plc
Consolidated Statements of Comprehensive Income (Loss)
(Unaudited)
(In millions)

	Fiscal Quarter Ended		Fiscal Nine Months Ended	
	October 3, 2021	September 27, 2020	October 3, 2021	September 27, 2020
Net income (loss)	$ 14.7	$ (28.5)	$ (44.4)	$ (171.0)
Other comprehensive income (loss), before tax:				
Foreign currency derivatives	2.1	(3.5)	6.4	(2.3)
Interest rate derivatives	5.9	1.0	22.7	(49.0)
Foreign currency translation adjustments	(13.9)	8.1	(21.7)	1.7
Other comprehensive income (loss), before tax	(5.9)	5.6	7.5	(49.6)
Income tax provision related to items of other comprehensive income (loss)	—	—	—	—
Other comprehensive income (loss), net of tax	(5.9)	5.6	7.5	(49.6)
Comprehensive income (loss)	$ 8.7	$ (22.9)	$ (36.9)	$ (220.6)

The accompanying notes are an integral part of these unaudited consolidated financial statements.

Ortho Clinical Diagnostics Holdings plc
Consolidated Balance Sheets
(Unaudited)
(In millions, except share and per share data)

	October 3, 2021	January 3, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 255.9	$ 132.8
Accounts receivable (net of allowance for credit losses of $9.7 and $9.8, respectively)	237.8	318.7
Inventories	308.3	278.7
Other current assets	141.8	127.0
Total current assets	943.8	857.2
Property, plant and equipment, net	782.6	832.0
Goodwill	570.8	580.1
Intangible assets, net	912.5	1,016.7
Deferred income taxes	7.1	8.0
Other assets	93.0	107.5
Total assets	$ 3,309.9	$ 3,401.5
Liabilities and Shareholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 139.3	$ 146.2
Accrued liabilities	251.5	284.7
Deferred revenue	32.6	35.5
Current portion of borrowings	64.4	160.0
Total current liabilities	487.7	626.4
Long-term borrowings	2,206.9	3,558.5
Employee-related obligations	39.9	39.3
Other liabilities	94.2	120.8
Deferred income taxes	84.4	67.3
Total liabilities	2,913.0	4,412.3
Commitments and contingencies (Note 15)		
Shareholders' Equity (Deficit):		
Preferred redeemable shares, $1.39 nominal value per share, 50,000 and no shares issued and outstanding as of October 3, 2021 and January 3, 2021, respectively	0.1	—
Ordinary shares, $0.00001 par, 1,000,000,000 shares authorized, 236,679,437 and 147,295,511 shares issued and outstanding as of October 3, 2021 and January 3, 2021, respectively	—	—
Additional paid-in capital	2,419.7	975.1
Accumulated deficit	(1,961.9)	(1,917.5)
Accumulated other comprehensive loss	(61.0)	(68.4)
Total shareholders' equity (deficit)	396.9	(1,010.8)
Total liabilities and shareholders' equity (deficit)	$ 3,309.9	$ 3,401.5

The accompanying notes are an integral part of these unaudited consolidated financial statements.

Ortho Clinical Diagnostics Holdings plc
Consolidated Statements of Changes in Shareholders' Equity (Deficit)
(Unaudited)
(In millions, except share data)

	Ordinary shares issued	Ordinary share par value	Preferred redeemable shares issued	Preferred redeemable shares par value	Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive loss	Total
Balance as of July 4, 2021	234,921,002	$ —	50,000	$ 0.1	$ 2,407.0	$ (1,976.6)	$ (54.9)	$ 375.6
Net income	—	—	—	—	—	14.7	—	14.7
Exercise of stock options	1,436,782	—	—	—	7.6	—	—	7.6
Restricted stock units vested, net of shares withheld for taxes	321,653	—	—	—	—	—	—	—
Recognition of stock-based compensation	—	—	—	—	5.1	—	—	5.1
Foreign currency derivatives, net of tax of $0.0	—	—	—	—	—	—	2.1	2.1
Interest rate derivatives, net of tax of $0.0	—	—	—	—	—	—	5.9	5.9
Foreign currency translation adjustments	—	—	—	—	—	—	(13.9)	(13.9)
Balance as of October 3, 2021	236,679,437	$ —	50,000	$ 0.1	$ 2,419.7	$ (1,961.9)	$ (61.0)	$ 396.9

	Ordinary shares issued	Ordinary share par value	Preferred redeemable shares issued	Preferred redeemable shares par value	Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive loss	Total
Balance as of June 28, 2020	146,560,341	$ —	—	$ —	$ 968.7	$ (1,848.1)	$ (127.1)	$ (1,006.5)
Net loss	—	—	—	—	—	(28.5)	—	(28.5)
Exercise of stock options	21,394	—	—	—	—	—	—	—
Restricted stock grant, net of shares retained for taxes	2,831	—	—	—	—	—	—	—
Recognition of stock-based compensation	—	—	—	—	2.4	—	—	2.4
Foreign currency derivatives, net of tax of $0.0	—	—	—	—	—	—	(3.5)	(3.5)
Interest rate derivatives, net of tax of $0.0	—	—	—	—	—	—	1.0	1.0
Foreign currency translation adjustments	—	—	—	—	—	—	8.1	8.1
Balance as of September 27, 2020	146,584,566	$ —	—	$ —	$ 971.1	$ (1,876.6)	$ (121.5)	$ (1,027.0)

The accompanying notes are an integral part of these unaudited consolidated financial statements.

Ortho Clinical Diagnostics Holdings plc
Consolidated Statements of Changes in Shareholders' Equity (Deficit)
(Unaudited)
(In millions, except share data)

	Ordinary shares issued	Ordinary share par value	Preferred redeemable shares issued	Preferred redeemable shares par value	Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive loss	Total
Balance as of January 3, 2021	147,295,511	$ —	—	$ —	$ 975.1	$ (1,917.5)	$ (68.4)	$ (1,010.8)
Net loss	—	—	—	—	—	(44.4)	—	(44.4)
Issuance of ordinary shares upon completion of initial public offering, net of commissions, underwriting discounts and offering costs	87,400,000	—	—	—	1,415.2	—	—	1,415.2
Issuance of incorporation shares consisting of ordinary share and preferred redeemable shares	1	—	50,000	0.1	—	—	—	0.1
Exercise of stock options	1,662,272	—	—	—	9.9	—	—	9.9
Restricted stock units vested, net of shares withheld for taxes	321,653	—	—	—	—	—	—	—
Recognition of stock-based compensation	—	—	—	—	19.6	—	—	19.6
Foreign currency derivatives, net of tax of $0.0	—	—	—	—	—	—	6.4	6.4
Interest rate derivatives, net of tax of $0.0	—	—	—	—	—	—	22.7	22.7
Foreign currency translation adjustments	—	—	—	—	—	—	(21.7)	(21.7)
Balance as of October 3, 2021	236,679,437	$ —	50,000	$ 0.1	$ 2,419.7	$ (1,961.9)	$ (61.0)	$ 396.9

	Ordinary shares issued	Ordinary share par value	Preferred redeemable shares issued	Preferred redeemable shares par value	Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive loss	Total
Balance as of December 29, 2019	146,437,574	$ —	—	$ —	$ 964.7	$ (1,705.6)	$ (71.9)	$ (812.8)
Net loss	—	—	—	—	—	(171.0)	—	(171.0)
Exercise of stock options	144,161	—	—	—	0.2	—	—	0.2
Restricted stock grant, net of shares retained for taxes	2,831	—	—	—	—	—	—	—
Recognition of stock-based compensation	—	—	—	—	6.2	—	—	6.2
Foreign currency derivatives, net of tax of $0.0	—	—	—	—	—	—	(2.3)	(2.3)
Interest rate derivatives, net of tax of $0.0	—	—	—	—	—	—	(49.0)	(49.0)
Foreign currency translation adjustments	—	—	—	—	—	—	1.7	1.7
Balance as of September 27, 2020	146,584,566	$ —	—	$ —	$ 971.1	$ (1,876.6)	$ (121.5)	$ (1,027.0)

The accompanying notes are an integral part of these unaudited consolidated financial statements.

Ortho Clinical Diagnostics Holdings plc
Consolidated Statements of Cash Flows
(Unaudited)
(Dollars in millions)

	Fiscal Nine Months Ended	
	October 3, 2021	September 27, 2020
Cash Flows from Operating Activities:		
Net loss	$ (44.4)	$ (171.0)
Adjustments to reconcile net loss to cash provided by (used in) operating activities:		
Depreciation and amortization	246.6	239.6
Unrealized foreign exchange (gains) losses, net	(18.2)	51.1
Loss on extinguishment of debt	50.3	12.6
Amortization of deferred financing costs and original issue discount	6.5	8.0
Stock-based compensation	19.6	6.2
Deferred tax provision	18.6	4.3
Change in allowance for credit losses	1.2	1.4
Other, net	(9.7)	1.4
Changes in operating assets and liabilities:		
Accounts receivable	73.7	34.5
Inventories	(117.3)	(126.9)
Other current and non-current assets	(14.4)	(27.6)
Accounts payable and accrued liabilities	(28.9)	(75.8)
Deferred revenue	(2.7)	(9.3)
Other current and non-current liabilities	7.3	2.9
Cash provided by (used in) operating activities	188.2	(48.6)
Cash Flows from Investing Activities:		
Purchases of property, plant and equipment	(27.2)	(28.4)
Proceeds from cross currency swaps	15.2	2.7
Milestone payments and other, net	0.2	(1.8)
Cash used in investing activities	(11.7)	(27.5)
Cash Flows from Financing Activities:		
Proceeds from initial public offering	1,426.4	—
Payment of initial public offering costs	(9.2)	—
Proceeds from long-term borrowings	—	1,421.0
Payments on long-term borrowings	(1,407.9)	(1,347.7)
Payments on short-term borrowings, net	(81.1)	(2.2)
Proceeds from exercise of stock options	9.9	0.2
Cash (used in) provided by financing activities	(61.9)	71.3
Effect of exchange rate changes on cash	(1.0)	0.5
Increase (decrease) in cash, cash equivalents and restricted cash	113.5	(4.3)
Cash, cash equivalents and restricted cash at beginning of period	144.2	84.0
Cash, cash equivalents and restricted cash at end of period	$ 257.7	$ 79.7

The accompanying notes are an integral part of these unaudited consolidated financial statements.

(1) General and description of the business

Ortho Clinical Diagnostics Holdings plc ("UK Holdco"), formerly known as Ortho-Clinical Diagnostics Bermuda Co. Ltd. ("Bermuda Holdco"), is a public limited company incorporated under the laws of England and Wales. UK Holdco became the new holding company of Bermuda Holdco and its subsidiaries and upon incorporation, UK Holdco had an initial share capital of one ordinary share and 50,000 preferred redeemable shares ("Incorporation Shares"). On January 25, 2021, The Carlyle Group L.P. ("Carlyle"), and all other shareholders of Bermuda Holdco contributed all of their outstanding equity interests in Bermuda Holdco to UK Holdco in exchange for ordinary shares of UK Holdco on a 1-for-1 basis ("Reorganization Transactions").

UK Holdco is a holding company with no business operations or assets other than cash, intercompany receivables, miscellaneous administrative costs and guarantees of certain obligations of Ortho-Clinical Diagnostics, Inc. ("Ortho U.S.") and 100% of its ownership interest of Ortho-Clinical Diagnostics Holdings Luxembourg S.à r.l., which itself is a holding company with no operations or assets other than cash, intercompany receivables, miscellaneous administrative costs and its ownership of 100% of the capital stock of Ortho-Clinical Diagnostics S.A. ("LuxCo"). LuxCo, together with its indirect wholly owned subsidiary, Ortho U.S., are co-borrowers under the Senior Secured Credit Facilities and co-issuers of the Notes (each as defined in Note 7). UK Holdco's global operations are conducted by indirect wholly owned subsidiaries. The terms "we", "us", "our", "its", and the "Company" refer to UK Holdco and its consolidated subsidiaries after giving effect to the Reorganization Transactions.

The Company is a leading global provider of in-vitro diagnostics ("IVD") solutions to the clinical laboratory and transfusion medicine communities. The Company maintains a commercial presence in more than 130 countries and territories. The Company's instruments, assays, reagents and other consumables are used in hospitals, laboratories, clinics, blood banks and donor centers worldwide. The Company is globally operated with manufacturing facilities in the United States ("U.S.") and the United Kingdom ("U.K.") and with sales centers, administrative offices and warehouses located throughout the world.

Both the Company's domestic and international operations have been and continue to be affected by the ongoing global pandemic of a novel strain of coronavirus ("COVID-19") and the resulting volatility and uncertainty it has caused in the U.S. and international markets. The Company has a direct commercial presence in more than 30 countries, including many of the regions most impacted by the COVID-19 pandemic. A decrease in shipments to the Company's customers began to occur during the fiscal quarter ended June 28, 2020 in many countries, including the U.S. As a result, during the fiscal year ended January 3, 2021, the Company experienced decreased revenues and incurred idle or underutilized facilities costs, higher freight and higher distribution costs compared to the periods prior to the pandemic. During the fiscal quarter ended January 3, 2021, the Company started to experience a recovery in the base business of its core revenue, which continued through the fiscal nine months ended October 3, 2021. During the same period, the Company also continued to experience higher distribution costs due to higher shipping rates as a result of the COVID-19 pandemic.

During the fiscal quarter ended April 4, 2021, the Company completed its initial public offering ("IPO") of ordinary shares at a price of $17.00 per share. The Company issued and sold 87,400,000 ordinary shares in the IPO, including 11,400,000 ordinary shares issued pursuant to the full exercise of the underwriters' option to purchase additional shares. The ordinary shares sold in the IPO were registered under the Securities Act of 1933, as amended (the "Securities Act") pursuant to a Registration Statement on Form S-1, which was declared effective by the Securities and Exchange Commission ("SEC") on January 29, 2021. The offering generated net proceeds of $1,426.4 million after deducting underwriting discounts and commissions.

The Company used a portion of the net proceeds from the IPO (i) to redeem $160.0 million of its 2025 Notes (as defined in Note 7), plus accrued interest thereon and $11.8 million of redemption premium, (ii) to redeem $270.0 million of its 2028 Notes (as defined in Note 7), plus accrued interest thereon and $19.6 million of redemption premium, (iii) to repay $892.7 million in aggregate principal amount of borrowings under its Dollar Term Loan Facility (as defined in Note 7) and (iv) for working capital and general corporate purposes.

In September 2021, the Company completed an underwritten secondary offering (the "Secondary Offering") of 25.3 million ordinary shares held by a selling shareholder affiliated with Carlyle, including 3.3 million ordinary shares pursuant to the full exercise of the underwriters' option to purchase additional shares. The ordinary shares sold in the Secondary Offering were registered under the Securities Act pursuant to a Registration Statement on Form S-1, which was declared effective by the SEC on September 9, 2021. The Company did not offer any ordinary shares in this transaction and did not receive any proceeds from the sale of the ordinary shares by the selling shareholder. The Company incurred costs of $1.1 million in relation to the Secondary Offering for the three and nine months ended October 3, 2021, which were recorded in selling, marketing and administrative expenses in the unaudited consolidated statement of operations.

These unaudited consolidated financial statements have been prepared on a basis which assumes that the Company will continue as a going concern and contemplates the realization of assets and satisfaction of liabilities and commitments in the normal course of business. As shown in the unaudited consolidated financial statements, the Company has total Cash and cash equivalents of $255.9 million and an

Accumulated deficit of $1,961.9 million as of October 3, 2021. The Company reported a Net loss of $44.4 million and Cash provided by operating activities of $188.2 million during the fiscal nine months ended October 3, 2021. The Company's primary future cash needs will be to meet debt service requirements, working capital needs and capital expenditures. Management is required to evaluate whether there are conditions and events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the financial statements are issued and, if so, disclose that fact.

The Company's debt agreements contain various covenants that may restrict the Company's ability to borrow on available credit facilities and future financing arrangements and require the Company to remain below a specific credit coverage threshold. The Company's Credit Agreement (as defined in Note 7) has a financial covenant referred to as the First Lien Net Leverage Ratio, (as defined in the Credit Agreement, not to exceed 5.5-to-1, subject to a 50 basis point step-down on September 30, 2022) that is tested when borrowings and letters of credit issued under the Revolving Credit Facility (as defined in Note 7) exceed 30% of the committed amount at any period end reporting date. Under the terms of the Credit Agreement, during the fiscal quarter ended July 4, 2021, the Company achieved a 50 basis point step-down on the interest rate on its Senior Secured Credit Facilities (as defined in Note 7) as a result of meeting its First Lien Net Leverage Ratio targets. As of October 3, 2021, the Company had no outstanding borrowings under its Revolving Credit Facility and letters of credit issued under the Revolving Credit Facility totaled $45.0 million. As of October 3, 2021, the Company was in compliance with the financial covenant. In the event the Company does not comply with the financial covenant of the Revolving Credit Facility, the lenders will have the right to call on all of the borrowings under the Revolving Credit Facility. If the lenders on the Revolving Credit Facility terminate their commitments and accelerate the loans, this would become a cross default to other material indebtedness.

The Company evaluated its liquidity position and ability to comply with financial covenants in its Revolving Credit Facility as of the date of the issuance of these unaudited consolidated financial statements. Based on this evaluation, management believes that the Company's financial position, Cash provided by operating activities combined with Cash and cash equivalents, and borrowing capacity available under its Revolving Credit Facility, will be sufficient to fund its current obligations, capital spending, debt service requirements and working capital requirements for a period of at least the next 12 months from the issuance of these unaudited consolidated financial statements.

Should it become necessary, the Company may seek to raise additional capital within the next 12 months through borrowings on credit facilities, other financing activities and/or the public or private sale of equity securities. The Company may also need to control discretionary spending, which could impact its planned general and administrative, research and development, or capital spend in an effort to provide sufficient funds to continue its operations or maintain compliance with the financial covenants, and the Company may be subject to adverse business conditions due to the global COVID-19 pandemic, all of which could adversely affect the Company's business.

(2) Basis of presentation of the unaudited consolidated financial statements

These unaudited consolidated financial statements for the Company include the accounts of UK Holdco and its subsidiaries. All intercompany accounts and transactions have been eliminated. These unaudited consolidated financial statements have been prepared in accordance with U.S. Generally Accepted Accounting Principles ("U.S. GAAP") and Regulation S-X. In the opinion of management, all adjustments, consisting only of normal recurring adjustments, considered necessary for a fair presentation have been included. Results for the fiscal quarter and nine months ended October 3, 2021 should not be considered indicative of results for the fiscal year ending January 2, 2022. These unaudited consolidated financial statements do not represent complete financial statements and should be read in conjunction with the Company's audited consolidated financial statements and footnotes thereto for the fiscal year ended January 3, 2021 in the Company's most recent Annual Report on Form 10-K.

The Company follows the concept of a fiscal year which ends on the Sunday nearest to the end of the month of December, and fiscal quarters which end on the Sunday nearest to the end of the months of March, June, and September. Each fiscal quarter presented in this Quarterly Report on Form 10-Q consists of 13 weeks.

Amounts reported in millions have been calculated based on underlying, unrounded amounts. Amounts presented in tables may not total due to rounding. Percentages have been calculated using underlying, unrounded amounts.

Stock Split

On January 18, 2021, the Company approved an issuance of 54,860,691 shares, or an additional 0.5934 share for each existing share, which effected a 1.5934-for-1 stock split of its ordinary shares. All references to share and per share amounts in the Company's unaudited consolidated financial statements have been retrospectively revised to reflect the stock split.

(3) Recent accounting pronouncements

In December 2019, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2019-12, *Income Taxes* (Topic 740): *Simplifying the Accounting for Income Taxes*, which enhances and simplifies various aspects of the income tax accounting guidance related to intra period tax allocations, interim period accounting for enacted changes in tax law, and the year-to-date loss limitation in interim period tax accounting. The Company adopted this guidance on January 4, 2021 and the adoption did not have a material impact on the Company's unaudited consolidated financial statements.

In January 2021, the FASB issued ASU 2021-01, *Reference Rate Reform* (Topic 848): *Scope*, which clarifies that certain optional expedients and exceptions in Topic 848 apply to derivative instruments that use an interest rate for margining, discounting, or contract price alignment that is modified as a result of reference rate reform. The guidance in ASU 2021-01 is optional and may be elected over time as reference rate reform activities occur. The optional amendments can be applied on a full retrospective basis as of any date from the beginning of an interim period that includes or is subsequent to March 12, 2020, or on a prospective basis to new modifications from any date within an interim period that includes or is subsequent to the date of the issuance of a final update, up to the date that financial statements are available to be issued. The guidance is not currently applicable to the Company. In a future period, the Company may apply elections and evaluate the impact of adoption, as applicable.

In July 2021, the FASB issued ASU 2021-05, *Leases (Topic 842): Lessors – Certain Leases with Variable Lease Payments*, which amends the accounting for lease contracts that have variable lease payments that do not depend on a reference index or rate, and which would have resulted in the recognition of a loss at lease commencement if classified as a sales-type or direct financing lease. Upon adoption, lessors will classify and account for leases with variable payments that do not depend on a reference index or rate as an operating lease if the lease would have been classified as a sales-type or direct financing lease, and if the lessor would have otherwise recognized a loss at lease commencement. The guidance in ASU 2021-05 is effective for fiscal years beginning after December 15, 2021 and can be applied either prospectively or retrospectively for reporting entities that have adopted Topic 842 prior to the issuance date of this amendment. The Company is currently evaluating the impact that adoption of this guidance will have on its consolidated financial statements.

(4) Net income (loss) per share

Basic net income (loss) per ordinary share is based on the weighted-average number of ordinary shares outstanding during the period. Diluted net income (loss) per ordinary share is based on the weighted-average number of ordinary shares and ordinary share equivalents, calculated using the treasury stock method, outstanding during the period. The Company excludes potential ordinary share equivalents from the calculation if the effect would be anti-dilutive. For each period specified below, the Company incurred a Net loss, except for fiscal quarter ended October 3, 2021, in which the Company reported Net income. For the periods in which the Company incurred a Net loss, it excluded potential ordinary share equivalents from the calculations of Diluted net loss per ordinary share because the effect was anti-dilutive. The weighted-average number of ordinary shares used in the computation of basic and diluted net income (loss) per share were as follows:

	Fiscal Quarter Ended		Fiscal Nine Months Ended	
(In millions)	**October 3, 2021**	**September 27, 2020**	**October 3, 2021**	**September 27, 2020**
Basic weighted-average ordinary shares outstanding	235.6	146.4	225.4	146.4
Effect of stock options, unvested restricted shares and restricted stock units	7.2	—	—	—
Diluted weighted-average ordinary shares	242.8	146.4	225.4	146.4

The following table provides the total outstanding ordinary share equivalents, unaffected by the treasury stock method weighted-average calculation, as of the end of each period below:

	Fiscal Quarter Ended		Fiscal Nine Months Ended	
(In millions)	**October 3, 2021**	**September 27, 2020**	**October 3, 2021**	**September 27, 2020**
Stock options	13.9	16.2	13.9	16.2
Unvested restricted shares and restricted stock units	0.6	0.3	0.6	0.3
	14.5	16.5	14.5	16.5

(Dollars in millions, unless otherwise stated)

(5) Revenue

Contract balances

Timing of revenue recognition may differ from timing of invoicing to customers. The Company records an asset when revenue is recognized prior to invoicing a customer ("contract asset"). Contract assets are included within Other current assets or Other assets in the Company's unaudited consolidated balance sheet and are transferred to accounts receivable when the right to payment becomes unconditional. The balance of Contract assets recorded in the Company's consolidated balance sheets were as follows:

	October 3, 2021	January 3, 2021
Other current assets	$ 47.8	$ 40.4
Other assets	0.8	2.4
Total contract assets	$ 48.7	$ 42.8

The contract asset balance consists of the following components:

- A customer supply agreement under which the difference between the timing of invoicing and revenue recognition resulted in a contract asset of $12.7 million and $15.1 million as of October 3, 2021 and January 3, 2021, respectively, of which $0.8 million and $2.4 million were recorded in Other assets as of October 3, 2021 and January 3, 2021 respectively.
- Contractual arrangements with certain customers under which the Company invoices the customers based on reportable results generated by its reagents; however, control of the goods transfers to the customers upon shipment or delivery of the products, as determined under the terms of the contract. Using the expected value method, the Company estimates the number of reagents that will generate a reportable result. The Company records the revenue upon shipment and an associated contract asset, and relieves the contract asset upon completion of the invoicing. The balance of the contract asset related to these arrangements was $36.0 million and $24.3 million as of October 3, 2021 and January 3, 2021, respectively.
- One of the Company's contract manufacturing agreements that recognizes revenue as the products are manufactured. The balance of the contract asset related to this arrangement was immaterial as of October 3, 2021 and $3.4 million as of January 3, 2021.

The Company reviews contract assets for expected credit losses resulting from the collectability of customer accounts. Expected losses are established based on historical losses, customer mix and credit policies, current economic conditions in customers' country or industry, and expectations associated with reasonable and supportable forecasts. No credit losses related to contract assets were recognized during the fiscal quarter and nine months ended October 3, 2021 and September 27, 2020, respectively.

The Company recognizes a contract liability when a customer pays an invoice prior to the Company transferring control of the goods or services ("contract liabilities"). The Company's contract liabilities consist of deferred revenue primarily related to customer service contracts. The Company classifies deferred revenue as current or noncurrent based on the timing of the transfer of control or performance of the service. The balance of the Company's current deferred revenue was $32.6 million and $35.5 million as of October 3, 2021 and January 3, 2021, respectively. The Company has one arrangement with a customer where the revenue is expected to be recognized beyond one year. The balance of the deferred revenue included in long-term liabilities was $5.8 million and $6.6 million as of October 3, 2021 and January 3, 2021, respectively, and was included in Other liabilities in the unaudited consolidated balance sheets. The amount of deferred revenue as of January 3, 2021 that was recorded in Net revenue during the fiscal nine months ended October 3, 2021 was $31.3 million.

Disaggregation of revenue

The Company generates product revenue in the following lines of business:

- Clinical Laboratories—Focused on clinical chemistry and immunoassay instruments and tests to detect and monitor disease progression across a broad spectrum of therapeutic areas.
- Transfusion Medicine—Focused on (i) immunohematology instruments and tests used for blood typing to ensure patient-donor compatibility in blood transfusions, and (ii) donor screening instruments and tests used for blood and plasma screening for infectious diseases for customers primarily in the United States.
- Other Product Revenue—Includes revenues primarily from contract manufacturing.

(Dollars in millions, unless otherwise stated)

The Company also enters into collaboration and license agreements pursuant to which the Company derives collaboration and royalty revenues. During the fiscal quarter ended October 3, 2021, the Company received an award of $8.5 million in connection with an arbitration proceeding related to one of its collaboration agreements, which was recorded in Net revenue. During the fiscal quarter ended September 27, 2020, the Company entered into two agreements with the Biomedical Advanced Research and Development Authority ("BARDA"), a division of the U.S. Department of Health and Human Services ("HHS"), for two awards of up to $13.6 million to develop and submit Emergency Use Authorizations and 510(k) applications to the U.S. Food and Drug Administration ("FDA") for its COVID-19 antigen and antibody tests, respectively. An additional award was granted to the Company on April 16, 2021 for an amount up to $3.6 million to submit a 510(k) application for its COVID-19 antigen test. During the fiscal quarter and nine months ended October 3, 2021, the Company recognized $1.5 million and $7.3 million, respectively, of Net revenue related to these grants based upon project milestones completed to date. During both the fiscal quarter and nine months ended September 27, 2020, the Company recognized $2.5 million of Net revenue related to these grants.

The following table summarizes Net revenue by line of business for the fiscal quarter and nine months ended October 3, 2021 and September 27, 2020:

	Fiscal Quarter Ended		Fiscal Nine Months Ended	
	October 3, 2021	September 27, 2020	October 3, 2021	September 27, 2020
Clinical Laboratories	$ 336.6	$ 300.1	$ 993.9	$ 816.7
Transfusion Medicine	170.7	140.6	494.5	414.5
Other Product Revenue	—	3.3	5.6	3.7
Total Product Revenue	507.4	444.1	1,494.1	1,234.9
Collaborations and Other Revenue	15.1	7.0	27.8	14.7
Net Revenue	$ 522.5	$ 451.1	$ 1,521.8	$ 1,249.6

(6) Inventories

The Company's inventories were as follows:

	October 3, 2021	January 3, 2021
Raw materials and supplies	$ 71.5	$ 77.2
Goods in process	38.3	35.2
Finished goods	198.6	166.3
Total Inventories	$ 308.3	$ 278.7

(7) Borrowings and other arrangements

As of October 3, 2021 and January 3, 2021, the components of borrowings were as follows:

	October 3, 2021	January 3, 2021
Senior Secured Credit Facilities		
Dollar Term Loan Facility	$ 1,292.8	$ 2,185.5
Euro Term Loan Facility	357.2	408.9
Revolving Credit Facility	—	—
2028 Notes	405.0	675.0
2025 Notes	240.0	400.0
Accounts Receivable Financing	—	75.0
Sale and Leaseback Financing	—	20.5
Finance lease obligation	0.8	1.0
Other short-term borrowings	0.8	0.9
Other long-term borrowings	2.9	3.9
Unamortized deferred financing costs	(22.6)	(40.9)
Unamortized original issue discount	(5.6)	(11.3)
Total borrowings	2,271.3	3,718.5
Less: Current portion	(64.4)	(160.0)
Long-term borrowings	$ 2,206.9	$ 3,558.5

(Dollars in millions, unless otherwise stated)

Senior secured credit facilities

On February 5, 2021, the Company entered into a fifth amendment of its credit agreement (as amended, the "Credit Agreement") governing its senior secured credit facilities, which consist of (i) the Dollar Term Loan Facility, (ii) the euro-denominated senior secured term loan facility in an amount equal to €337.4 million (the "Euro Term Loan Facility" and, together with the Dollar Term Loan Facility, the "Term Loan Facilities"), and (iii) the multi-currency senior secured revolving facility with commitments of $500.0 million (the "Revolving Credit Facility") (collectively, the "Senior Secured Credit Facilities"), which increased the Revolving Credit Facility contained in the credit agreement by $150.0 million to an aggregate amount of $500.0 million and extended the maturity date to February 5, 2026, provided that such date may be accelerated subject to certain circumstances as set forth in the fifth amendment. To the extent that the aggregate principal amount of the Dollar Term Loan Facility and Euro Term Loan Facility (and any Refinancing Indebtedness (as defined in the Credit Agreement) with respect thereto that matures on or prior to June 30, 2025) outstanding as of March 31, 2025 exceeds $500.0 million then the maturity date with respect to the Revolving Credit Facility shall be March 31, 2025. All other terms of the Senior Secured Credit Facilities will remain substantially the same except as otherwise amended by the fifth amendment.

In February 2021, the Company used a portion of the proceeds from its IPO to repay $892.7 million of borrowings under the Dollar Term Loan Facility and recognized a loss on early extinguishment of debt of $11.4 million, which is recorded as a component of Other expense, net during the fiscal nine months ended October 3, 2021.

As of October 3, 2021, there was no outstanding balance under the Revolving Credit Facility and letters of credit issued under the Revolving Credit Facility totaled $45.0 million, which reduced the availability under the Revolving Credit Facility to $455.0 million. The Senior Secured Credit Facilities are subject to various covenants that may restrict the Company's ability to borrow on available credit facilities and future financing arrangements or require the Company to remain below a specific credit coverage threshold as indicated in our debt agreements. The Senior Secured Credit Facilities include a financial covenant that is tested when borrowings and letters of credit issued under the Revolving Credit Facility exceed 30% of the committed amount at any period end reporting date and provides that LuxCo will not permit the First Lien Net Leverage Ratio as of the end of such fiscal quarter of the LuxCo and its Restricted Subsidiaries (as defined in the Credit Agreement) to be greater than (i) 5.50:1.00 for each fiscal quarter ending on or prior to September 30, 2022 and (ii) 5.00:1:00 for each fiscal quarter ending thereafter. Under the terms of the Credit Agreement, during the fiscal quarter ended July 4, 2021, the Company achieved a 50 basis point step-down on the interest rate on its Senior Secured Credit Facilities as a result of meeting its First Lien Net Leverage Ratio targets. The Company was in compliance with the covenants as of October 3, 2021.

As of October 3, 2021 and January 3, 2021, the remaining balance of deferred financing costs related to the Dollar Term Loan Facility was $8.6 million and $17.3 million, respectively. As of October 3, 2021 and January 3, 2021, the remaining balance of deferred financing costs related to the Euro Term Loan Facility was $3.8 million and $4.6 million, respectively. As of October 3, 2021 and January 3, 2021, the remaining unamortized balance related to the Revolving Credit Facility was $3.1 million and $3.4 million, respectively. The effective interest rate of the Dollar Term Loan Facility and Euro Term Loan Facility as of October 3, 2021 is 5.76% and 3.88%, respectively.

2025 Notes

On June 11, 2020, the LuxCo and Ortho U.S. (collectively, the "Issuers"), issued $400.0 million aggregate principal amount of 7.375% Senior Notes due 2025 (the "2025 Notes'), on which interest is payable semi-annually in arrears on June 1 and December 1 of each year. The 2025 Notes will mature on June 1, 2025. The 2025 Notes and guarantees thereof are senior unsecured obligations and rank equally in right of payment with all of the Issuers' and guarantors' existing and future senior debt, including the 2028 Notes (as defined below). The 2025 Notes and the guarantees thereof are effectively subordinated to any of the Issuers' and guarantors' existing and future secured debt, including the Senior Secured Credit Facilities, to the extent of the value of the assets securing such debt. In addition, the 2025 Notes and the guarantees thereof rank senior in right of payment to all of the Issuers' and guarantors' future subordinated debt and will be structurally subordinated to the liabilities of the Issuers' non-guarantor subsidiaries. The Company incurred deferred financing costs of $7.5 million related to the 2025 Notes, which were capitalized as deferred financing costs and are being amortized using the effective interest method as a component of interest expense over the life of the 2025 Notes.

On or after June 1, 2022, the Issuers have the option to redeem all or part of the 2025 Notes at the following redemption prices (expressed as percentages of principal amount):

Year	Price
2022	103.688%
2023	101.844%
2024 and thereafter	100.000%

(Dollars in millions, unless otherwise stated)

Notwithstanding the foregoing, at any time and from time to time prior to June 1, 2022, the Issuers may at their option redeem in the aggregate up to 100% of the original aggregate principal amount of the 2025 Notes plus accrued and unpaid interest, if any to, but not including, the date of redemption, plus a "make-whole premium." The Issuers may also, at their option, redeem up to 40% of the principal amount of the 2025 Notes with the net cash proceeds of certain equity offerings at a redemption price of 107.375% of the principal amount of the 2025 Notes redeemed, plus accrued and unpaid interest, if any, to, but not including, the date of redemption.

On February 5, 2021, the Company used a portion of the proceeds from its IPO to redeem $160.0 million aggregate principal amount of the 2025 Notes, plus accrued interest thereon and $11.8 million of redemption premium, which was recorded as a component of Other expense, net, during the fiscal nine months ended October 3, 2021. The redemption resulted in an extinguishment loss recognized of $14.5 million, which consisted of $2.7 million of unamortized deferred issuance costs and $11.8 million of the redemption premium. As of October 3, 2021 and January 3, 2021, the remaining unamortized balance of deferred issuance costs was $3.6 million and $7.0 million, respectively. The effective interest rate on the 2025 Notes is 8.03%.

2028 Notes

On January 27, 2020, the Issuers, issued $675.0 million aggregate principal amount of 7.250% Senior Notes due 2028 (the "2028 Notes" and together with the 2025 Notes, the "Notes"), on which interest is payable semi-annually in arrears on February 1 and August 1 of each year. The 2028 Notes will mature on February 1, 2028. The 2028 Notes and the guarantees thereof are senior unsecured obligations and rank equally in right of payment with all of the Issuers' and guarantors' existing and future senior debt, including the 2025 Notes. The 2028 Notes and the guarantees thereof are effectively subordinated to any of the Issuers' and guarantors' existing and future secured debt, including the Senior Secured Credit Facilities, to the extent of the value of the assets securing such debt. In addition, the 2028 Notes and the guarantees thereof rank senior in right of payment to all of the Issuers' and guarantors' future subordinated debt and will be structurally subordinated to the liabilities of the Issuers' non-guarantor subsidiaries. The Company incurred deferred financing costs of $12.9 million related to the 2028 Notes, which were capitalized as deferred financing costs and are being amortized using the effective interest method as a component of interest expense over the life of the 2028 Notes.

On or after February 1, 2023, the Issuers have the option to redeem all or part of the 2028 Notes at the following redemption prices (expressed as percentages of principal amount):

Year	Price
2023	103.625%
2024	101.813%
2025 and thereafter	100.000%

Notwithstanding the foregoing, at any time and from time to time prior to February 1, 2023, the Issuers may at their option redeem in the aggregate up to 100% of the original aggregate principal amount of the 2028 Notes plus accrued and unpaid interest, if any to, but not including, the date of redemption, plus a "make-whole premium." The Issuers may also, at their option, redeem up to 40% of the principal amount of the 2028 Notes with the net cash proceeds of certain equity offerings at a redemption price of 107.25% of the principal amount of the 2028 Notes redeemed, plus accrued and unpaid interest, if any, to, but not including, the date of redemption.

On February 5, 2021, the Company used a portion of the proceeds from its IPO to redeem $270.0 million aggregate principal amount of the 2028 Notes, plus accrued interest thereon and $19.6 million of redemption premium. The redemption resulted in an extinguishment loss recognized of $24.3 million, which consisted of $4.7 million of unamortized deferred issuance costs and $19.6 million of the redemption premium, which is recorded as a component of Other expense, net during the fiscal nine months ended October 3, 2021. As of October 3, 2021 and January 3, 2021, the remaining unamortized balance of deferred issuance costs was $6.6 million and $11.8 million, respectively. The effective interest rate on the 2028 Notes is 7.76%.

2022 Notes

On January 28, 2020, the Company used the net proceeds from the issuance of the Euro Term Loan Facility and 2028 Notes, after payment of fees and expenses, to fund the redemption and discharge of $1.0 billion of the $1.3 billion in aggregate principal amount of 6.625% Senior Notes due 2022 (the "2022 Notes"). On June 12, 2020 the Company used the net proceeds from the issuance of the 2025 Notes, after payments of fees and expenses, to fund the redemption and discharge of the remaining $300.0 million of the 2022 Notes. The redemption of the 2022 Notes was accounted for as an extinguishment of debt. During the fiscal nine months ended September 27, 2020, the Company

recorded a $12.6 million loss on extinguishment of debt, primarily related to the unamortized deferred financings costs on the redeemed 2022 Notes, included as a component of Other expense, net.

Sale and leaseback financing

In June 2016, the Company entered into a sale-leaseback financing arrangement with a third-party financing company (the "Buyer-lessor") related to specific property and equipment of the Company. The property and equipment were sold for $36.3 million and leased back over an initial term of two years. The monthly lease payments were $1.5 million until the equipment is repurchased or the lease is terminated. At the end of the initial term, the Company could repurchase the property and equipment at a price to be negotiated with the Buyer-lessor or terminate the lease arrangement, return the property or (possibly) enter into a new lease agreement. During the fiscal quarter ended July 1, 2018, the Company gave notice to the Buyer-lessor that it intends to negotiate with the Buyer-lessor the purchase of the property and equipment at the end of the initial term and have had discussions on negotiating the repurchase price for the property and equipment. Pursuant to the sale-leaseback financing agreement, if the parties do not reach a new lease agreement to purchase the property and equipment at the end of the initial term, the lease will automatically renew for another year, and afterwards, the lease will automatically be renewed for successive six month periods, provided that each of the Company and the Buyer-lessor have a right to terminate the lease agreement 30 days prior to the end of each six month renewal period. A security deposit for the leaseback was retained by the third-party financing company, the balance of which was $9.1 million as of January 3, 2021 and was included in Other current assets in the consolidated balance sheet. The transaction did not meet the criteria for sale-leaseback accounting as the security deposit constitutes a continuing involvement. Therefore, the Company accounted for this arrangement as a financing over 42 months and recorded a financing obligation amounting to $36.3 million at inception.

On February 9, 2021, the Company and the Buyer-lessor agreed on a re-purchase price for the property and equipment, which included the outstanding balance of the financing plus accrued interest. The Company paid the full amount of the negotiated price during the fiscal nine months ended October 3, 2021.

Accounts receivable financing

In September 2016, the Company entered into an accounts receivable financing program (the "Financing Program") with a financial institution. The Financing Program, which was fully paid off in June 2021 in connection with entry into the RPA (as defined below), was set to mature on January 24, 2022 and was secured by receivables from the Company's U.S. business that are sold or contributed to a wholly-owned, consolidated, bankruptcy remote subsidiary. The bankruptcy remote subsidiary's sole business consisted of the purchase or receipt of the receivables and subsequent granting of a security interest to the financial institution under the program, and its assets were available first to satisfy obligations and were not available to pay creditors of the Company's other legal entities. Under the Financing Program, the Company could borrow up to the lower of $75.0 million or 85% of the accounts receivable borrowing base.

Interest on outstanding borrowings under the Financing Program was charged based on a per annum rate equal to the London Inter-bank Offered Rate (the "LIBOR Rate") (with a floor of zero percent and as defined in the agreement) plus the LIBOR Rate margin (2.25 percentage points) if the related loan was a LIBOR Rate loan. Otherwise, the per annum rate was equal to a Base Rate (as defined in the Financing Program agreement) plus the base rate margin (1.25 percentage points). Interest was due and payable, in arrears, on the first day of each month. The Financing Program was also subject to termination under standard events of default as defined.

On June 11, 2021, Ortho-Clinical Diagnostics FinanceCo I, LLC ("Ortho FinanceCo I"), a wholly owned receivables financing subsidiary of the Company, entered into a receivables purchase agreement (the "RPA") with Wells Fargo Bank, N.A., as administrative agent (the "Agent"), and certain purchasers. Under the RPA, Ortho FinanceCo I may sell receivables in amounts up to a $75.0 million limit. Transfers of receivables under the RPA are accounted for as a sale by the Company, resulting in a reduction in accounts receivables on the unaudited consolidated balance sheet.

The $75.0 million limit is subject to certain conditions, including that, at any date of determination, the aggregate capital paid to Ortho FinanceCo I does not exceed a "capital coverage amount," equal to an adjusted net receivables pool balance minus a required reserve. Ortho FinanceCo I has guaranteed the prompt payment of the sold receivables, and to secure the prompt payment and performance of such guaranteed obligations, Ortho FinanceCo I has granted a security interest to the Agent, for the benefit of the purchasers, in all assets of Ortho FinanceCo I. The Company, in its capacity as master servicer under the RPA, is responsible for administering and collecting the receivables and has made customary representations, warranties, covenants and indemnities. The Company has also provided a performance guarantee for the benefit of Ortho FinanceCo I to cause the due and punctual performance by Ortho of its obligations as master servicer. The proceeds of the RPA were used, in part, to pay off the outstanding balance of the Financing Program. The impact on the Company's unaudited consolidated statements of operations related to the RPA during the fiscal quarter and nine months ended October 3, 2021 was not material.

(Dollars in millions, unless otherwise stated)

The RPA is subject to customary events of termination for transactions of this type and, in addition, includes a financial covenant termination event if the "first lien net leverage ratio," calculated as of the last day of each fiscal quarter, of the Company exceeds (i) 5.50:1.00 for each fiscal quarter ending on or prior to September 30, 2022, and (ii) 5.00:1:00 for each fiscal quarter ending thereafter. The RPA has a scheduled termination date which is the earlier of (i) June 11, 2024, and (ii) the date that is 90 days prior to the maturity of the indebtedness incurred under the Company's Senior Secured Credit Facilities. As of October 3, 2021, the Company was in full compliance with all debt covenant requirements.

The following table provides the detail of amounts within Interest expense, net for the fiscal quarter and nine months ended October 3, 2021 and September 27, 2020:

	Fiscal Quarter Ended		Fiscal Nine Months Ended	
	October 3, 2021	September 27, 2020	October 3, 2021	September 27, 2020
Interest expense:				
Dollar Term Loan Facility	$ 10.2	$ 19.1	$ 34.8	$ 68.6
Euro Term Loan Facility	3.3	3.5	10.3	9.0
Revolving Credit Facility	1.5	0.2	2.1	3.4
2028 Notes	7.3	12.1	23.7	32.8
2025 Notes	4.4	7.3	14.3	8.8
2022 Notes	—	—	—	14.1
Accounts Receivable Financing	—	1.1	0.7	3.7
Amortization of:				
Deferred financing costs	1.6	2.2	4.9	6.5
Original issue discount	0.4	0.6	1.1	1.8
Derivative instruments and other	7.6	2.8	20.7	(0.1)
Interest expense, net	$ 36.1	$ 48.9	$ 112.5	$ 148.6

Future repayments

Below is a schedule of required future repayments of all borrowings outstanding as of October 3, 2021:

Remainder of 2021	$ 45.8
2022	63.5
2023	63.1
2024	62.8
2025	1,659.4
Thereafter	405.0
	$ 2,299.5

(8) Supplemental balance sheet information

Cash and cash equivalents and restricted cash within the unaudited consolidated balance sheets are presented below:

	October 3, 2021	January 3, 2021
Cash and cash equivalents	$ 255.9	$ 132.8
Restricted cash included in Other assets	1.8	11.4
Cash, cash equivalents and restricted cash	$ 257.7	$ 144.2

(Dollars in millions, unless otherwise stated)

Accrued liabilities included in Total current liabilities consisted of the following:

	October 3, 2021	January 3, 2021
Accrued compensation and employee-related obligations	$ 101.8	$ 110.5
Accrued commissions and rebates	28.3	24.9
Accrued taxes other than income	18.7	14.3
Accrued interest	17.3	42.2
Current portion of operating lease liabilities	12.0	15.1
Derivatives	3.2	10.3
Other accrued liabilities	70.3	67.4
Total accrued liabilities	$ 251.5	$ 284.7

(9) Collaborations and other relationships

In the normal course of business, the Company has entered into various collaboration arrangements which provide the Company with rights to develop, produce and market products using certain know-how, technology and patent rights maintained by the Company's collaborative partners. The arrangements are often entered into in order to share risks and rewards related to a specific program or product. The Company's collaborative arrangements include agreements with respect to transition services and a number of on-going relationships.

Grifols / Novartis Vaccines and Diagnostics, Inc.

The Company and Grifols Diagnostic Solutions, Inc. ("Grifols") have an ongoing collaboration arrangement (the "Joint Business") to pursue income-generating opportunities through the development of certain intellectual properties ("IP"). The Company's portion of the pre-tax net profit shared under the Joint Business was $21.3 million and $45.5 million during the fiscal quarter and nine months ended October 3, 2021, respectively. The Company's portion of the pre-tax net profit shared under the Joint Business was $13.4 million and $35.9 million during the fiscal quarter and nine months ended September 27, 2020, respectively.

Quotient Limited

In January 2015, the Company entered into an exclusive agreement with Quotient Limited ("Quotient"), a commercial-stage diagnostics company, to distribute and sell Quotient's transfusion diagnostics platform MosaiQ™. Under the terms of a distribution and supply agreement, Quotient is responsible for the development and launch of MosaiQ™, while the Company will leverage its worldwide commercial capabilities to sell the product to customers. The Company has exclusive rights to distribute MosaiQ™ for the global patient testing market (for blood grouping) and the donor testing market in the developing world and Japan (for blood grouping and serological disease screening). Quotient retains all rights to commercialize MosaiQ™ in the developed world, excluding Japan, for the donor testing market. On September 4, 2020, the Company and Quotient amended the distribution and supply agreement and entered into a binding letter agreement (the "Letter Agreement").

Pursuant to the Letter Agreement, the Company made an initial, non-refundable upfront payment of $7.5 million to Quotient on the date of the Letter Agreement, and recorded a corresponding $7.5 million charge to Research and development expense for the fiscal quarter and nine months ended September 27, 2020. In addition to the initial $7.5 million upfront payment, the Company may be required to make up to an additional $60.0 million of payments upon achievement of certain regulatory milestones and commercial sales benchmarks, which include up to $25.0 million of payments upon the achievement by the Company of certain cumulative revenue milestones. The Company did not make such payments during the fiscal nine months ended October 3, 2021 and does not anticipate making any such payments for the remainder of fiscal year 2021.

In the Letter Agreement, the Company and Quotient have agreed that the Company will have the right to distribute exclusively in the U.S., the European Economic Area, the U.K. and Switzerland a transfusion diagnostic patient immunohematology microarray ("PIM"), intended for use with Quotient's MosaiQ Instruments, on which multiple compounds are placed which, when exposed to human blood samples, generate reactions that indicate the presence or absence of certain blood characteristics and antigens and is intended for immuno-hematological testing of the blood of medical patients during the course of their care or treatment.

During the fiscal quarter and nine months ended October 3, 2021, under a separate supply agreement, the Company purchased inventories from a subsidiary of Quotient amounting to $5.1 million and $17.1 million, respectively. The Company purchased inventories from

(Dollars in millions, unless otherwise stated)

the Quotient subsidiary amounting to $6.4 million and $17.1 million during the fiscal quarter and nine months ended September 27, 2020, respectively. As of October 3, 2021 and January 3, 2021, Accounts payable included amounts related to purchases from the Quotient subsidiary of $2.9 million and $2.3 million, respectively. During both the fiscal quarter and nine months ended October 3, 2021, sales to Quotient were $0.1 million. During the fiscal quarter and nine months ended September 27, 2020, sales to Quotient were $0.1 million and $0.2 million, respectively. As of October 3, 2021 and January 3, 2021, amounts due from Quotient were immaterial.

(10) Income taxes

During the fiscal quarter ended October 3, 2021, the Company reported income before provision for income taxes of $20.7 million and recognized a provision for income taxes of $6.0 million, resulting in an effective tax rate of 29.1%. During the fiscal nine months ended October 3, 2021, the Company incurred a loss before provision for income taxes of $20.0 million and recognized a provision for income taxes of $24.4 million, resulting in a negative effective tax rate of 122.2%. The effective tax rate for the fiscal nine months ended October 3, 2021 differs from the U.S. federal statutory rate primarily due to (i) a net cost of $27.5 million for the impacts of operating losses in certain subsidiaries not being benefited due to the establishment of valuation allowances, (ii) a net benefit of $10.9 million related to non-U.S. earnings being taxed at rates that are different than the U.S. statutory rate, and (iii) a net cost of $10.6 million for the tax expense associated with the remeasurement of deferred tax assets and liabilities due to the enactment of new tax rates, primarily in the United Kingdom.

During the fiscal quarter ended September 27, 2020, the Company incurred a loss before provision for income taxes of $38.8 million and recognized an income tax benefit of $10.3 million, resulting in an effective tax rate of 26.5%. During the fiscal nine months ended September 27, 2020, the Company incurred a loss before provision for income taxes of $173.4 million and recognized an income tax benefit of $2.4 million, resulting in an effective tax rate of 1.4%. The effective tax rate for the fiscal nine months ended September 27, 2020 differs from the U.S. federal statutory rate primarily due to (i) a net cost of $39 million for the impacts of operating losses in certain subsidiaries not being benefited due to the establishment of valuation allowances, (ii) a net benefit of $12 million related to the increase in the Company's interest expense on prior year reserves for uncertain tax positions, and (iii) a net cost of $9.7 million due to the non-U.S. earnings being taxed at rates that are different than the U.S. statutory rate.

The balance of unrecognized tax benefits at October 3, 2021, not including interest and penalties, was $28.3 million, of which $23.8 million would affect the effective income tax rate in future periods, if recognized. The Company also recognizes interest and penalties related to unrecognized tax benefits in tax expense. At October 3, 2021, the Company had approximately $6.7 million of interest and penalties accrued related to unrecognized tax benefits. The Company estimates that within the next twelve months, its uncertain tax positions, excluding interest, will not significantly decrease.

Indemnification assets

On January 16, 2014, Bermuda Holdco entered into a stock and asset purchase agreement (the "Acquisition Agreement") of (i) certain assets and liabilities, and (ii) all of the equity interests and substantially all of the assets and liabilities of certain entities which, together with their subsidiaries, comprised the Ortho Clinical Diagnostics business from Johnson & Johnson. The Acquisition Agreement generally provided that Johnson & Johnson retained all income tax liabilities accrued as of the date of the acquisition, including reserves for unrecognized tax benefits. The indemnification receivable from Johnson & Johnson totaled $17.6 million and $17.0 million as of October 3, 2021 and January 3, 2021, respectively. The Company recorded $0.2 million and $0.6 million of interest and penalties during the fiscal quarter and nine months ended October 3, 2021, respectively. These receivables are included as a component of Other current assets and Other assets on the unaudited consolidated balance sheets.

(11) Stock-based compensation

Stock-based compensation for the fiscal quarter and nine months ended October 3, 2021 and September 27, 2020 are presented in the unaudited consolidated statements of operations in the following captions:

	Fiscal Quarter Ended		Fiscal Nine Months Ended	
	October 3, 2021	September 27, 2020	October 3, 2021	September 27, 2020
Cost of revenue	$ 0.1	$ 0.2	$ 0.4	$ 0.6
Selling, marketing and administrative expenses	4.9	2.1	18.9	5.4
Research and development expense	0.1	0.1	0.4	0.2
Total stock-based compensation	$ 5.1	$ 2.4	$ 19.6	$ 6.2

(Dollars in millions, unless otherwise stated)

On May 3, 2021, the Board of Directors approved the modifications to the vesting of restricted stock and Liquidity Event option awards held by certain current and former members of management. The modification of restricted stock pertained to an award granted to a current member of management, for which the original vesting pattern was on a cliff-vesting basis over a three-year period. Upon modification, the vesting for 50% of the award was accelerated to six months from the date of the Company's IPO. The result of the modification was an additional $0.3 million and $1.6 million of stock-based compensation expense recorded for the fiscal quarter and nine months ended October 3, 2021, respectively. There was no modification to the vesting conditions for the remaining 50% of the award and no additional shares granted as a result of the modification. The total unrecognized expense relating to unvested shares for this award as of the fiscal quarter ended October 3, 2021 was $0.7 million and will be recognized over a period of one year. The other modification related to an award granted to a former member of management for which the original vesting was contingent on a certain liquidity event as defined by the option agreement. The modification changed the vesting for the award such that the entirety of the award vested on the date the modification was approved by the Board of Directors. The modification resulted in an additional $4.6 million of stock-based compensation expense recognized during the fiscal quarter ended July 4, 2021. The additional expense related to both award modifications is recorded as a component of Selling, marketing and administrative expenses.

(12) Segment and geographic information

The Company has three geographically-based reportable segments: Americas, Europe, the Middle East and Africa ("EMEA"), and Greater China. Although all three segments are engaged in the marketing, distribution and sale of diagnostic instruments and assays for hospitals, laboratories and/or blood and plasma centers worldwide, each region is managed separately to better align with the market dynamics of the specific geographic region. Japan and Asia Pacific ("ASPAC") are immaterial operating segments not considered as reportable segments and are included in "Other."

Net revenue by segment is as follows:

	Fiscal Quarter Ended		Fiscal Nine Months Ended	
	October 3, 2021	September 27, 2020	October 3, 2021	September 27, 2020
Americas	$ 306.5	$ 264.2	$ 924.2	$ 755.8
EMEA	67.2	58.6	203.5	168.2
Greater China	85.6	72.7	199.1	162.3
Net revenue of reportable segments	$ 459.3	$ 395.5	$ 1,326.8	$ 1,086.3
Other	63.2	55.6	195.1	163.2
Net revenue	$ 522.5	$ 451.1	$ 1,521.8	$ 1,249.6

Effective January 4, 2021, the Company changed the basis for which it measures segment profit or loss from Management EBITDA to Adjusted EBITDA. The new basis has been retroactively applied to the prior year period presented. Adjusted EBITDA by segment is as follows:

	Fiscal Quarter Ended		Fiscal Nine Months Ended	
	October 3, 2021	September 27, 2020	October 3, 2021	September 27, 2020
Americas	$ 125.0	$ 116.8	$ 394.2	$ 329.9
EMEA	17.2	10.7	47.7	31.4
Greater China	42.2	41.1	91.7	78.9
Other	19.0	16.7	61.4	49.9
Corporate(a)	(63.8)	(65.9)	(174.8)	(167.8)
Adjusted EBITDA	$ 139.6	$ 119.5	$ 420.1	$ 322.4

(a) Corporate primarily consists of costs related to executive and staff functions, including certain finance, human resources, manufacturing and information technology, which benefit the Company as a whole. These costs are primarily related to the general management of these functions on a corporate level and the design and development of programs, policies and procedures that are then implemented in the individual segments, with each segment bearing its own cost of implementation. The Company's corporate function also includes debt and stock-based compensation associated with all employee stock-based awards.

(Dollars in millions, unless otherwise stated)

The reconciliation of Net income (loss) to Adjusted EBITDA is as follows:

	Fiscal Quarter Ended		Fiscal Nine Months Ended	
	October 3, 2021	September 27, 2020	October 3, 2021	September 27, 2020
Net income (loss)	$ 14.7	$ (28.5)	$ (44.4)	$ (171.0)
Interest expense, net	36.1	48.9	112.5	148.6
Provision for (benefit from) income taxes	6.0	(10.3)	24.4	(2.4)
Depreciation and amortization	80.8	79.9	246.6	239.6
Stock-based compensation	5.0	2.4	19.5	6.2
Restructuring and severance-related costs	1.7	4.7	4.7	9.3
Arbitration award	(7.4)	—	(7.4)	—
Tax indemnification (income) expense, net	(0.2)	16.5	(0.6)	11.6
Loss on extinguishment of debt	—	—	50.3	12.6
Quotient upfront payment	—	7.5	—	7.5
Unrealized foreign currency exchange (gains) losses, net	—	(6.3)	—	46.0
Other adjustments	2.9	4.7	14.5	14.4
Adjusted EBITDA	$ 139.6	$ 119.5	$ 420.1	$ 322.4

For the fiscal quarter and nine months ended September 27, 2020, unrealized foreign currency exchange (gains) losses, net relate to the remeasurement of transactions denominated in foreign currencies, primarily intercompany loans. Beginning in fiscal 2021, the Company initiated programs to mitigate the impact of foreign currency exchange rate fluctuations from intercompany loans. The Company recognized unrealized foreign currency exchange net gains of $4.3 million in the fiscal quarter ended October 3, 2021 and $38.0 million in the fiscal nine months ended October 3, 2021. The Company intends for these programs to mitigate the impact of foreign currency exchange rate fluctuations related to intercompany loans in current and future periods. Therefore, effective January 4, 2021, the Company no longer excludes noncash unrealized gains and losses from Adjusted EBITDA.

(13) Noncash investing and financing activities

During the fiscal nine months ended October 3, 2021 and September 27, 2020, the Company made noncash transfers of instrument inventories from Inventories to Property, plant and equipment, net of $82.6 million and $91.5 million, respectively.

As of October 3, 2021 and January 3, 2021, Accounts payable and Accrued liabilities included amounts related to purchases of property, plant and equipment and capitalized internal-use software costs of $10.4 million and $11.4 million, respectively. As of September 27, 2020 and December 29, 2019, Accounts payable and Accrued liabilities included amounts related to purchases of property, plant and equipment and capitalized internal-use software costs of $3.5 million and $14.1 million, respectively. The changes in these balances are excluded from changes in Accounts payable and Accrued liabilities in the unaudited consolidated statements of cash flows.

There was $3.0 million of initial public offering costs remaining in Accounts payable and Accrued liabilities as of January 3, 2021. There were no amounts related to initial public offering costs in Accounts payable and Accrued liabilities as of October 3, 2021.

(14) Related party transactions

The Company entered into consulting services agreements with Carlyle Investment Management, L.L.C. (“CIM”), pursuant to which the Company pays CIM a fee for advisory, consulting and other services to be provided to the Company (the “Consulting Services Agreement”). Pursuant to the Consulting Services Agreement, which has an initial term of ten years, the Company pays an annual management fee to CIM of $3.0 million (the “Management Fee”). The Management Fee is payable on a quarterly basis. The Company will also reimburse CIM’s reasonable out-of-pocket expenses incurred in connection with services provided pursuant to the Consulting Services Agreement, and the Company may pay CIM additional fees associated with other future transactions or in consideration of any additional services provided to the Company under the Consulting Services Agreement. During both the fiscal quarter ended October 3, 2021 and September 27, 2020, the Company recorded $0.8 million of Management Fee and other out-of-pocket expenses. During both the fiscal nine months ended October 3, 2021 and September 27, 2020, the Company recorded $2.3 million of Management Fee and other out-of-pocket expenses. As of January 3, 2021 and October 3, 2021, amounts due to CIM were immaterial.

The Company, as part of the normal course of business, entered into agreements to sell products and provide services to health care diagnostics companies that are portfolio companies of a fund affiliated with Carlyle. During the fiscal quarter ended October 3, 2021 and

September 27, 2020, the Company recognized revenues from business conducted with these health care diagnostics companies of $3.2 million and $0.4 million, respectively. During the fiscal nine months ended October 3, 2021 and September 27, 2020, the Company recognized revenues from business conducted with these health care diagnostics companies of $5.0 million and $1.3 million, respectively. As of both October 3, 2021 and January 3, 2021, Accounts receivable included amounts related to these health care diagnostics companies of $1.2 million.

The Company, as part of the normal course of business, purchased inventories from a healthcare equipment company that is a portfolio company of a fund affiliated with Carlyle. During the fiscal quarter and nine months ended October 3, 2021, the Company recorded expenses for business conducted with this healthcare equipment company of $1.3 million and $2.2 million, respectively. The Company did not record any expenses for business conducted with this healthcare equipment company during fiscal quarter and nine months ended September 27, 2020. As of October 3, 2021, Accounts payable included immaterial amounts due to this healthcare equipment company. As of January 3, 2021, there were no amounts due to this healthcare equipment company.

Portfolio companies of funds affiliated with Carlyle provide Information Technology (“IT”) services to the Company. During the fiscal quarter ended October 3, 2021 and September 27, 2020, the Company recorded expenses for business conducted with these companies of $0.3 million and $0.2 million, respectively. During the fiscal nine months ended October 3, 2021 and September 27, 2020, the Company recorded expenses for business conducted with these companies of $1.0 million and $0.2 million, respectively. As of both October 3, 2021 and January 3, 2021, Accounts payable included amounts related to these companies of $0.1 million.

A portfolio company of a fund affiliated with Carlyle provides consulting services to the Company. During the fiscal quarter ended October 3, 2021 and September 27, 2020, the Company recorded expenses for business conducted with this portfolio company of $0.1 million and $0.3 million, respectively. During the fiscal nine months ended October 3, 2021 and September 27, 2020, the Company recorded expenses for business conducted with this portfolio company of $1.3 million and $0.7 million, respectively. As of January 3, 2021, Accounts payable included amounts related to this portfolio company of $0.3 million. As of October 3, 2021, there were no amounts due to this portfolio company.

A security services company that is affiliated with Carlyle provides services to the Company at one of its facilities. This was a new Carlyle investment in 2021. During the fiscal quarter and nine months ended October 3, 2021, the Company recorded expenses for these services of $0.2 million and $0.8 million, respectively. As of both October 3, 2021 and January 3, 2021, Accounts payable included $0.1 million of amounts due to this company.

A pharmacy benefit management organization that is a portfolio company of a fund affiliated with Carlyle provides pharmacy services to the Company. During the fiscal quarter ended October 3, 2021 and September 27, 2020, the Company recorded expenses for business conducted with this pharmacy benefit management organization of $1.5 million and $1.6 million, respectively. During the fiscal nine months ended October 3, 2021 and September 27, 2020, the Company recorded expenses for business conducted with this pharmacy benefit management organization of $4.4 million and $4.6 million, respectively. As of October 3, 2021, Accounts payable included amounts related to this pharmacy benefit management organization of $0.4 million. As of January 3, 2021, Accrued liabilities included amounts related to this pharmacy benefit management organization of $0.6 million.

As part of the normal course of business, the Company may purchase from or sell to portfolio companies of funds affiliated with Carlyle or the Company’s officers and directors. These expenses and revenues are not expected to be material.

(15) Commitments and contingencies

At times, the entities that carry out the Company’s business are the subject of governmental investigations and various legal actions and claims from governmental agencies and other parties. The outcomes of these matters are not within the Company’s complete control and may not be known for prolonged periods of time. The Company records a liability in the unaudited consolidated financial statements for loss contingencies when a loss is known or considered probable and the amount can be reasonably estimated. If the reasonable estimate of a known or probable loss is a range, and no amount within the range is a better estimate than any other, the minimum amount of the range is accrued. When determining the estimated loss or range of loss, significant judgment is required to estimate the amount and timing of a loss to be recorded. Estimates of probable losses resulting from these matters are inherently difficult to predict.

The Company is involved in an arbitration related to a commercial contract dispute. Although the Company believes it has meritorious defenses against the claim which it intends to pursue vigorously, arbitration is inherently uncertain and it could result in an unfavorable ruling to the Company. Given the early stage of this matter, an estimate of the possible loss or range of loss cannot be made at this time.

(Dollars in millions, unless otherwise stated)

(16) Fair value measurements

The carrying amount of cash and cash equivalents, current accounts receivable, accounts payable, and short term borrowings approximates fair value because of their short outstanding terms.

The estimated fair values of the Company's Long-term borrowings were based on trades as reported by a third-party bond pricing service. Due to the infrequency of trades of the Notes and Term Loans, these inputs are considered Level 2 inputs. The following table presents the fair values of Long-term borrowings:

	October 3, 2021	January 3, 2021
Long-term borrowings:		
Dollar Term Loan Facility	$ 1,496.8	$ 2,627.7
Euro Term Loan Facility	357.1	401.1
2028 Notes	434.4	710.4
2025 Notes	252.0	424.0

(17) Derivative instruments and hedging activities

The Company selectively uses derivative and non-derivative instruments to manage market risk associated with changes in interest rates and foreign currency exchange rates. The use of derivatives is intended for hedging purposes only, and the Company does not enter into derivative transactions for speculative purposes. The Company's derivative contracts do not require cash collateral.

Interest rate hedging instruments

The Company's interest rate risk relates primarily to interest rate exposures on variable rate debt including the Senior Secured Credit Facilities. Refer to Note 7 for additional information on the currently outstanding components of the Senior Secured Credit Facilities. The Company entered into a series of interest rate cap and swap agreements to hedge the related risk of the variability to the Company's cash flows due to the rates specified for these credit facilities.

The Company designates certain interest rate derivative instruments as cash flow hedges, including a portion of the outstanding interest rate swaps. The Company records gains and losses due to changes in fair value of the derivatives within Other comprehensive income ("OCI") and reclassifies these amounts to Interest expense, net in the same period or periods for which the underlying hedged transaction affects earnings. In the event the Company determines the hedged transaction is no longer probable to occur or concludes the hedge relationship is no longer effective, the remaining gain or loss within Accumulated other comprehensive income ("AOCI") is reclassified to earnings at that time. The pre-tax unrealized loss of $16.2 million within OCI as of October 3, 2021 is expected to be reclassified to earnings in the next 12 months.

The following tables summarize the Company's interest rate derivative agreements as of October 3, 2021:

Effective date	Expiration date	Interest rate cap amount	Notional amount	Hedge designation
December 31, 2020	December 31, 2023	3.5%	$ 1,500.0	Non-designated

Effective date	Expiration date	Description	Fixed rate	Floating rate	Notional amount[(a)]	Hedge designation
September 27, 2019	December 31, 2023	Pay fixed, receive float	1.635%	1-month LIBOR rate	$ 1,500.0	Cash Flow Hedge

(a) The notional value of this instrument is expected to be $1,000 million in fiscal 2022 and $500 million in fiscal 2023.

The Company previously entered into an interest rate cap that was designated as a cash flow hedge. During the fiscal quarter ended September 29, 2019, the Company de-designated its 3.5% interest rate caps upon entering into the interest rate swap agreement that hedges a portion of the Company's borrowings under the Senior Secured Credit Facilities. Upon de-designation, the Company began prospectively recognizing mark-to-market gains and losses within Other expense, net on the interest rate caps. The remaining loss on the interest rate caps that was deferred in OCI was amortized to Interest expense, net until the Company concluded that a portion of the interest on the Company's previously hedged borrowings was no longer probable of being paid due to the pay down of a portion of the borrowings using proceeds from the IPO. Accordingly, $0.6 million of losses that had previously been deferred within OCI were released into Interest expense, net during the fiscal quarter ended April 4, 2021. During the fiscal quarter and nine months ended October 3, 2021, the Company reclassified $0.9 million and $2.6 million, respectively, of deferred losses from AOCI to Interest expense, net. As of October 3, 2021, the remaining balance of the deferred loss in AOCI was $6.7 million. As of January 3, 2021, the balance of the deferred loss in AOCI was $9.8 million.

(Dollars in millions, unless otherwise stated)

During the fiscal quarter ended April 4, 2021, the Company concluded that a portion of the interest on the Company's previously hedged borrowings related to the interest rate swap was no longer probable of being paid due to the pay down of a portion of the borrowings using the proceeds from the IPO. Due to this reduction in the hedged borrowings, the Company de-designated the hedging relationship, and contemporaneously re-designated the remaining borrowings. Accordingly, $3.1 million of losses that had previously been deferred within AOCI were released into Interest expense, net during the fiscal quarter ended April 4, 2021. As of October 3, 2021, the remaining balance of the deferred loss in AOCI was $24.5 million.

Currency hedging instruments

The Company has currency risk exposures relating primarily to foreign currency denominated monetary assets and liabilities and forecasted foreign currency denominated intercompany and third-party transactions. The Company uses foreign currency forward, option contracts and cross currency swaps to manage its currency risk exposures. The Company's foreign currency forward contracts are denominated primarily in Australian Dollar, Brazilian Real, British Pound, Canadian Dollar, Chilean Peso, Chinese Yuan/Renminbi, Colombian Peso, Euro, Indian Rupee, Japanese Yen, Mexican Peso, Philippine Peso, Swiss Franc and the Thai Baht.

The Company designates certain foreign currency forward contracts as cash flow hedges. The Company records gains and losses due to changes in fair value of the derivatives within OCI and reclassifies these amounts to Cost of revenue, excluding amortization of intangible assets in the same period or periods for which the underlying hedged transaction affects earnings. In the event the Company determines the hedged transaction is no longer probable to occur or concludes the hedge relationship is no longer effective, the remaining gain or loss within AOCI is reclassified to earnings at that time. The pre-tax unrealized gain of $1.6 million within OCI as of October 3, 2021 is expected to be reclassified to earnings in the next 12 months.

Foreign exchange risk is also managed through the use of foreign currency debt. During the fiscal quarter ended October 3, 2021, €260.0 million ($301.5 million) of the Company's senior secured Euro Term Loan Facility has been designated as, and is effective as, economic hedges of the net investment in a foreign operation. Accordingly, foreign currency transaction gains or losses due to spot rate fluctuations on the Euro-denominated debt instruments are included in foreign currency translation adjustments within AOCI.

The Company also enters into foreign currency forward contracts that are not part of designated hedging relationships, which are intended to mitigate exchange rate risk of monetary assets and liabilities and related forecasted transactions. The Company records these non-designated derivatives at mark-to-market with gains and losses recognized currently in earnings within Other expense, net.

Concurrent with the issuance of the 2028 Notes, the Company entered into U.S. Dollar to Japanese Yen cross currency swaps for total notional of $350.0 million at a weighted average interest rate of 5.56%, with a five-year term to lower interest expense on the 2028 Notes. These cross currency swaps were not designated for hedge accounting, and consequently, changes in their fair value are recorded to Other expense, net. The Company terminated the cross currency swaps on April 1, 2021 and received $12.8 million of cash from net settlement during the fiscal nine months ended October 3, 2021.

The following table provides details of the currency hedging instruments outstanding as of October 3, 2021:

Description	Notional amount	Hedge designation
Foreign Currency Forward Contracts	$ 161.5	Cash Flow Hedge
Foreign Currency Forward Contracts	262.2	Non-designated

(Dollars in millions, unless otherwise stated)

Gains and losses from designated derivative and non-derivative instruments within AOCI during the fiscal quarter and nine months ended October 3, 2021 and September 27, 2020 were recorded as follows:

Designated Hedging Instruments	Amount of loss (gain) recognized in OCI on hedges	Location of amounts reclassified from AOCI into income	Amount of loss (gain) reclassified from AOCI into income
Fiscal Quarter Ended October 3, 2021			
Cash flow hedges:			
Foreign currency forward contracts	$ (1.0)	Cost of revenue, excluding amortization of intangible assets	$ 1.1
Interest rate derivative contracts	—	Interest expense, net	5.9
Net investment hedges:			
Foreign currency-denominated debt[(a)]	0.8	N/A	N/A
Fiscal Nine Months Ended October 3, 2021			
Cash flow hedges:			
Foreign currency forward contracts	$ (3.7)	Cost of revenue, excluding amortization of intangible assets	$ 2.7
Interest rate derivative contracts	(1.8)	Interest expense, net	20.9
Net investment hedges:			
Foreign currency-denominated debt[(a)]	3.8	N/A	N/A

(a) The amount of loss (gain) recognized in OCI for the foreign-currency denominated debt is presented within the CTA component of OCI. These gains and losses will remain in CTA until the related hedged item affects earnings, which would occur upon disposal or complete or substantial liquidation of the underlying hedged entities.

Designated Hedging Instruments	Amount of loss (gain) recognized in OCI on hedges	Location of amounts reclassified from AOCI into income	Amount of loss (gain) reclassified from AOCI into income
Fiscal Quarter Ended September 27, 2020			
Cash flow hedges:			
Foreign currency forward contracts	$ 1.5	Cost of revenue, excluding amortization of intangible assets	$ (2.0)
Interest rate derivative contracts	(0.5)	Interest expense, net	0.5
Fiscal Nine Months Ended September 27, 2020			
Cash flow hedges:			
Foreign currency forward contracts	$ (2.2)	Cost of revenue, excluding amortization of intangible assets	$ (4.5)
Interest rate derivative contracts[(a)]	47.1	Interest expense, net	(1.9)

(a) For the fiscal nine months ended September 27, 2020, the $47.1 million loss recognized in OCI for the interest rate derivative contracts does not include the $3.7 million loss from the cumulative effect of change in accounting standard, which is presented in Note 18.

(Dollars in millions, unless otherwise stated)

The following tables present the effect of the Company's designated derivative instruments within Interest expense, net and Cost of revenue, excluding amortization of intangible assets in the unaudited consolidated statements of operations:

	Fiscal quarter ended October 3, 2021		Fiscal quarter ended September 27, 2020	
	Interest expense, net	Cost of revenue, excluding amortization of intangible assets	Interest expense, net	Cost of revenue, excluding amortization of intangible assets
Total amount of line item in unaudited consolidated statements of operations where effects of hedges are presented:	$ 36.1	$ 252.4	$ 48.9	$ 234.1
Effects of cash flow hedging relationships				
Foreign currency forward contracts:				
Amount of loss (gain) reclassified from AOCI into income	N/A	1.1	N/A	(2.0)
Amount reclassified from AOCI into income due to forecast transaction that is no longer probable of occurring	N/A	—	N/A	(0.1)
Interest rate derivative contracts:				
Amount of net loss reclassified from AOCI into income	5.9	N/A	0.5	N/A

	Fiscal nine months ended October 3, 2021		Fiscal nine months ended September 27, 2020	
	Interest expense, net	Cost of revenue, excluding amortization of intangible assets	Interest expense, net	Cost of revenue, excluding amortization of intangible assets
Total amount of line item in unaudited consolidated statements of operations in which effects of hedges are presented:	$ 112.5	$ 748.7	$ 148.6	$ 650.2
Effects of cash flow hedging relationships				
Foreign currency forward contracts:				
Amount of loss (gain) reclassified from AOCI into income	N/A	2.7	N/A	(4.5)
Amount reclassified from AOCI into income due to forecast transaction that is no longer probable of occurring	N/A	—	N/A	(0.2)
Interest rate derivative contracts:				
Amount of loss (gain) reclassified from AOCI into income	20.9	N/A	(1.9)	N/A
Amount reclassified from AOCI into income due to forecast transaction that is no longer probable of occurring[(a)]	3.7	N/A	—	N/A

(a) The amount is included within the total amount of loss (gain) reclassified from accumulated OCI into income.

The following table presents mark-to-market (gains) and losses on non-designated derivatives recognized currently within the unaudited consolidated statements of operations:

		Fiscal Quarter Ended		Fiscal Nine Months Ended	
Non-designated hedging instruments	Location of amounts recognized in earnings on derivatives	October 3, 2021	September 27, 2020	October 3, 2021	September 27, 2020
Interest rate derivative contracts	Other expense, net	$ 0.1	$ 0.4	$ —	$ 1.3
Foreign currency forward contracts	Other expense, net	(1.6)	1.5	32.6	3.1
Cross-currency interest rate swap contracts	Other expense, net	—	2.5	(24.0)	(2.6)

(Dollars in millions, unless otherwise stated)

The following table presents the location and fair values of designated hedging instruments recognized within the unaudited consolidated balance sheets. The fair values of designated hedging instruments have been determined using Level 2 inputs.

	October 3, 2021	January 3, 2021
Interest rate derivative contracts:		
Accrued liabilities	$ 0.1	$ 0.1
Other liabilities	25.4	44.1
Foreign currency forward contracts:		
Other current assets	3.8	4.2
Accrued liabilities	2.4	10.0

The following table presents the location and fair values of non-designated hedging instruments recognized within the unaudited consolidated balance sheets. The fair values of non-designated hedging instruments have been determined using Level 2 inputs.

	October 3, 2021	January 3, 2021
Interest rate derivative contracts:		
Accrued liabilities	$ —	$ 0.1
Other liabilities	6.8	11.1
Foreign currency forward contracts:		
Other current assets	1.7	0.3
Accrued liabilities	0.7	0.1
Cross currency interest rate swap contracts:		
Other current assets	—	2.0
Other liabilities	—	10.8

(18) Accumulated other comprehensive income (loss)

The balances of accumulated other comprehensive income (loss), net of tax, were as follows for the fiscal quarter and nine months ended October 3, 2021 and September 27, 2020:

	Pension and Other Postemployment Benefits	Foreign Currency Derivatives	Interest Rate Derivatives	Unrealized Foreign Currency Translation Adjustments	Accumulated Other Comprehensive Loss
Balance at July 4,2021	$ (4.5)	$ (0.6)	$ (37.1)	$ (12.8)	$ (54.9)
Current period deferrals	—	1.0	—	(13.9)	(12.9)
Amounts reclassified to net income	—	1.1	5.9	—	7.0
Net change	—	2.1	5.9	(13.9)	(5.9)
Balance at October 3, 2021	$ (4.5)	$ 1.5	$ (31.2)	$ (26.7)	$ (61.0)

	Pension and Other Postemployment Benefits	Foreign Currency Derivatives	Interest Rate Derivatives	Unrealized Foreign Currency Translation Adjustments	Accumulated Other Comprehensive Loss
Balance at June 28, 2020	$ (4.3)	$ 3.9	$ (55.8)	$ (70.9)	$ (127.1)
Current period deferrals	—	(1.5)	0.5	8.1	7.1
Amounts reclassified to net loss	—	(2.0)	0.5	—	(1.5)
Net change	—	(3.5)	1.0	8.1	5.6
Balance at September 27, 2020	$ (4.3)	$ 0.4	$ (54.8)	$ (62.8)	$ (121.5)

(Dollars in millions, unless otherwise stated)

	Pension and Other Postemployment Benefits	Foreign Currency Derivatives	Interest Rate Derivatives	Unrealized Foreign Currency Translation Adjustments	Accumulated Other Comprehensive Loss
Balance at January 3, 2021	$ (4.5)	$ (4.9)	$ (53.9)	$ (5.1)	$ (68.4)
Current period deferrals	—	3.7	1.8	(21.7)	(16.1)
Amounts reclassified to net loss	—	2.7	20.9	—	23.6
Net change	—	6.4	22.7	(21.7)	7.5
Balance at October 3, 2021	$ (4.5)	$ 1.5	$ (31.2)	$ (26.7)	$ (61.0)

	Pension and Other Postemployment Benefits	Foreign Currency Derivatives	Interest Rate Derivatives	Unrealized Foreign Currency Translation Adjustments	Accumulated Other Comprehensive Loss
Balance at December 29, 2019	$ (4.3)	$ 2.7	$ (5.8)	$ (64.5)	$ (71.9)
Current period deferrals	—	2.2	(43.4)	1.7	(39.5)
Amounts reclassified to net loss	—	(4.5)	(1.9)	—	(6.4)
Cumulative effect of change in accounting standard	—	—	(3.7)	—	(3.7)
Net change	—	(2.3)	(49.0)	1.7	(49.6)
Balance at September 27, 2020	$ (4.3)	$ 0.4	$ (54.8)	$ (62.8)	$ (121.5)

(19) Other (income) expense, net

Other income, net was $2.6 million for the fiscal quarter ended October 3, 2021, comprised primarily of $0.7 million of net foreign currency gains and fair value gains of $1.5 million from interest rate caps. Other expense, net was $50.8 million for the fiscal nine months ended October 3, 2021 and was comprised primarily of loss on early extinguishment of debt of $50.3 million, which was related to the use of proceeds from the IPO to redeem portions of the Company's outstanding 2025 Notes, 2028 Notes and Dollar Term Loan Facility.

Other income, net was $5.9 million for the fiscal quarter ended September 27, 2020, comprised primarily of $5.4 million of net foreign currency gains, of which $3.9 million was unrealized, primarily related to intercompany loans denominated in currencies other than the functional currency of the affected subsidiaries and fair value gains of $0.5 million from interest rate caps. Other expense, net was $61.1 million for the fiscal nine months ended September 27, 2020 and was comprised primarily of $49.4 million of net foreign currency losses, of which $51.1 million was unrealized, mainly related to intercompany loans denominated in currencies other than the functional currency of the affected subsidiaries, and loss on early extinguishment of $12.6 million related to debt refinancing activities.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion summarizes the significant factors affecting the operating results, financial condition, liquidity and cash flows of our company as of and for the periods presented below. The following discussion and analysis should be read in conjunction with the unaudited interim consolidated financial statements and the related notes thereto included elsewhere in this Quarterly Report on Form 10-Q. Some of the discussion includes forward-looking statements related to future events and our future operating performance that are based on current expectations and are subject to risk and uncertainties. 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. The cautionary statements made in this report should be read as applying to all related forward-looking statements wherever they appear in this report. Actual results could differ materially from those discussed in or implied by forward-looking statements as a result of various factors, including, but not limited to:

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 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 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 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"; and risks related to the ownership of our ordinary shares, as well as other risks discussed from time to time in our filings with the Securities and Exchange Commission, including, without limitation, the risk factors set forth in Part II, Item 1A,"Risk Factors" of this Quarterly Report on Form 10-Q, if any, as well as the risk factors set forth in Part I, Item 1A, "Risk Factors" of our Annual Report on Form 10-K for the fiscal year ended January 3, 2021.

Overview

We are a pure-play in vitro diagnostics ("IVD") business driven by our credo, "Because Every Test is A Life." This guiding principle reflects the crucial role diagnostics play in global health and guides our priorities as an organization. As a leader in IVD, we impact approximately 800,000 patients every day. We are dedicated to improving outcomes for these patients and saving lives through providing innovative and reliable diagnostic testing solutions to the clinical laboratory and transfusion medicine communities. Our

global infrastructure and commercial reach allow us to serve these markets with significant scale. We have an intense focus on the customer. We support our customers with high quality diagnostic instrumentation, a broad test portfolio and market leading service. Our products deliver consistently fast, accurate and reliable results that allow clinicians to make better-informed treatment decisions. Our business model generates significant recurring revenues and strong cash flow streams from ongoing sales of high margin consumables. These consumables contribute more than 90% of our total revenue. We maintain close connectivity with our customers through our global presence, with approximately 4,700 employees, including approximately 2,200 commercial sales, service and marketing teammates. This global organization allows us to support our customers across more than 130 countries and territories.

We manage our business geographically to better align with the market dynamics of the specific geographic region with our reportable segments being Americas, EMEA and Greater China. We generate revenue primarily in the following lines of business:

Core:

- Clinical Laboratories—Focused on (i) clinical chemistry, which is the measurement of target chemicals in bodily fluids for the evaluation of health and the clinical management of patients, (ii) immunoassay instruments, which test the measurement of proteins as they act as antigens in the spread of disease, antibodies in the immune response spurred by disease, or markers of proper organ function and health, and (iii) tests to detect and monitor disease progression across a broad spectrum of therapeutic areas, including grant revenue related to development of our COVID-19 antibody and antigen tests.

- Transfusion Medicine—Focused on (i) immunohematology instruments and tests used for blood typing to ensure patient-donor compatibility in blood transfusions, and (ii) donor screening instruments and tests used for blood and plasma screening for infectious diseases for customers primarily in the United States.

Non-core:

- Other Product Revenue—Includes revenues primarily from contract manufacturing.

- Collaboration and Other Revenue—Includes collaboration and license agreements pursuant to which we derive collaboration and royalty revenues.

All non-core revenue is recorded in the Americas segment for all periods presented.

Impact of the initial public offering

Use of proceeds and impact of debt extinguishment

On February 1, 2021, we completed the initial public offering (“IPO”) of our ordinary shares at a price of $17.00 per share. We issued and sold 76,000,000 ordinary shares in the IPO and issued and sold an additional 11,400,000 ordinary shares on February 4, 2021 pursuant to the full exercise of the underwriters’ option to purchase additional shares from us. The ordinary shares sold in the IPO were registered under the Securities Act pursuant to a Registration Statement on Form S-1 (the “IPO Registration Statement”), which was declared effective by the SEC on January 29, 2021. Our ordinary shares are listed on Nasdaq under the symbol “OCDX.” The offering, including proceeds from the full exercise of the underwriters’ option to purchase additional shares, generated net proceeds to us of $1,426.4 million after deducting underwriting discounts and commissions.

We used the net proceeds from the IPO (i) to redeem $160 million of our 2025 Notes, plus accrued interest thereon and $11.8 million of redemption premium, (ii) to redeem $270 million of our 2028 Notes, plus accrued interest thereon and $19.6 million of redemption premium, (iii) to repay $892.7 million in aggregate principal amount of borrowings under our Dollar Term Loan Facility, and (iv) for working capital and general corporate purposes.

Incremental public company expenses

As a new public company, we will incur significant expenses on an ongoing basis that we did not incur as a private company, including increased director and officer liability insurance expense, as well as third-party and internal resources related to accounting, auditing, Sarbanes-Oxley Act compliance, legal, and investor and public relations expenses. These costs will generally be included in selling, marketing and administrative expenses.

Stock-based compensation expense

In connection with our IPO, in the fiscal year 2021, we may incur a one-time stock-based compensation expense related to performance-based options held by members of management that may vest upon the completion of certain liquidity and realization

events. On May 3, 2021, the Board of Directors approved the modifications to the vesting of restricted stock and Liquidity Event option awards held by certain current and former members of management in accordance with the 2014 Equity Incentive Plan, which governs these grants. As a result of the modification, we recorded additional stock-based compensation expense of $0.3 million for the fiscal quarter ended October 3, 2021 and $1.6 million for the fiscal nine months ended October 3, 2021. Furthermore, during the fiscal quarter ended April 4, 2021, the Board of Directors approved the share pool associated with our long-term equity incentive plan.

Underwritten secondary offering

In September 2021, we completed an underwritten secondary offering of 25.3 million ordinary shares held by a selling shareholder affiliated with Carlyle, including 3.3 million ordinary shares pursuant to the full exercise of the underwriters' option to purchase additional shares. The ordinary shares sold in the secondary offering were registered under the Securities Act pursuant to a Registration Statement on Form S-1, which was declared effective by the SEC on September 9, 2021. We did not offer any ordinary shares in this transaction and did not receive any proceeds from the sale of the ordinary shares by the selling shareholder. We incurred costs of $1.1 million in relation to the secondary public offering for the three and nine months ended October 3, 2021, which were recorded in Selling, marketing and administrative expenses in the unaudited consolidated statement of operations.

Impact of COVID-19 pandemic

In response to the global COVID-19 pandemic, we mobilized our research and development teams to bring to market COVID-19 antibody and antigen tests. Our COVID-19 antibody tests detect whether a patient has been previously infected by COVID-19 and our COVID-19 antigen test detects whether a patient is currently infected by COVID-19. We have received a combination of Emergency Use Authorization ("EUA") from the U.S. Food and Drug Administration (the "FDA"), authority to affix a CE Mark for sale in the European Union and various other regulatory approvals globally for our COVID-19 antibody tests. We have also received authority to affix a CE Mark for sale in the European Union and the FDA accepted our EUA for our COVID-19 antigen test. We sell these tests in various other markets globally and continue to work on gaining further regulatory approvals in other markets. All of our COVID-19 antibody and antigen tests run on our existing instruments.

In February 2020, we began to see a decrease in the number of tests run in China. This decline spread to certain other countries in EMEA and ASPAC in early March 2020 and resulted in a worldwide decrease in the number of tests run globally by the end of that month. In many countries, we also experienced a lag between the timing of the decrease in the number of tests run and the decrease in shipments of additional products to our customers, which began to occur during the fiscal quarter ended June 28, 2020. As a result, during the fiscal year ended January 3, 2021, we experienced decreased revenues and incurred idle or underutilized facilities costs, higher freight and higher distribution costs compared to the periods prior to the pandemic.

During the fiscal quarter ended January 3, 2021, we started to experience a recovery in the base business of our core revenue, which continued through the fiscal nine months ended October 3, 2021. Additionally, since the fiscal quarter ended June 28, 2020, our results of operations were supplemented with revenue from sales of our COVID-19 antibody and antigen tests. However, starting in the fiscal quarter ended July 4, 2021 and continuing through the fiscal quarter ended October 3, 2021, this supplemental revenue from sales of our COVID-19 antibody and antigen tests began to decline and we expect such decline to continue into the fourth quarter of fiscal year 2021. During the fiscal nine months ended October 3, 2021, we also continued to experience higher distribution costs due to higher shipping rates as a result of the COVID-19 pandemic, and during the fiscal quarter ended October 3, 2021, began to experience some supply chain disruptions. We continue to monitor the potential impact of these issues on our business.

We are continually monitoring our business continuity plans. Due to the fact that our products and services are considered to be medically critical, our manufacturing and research and development sites are generally exempt from governmental orders in the U.S. and other countries requiring businesses to cease or reduce operations. For these sites, we have implemented steps to protect our employees. Our office-based work sites in the U.S. are subject to operating restrictions consistent with applicable health guidelines. We permit limited domestic travel for our employees, which has reduced our travel-related operating expenses.

On September 9, 2021, President Biden issued Executive Order on Ensuring Adequate COVID Safety Protocols for Federal Contractors (the "Executive Order"), which directs executive departments and agencies to ensure that contracts covered by the Executive Order require relevant federal contractors and subcontractors to mandate their employees to be fully vaccinated against COVID-19 by December 18, 2021. We have been assessing our obligations under the Executive Order as it relates to any applicable contracts.

As the global COVID-19 pandemic is an ongoing matter, our future assessment of the magnitude and duration of the COVID-19 pandemic, as well as other factors, could result in material impacts to our consolidated financial statements in future reporting periods.

Results of operations

The following discussion should be read in conjunction with the information contained in the accompanying interim unaudited consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q. Our historical results of operations may not necessarily reflect what will occur in the future.

Net income (loss)

Net income for the fiscal quarter ended October 3, 2021 was $14.7 million compared to net loss of $28.5 million for fiscal quarter ended September 27, 2020, representing a change of $43.2 million. The change resulting in net income was primarily due to higher net revenue resulting from the growth of our base business, driven by strong instrument placements, especially of our integrated clinical lab systems, as well as a decrease in interest expense as a result of our debt pay down. These impacts were partially offset by an increase in operating expenses and a higher provision for income taxes.

During the fiscal nine months ended October 3, 2021, reported net loss of $44.4 million decreased by $126.6 million compared with the fiscal nine months ended September 27, 2020. The decrease in net loss was primarily due to higher net revenue, a reduction in interest expense as a result of the debt pay down and a decrease in foreign currency losses, partially offset by higher operating expense and provision for income taxes. We also incurred losses on early extinguishment of debt due to our use of proceeds from our IPO to redeem portions of our 2025 Notes, 2028 Notes and Dollar Term Loan Facility.

Net revenue

Net revenue for the fiscal quarter ended October 3, 2021 increased by $71.4 million, or 15.8%, compared with the fiscal quarter ended September 27, 2020. Revenues for the fiscal quarter ended October 3, 2021 included an operational net revenue increase of 14.3% and a positive impact of 1.5% from foreign currency fluctuations, which was primarily driven by the weakening of the U.S. Dollar against a variety of currencies, primarily the Chinese Yuan. The increase in revenues for the fiscal quarter ended October 3, 2021, excluding the impact of foreign currency exchange, was mainly driven by our Core lines of business, as we recorded higher revenues in all geographic segments of our Clinical Laboratories and Transfusion Medicine businesses.

Net revenue for the fiscal nine months ended October 3, 2021 increased by $272.3 million, or 21.8%, compared with the fiscal nine months ended September 27, 2020. Revenues for the fiscal nine months ended October 3, 2021 included an operational net revenue increase of 19.3% and a positive impact of 2.5% from foreign currency fluctuations, which was primarily driven by the weakening of the U.S. Dollar against a variety of currencies, primarily the Chinese Yuan, Euro and British Pound, partially offset by the strengthening of the Brazilian Real and Japanese Yen. The increase in revenues for the fiscal nine months ended October 3, 2021, excluding the impact of foreign currency exchange, was mainly driven by our Core lines of business, as we recorded higher revenues in certain geographic segments of our Clinical Laboratories business, and in all geographic segments of our Transfusion Medicine business.

The following table shows net revenue by line of business:

	Fiscal Quarter Ended			Fiscal Nine Months Ended		
(Dollars in millions)	October 3, 2021	September 27, 2020	% Change	October 3, 2021	September 27, 2020	% Change
Clinical Laboratories	$ 338.2	$ 302.7	11.7 %	$ 1,001.3	$ 819.2	22.2 %
Transfusion Medicine	170.7	140.6	21.4 %	494.5	414.5	19.3 %
Core Revenue	**508.9**	**443.3**	**14.8 %**	**1,495.8**	**1,233.7**	**21.2 %**
Other Product Revenue	—	3.3	(100.0 %)	5.6	3.7	59.8 %
Collaboration and Other Revenue	13.6	4.5	N.M.	20.4	12.2	66.9 %
Non-Core Revenue	**13.6**	**7.8**	**74.7 %**	**26.0**	**15.9**	**65.3 %**
Net Revenue	**$ 522.5**	**$ 451.1**	**15.8 %**	**$ 1,521.8**	**$ 1,249.6**	**21.8 %**

Core revenue

Clinical Laboratories revenue for the fiscal quarter ended October 3, 2021 increased by $35.5 million, or 11.7% compared with the fiscal quarter ended September 27, 2020, net of a decrease in sales of $9.1 million from our COVID-19 antibody and antigen tests. This increase included an operational net revenue increase of 9.8% and a positive impact of 1.9% from foreign currency fluctuations. The increase in Clinical Laboratories revenue was primarily due to higher reagent revenue sales across all regions, driven by strong instrument placements, especially of our integrated clinical lab systems.

Clinical Laboratories revenue for the fiscal nine months ended October 3, 2021 increased by $181.9 million, or 22.2%, compared with the fiscal nine months ended September 27, 2020, including an increase of $9.9 million from our COVID-19 antibody and antigen tests, driven by the year-over-year increase in revenue from COVID-19 antibody and antigen tests in the first half of the year. This increase included an operational net revenue increase of 19.7% and a positive impact of 2.5% from foreign currency fluctuations. The increase in Clinical Laboratories revenue was primarily due to higher reagent revenue, driven by the recovery of testing volumes, and higher instrument sales in the Americas, EMEA and Greater China regions.

Transfusion Medicine revenue for the fiscal quarter ended October 3, 2021 increased by $30.1 million, or 21.4%, compared with the fiscal quarter ended September 27, 2020. This increase included an operational net revenue increase of 20.6% and a positive impact of 0.8% from foreign currency fluctuations. The increase in Transfusion Medicine revenue, excluding the impact of foreign currency exchange, was primarily driven by strength in both Immunohematology and Donor Screening, including a new customer in our Donor Screening business in the United States.

Transfusion Medicine revenue for the fiscal nine months ended October 3, 2021 increased by $80.1 million, or 19.3%, compared with the fiscal nine months ended September 27, 2020. This increase included an operational net revenue increase of 16.8% and a positive impact of 2.5% from foreign currency fluctuations. The increase in Transfusion Medicine revenue, excluding the impact of foreign currency exchange, was primarily driven by a new customer in our Donor Screening business in the United States and higher reagent revenue in all geographical regions.

Non-core revenue

Other product revenue, related to our contract manufacturing business, decreased by $3.3 million for the fiscal quarter ended October 3, 2021 compared with the fiscal quarter ended September 27, 2020, due to the completion of our performance obligations related to a contract manufacturing arrangement.

Other product revenue, related to our contract manufacturing business, increased by $2.1 million for the fiscal nine months ended October 3, 2021 compared with the fiscal nine months ended September 27, 2020, due to the timing of satisfying certain performance obligations related to a contract manufacturing arrangement in the current fiscal period.

Collaboration and other revenue for the fiscal quarter ended October 3, 2021 increased by $9.1 million compared with the fiscal quarter ended September 27, 2020. The increase was primarily due to an $8.5 million award from an arbitration proceeding related to one of our collaboration agreements.

Collaboration and other revenue for the fiscal nine months ended October 3, 2021 increased by $8.2 million, or 66.9%, compared with the fiscal nine months ended September 27, 2020. The increase was primarily due to an $8.5 million award from an arbitration proceeding related to one of our collaboration agreements.

Cost of revenue, excluding amortization of intangible assets, and Gross profit

	Fiscal Quarter Ended				Fiscal Nine Months Ended			
(Dollars in millions)	October 3, 2021	% of Net Revenue	September 27, 2020	% of Net Revenue	October 3, 2021	% of Total Revenue	September 27, 2020	% of Total Revenue
Cost of revenue, excluding amortization of intangible assets	$ 252.4	48.3 %	$ 234.1	51.9 %	$ 748.7	49.2 %	$ 650.2	52.0 %
Gross profit	270.1	51.7 %	217.0	48.1 %	773.1	50.8 %	599.4	48.0 %

The decrease in Cost of revenue, excluding amortization of intangible assets, and increase in Gross profit as a percentage of net revenue for the fiscal quarter ended October 3, 2021 compared with the fiscal quarter ended September 27, 2020 was primarily due to lower manufacturing costs and lower underutilized facility costs and inventory reserves, as well as the impact of the previously mentioned award from an arbitration proceeding related to one of our collaboration agreements, partially offset by higher freight costs and the decrease in sales of COVID-19 antibody and antigen tests with favorable margin.

The decrease in Cost of revenue, excluding amortization of intangible assets, and increase in Gross profit as a percentage of net revenue for the fiscal nine months ended October 3, 2021 compared with the fiscal nine months ended September 27, 2020 was primarily due to favorable product mix, including sales of COVID-19 antibody and antigen tests, lower manufacturing costs and lower underutilized facility costs, as well as the impact of the previously mentioned award from an arbitration proceeding related to one of our collaboration agreements, partially offset by higher freight costs.

Operating expenses

The following table provides a summary of certain operating expenses:

(Dollars in millions)	Fiscal Quarter Ended October 3, 2021	% of Net Revenue	Fiscal Quarter Ended September 27, 2020	% of Net Revenue	Fiscal Nine Months Ended October 3, 2021	% of Total Revenue	Fiscal Nine Months Ended September 27, 2020	% of Total Revenue
Selling, marketing and administrative expenses	$ 140.9	27.0%	$ 121.0	26.8%	$ 411.0	27.0%	$ 347.9	27.8%
Research and development expense	32.1	6.1%	32.7	7.2%	91.3	6.0%	82.1	6.6%
Amortization of intangible assets	33.3	6.4%	33.1	7.3%	100.3	6.6%	98.7	7.9%
Other operating expense, net	9.8	1.9%	9.5	2.1%	27.7	1.8%	22.8	1.8%

Selling, marketing and administrative expenses

Selling, marketing and administrative expenses were $140.9 million for the fiscal quarter ended October 3, 2021, or 27.0% of net revenue, as compared with $121.0 million for the fiscal quarter ended September 27, 2020, or 26.8% of net revenue, an increase of $19.9 million. The increase in Selling, marketing and administrative expenses was primarily due to higher employee-related costs, including stock-based compensation.

Selling, marketing and administrative expenses were $411.0 million for the fiscal nine months ended October 3, 2021, or 27.0% of net revenue, as compared with $347.9 million for the fiscal nine months ended September 27, 2020, or 27.8% of net revenue, an increase of $63.1 million. The increase in Selling, marketing and administrative expenses was primarily due to higher employee-related costs, including stock-based compensation, increased distribution costs due to higher shipment volumes and higher shipping rates as a result of the ongoing global COVID-19 pandemic, partially offset by decreased travel-related costs for our employees due to global travel restrictions.

Research and development expense

Research and development expense was $32.1 million for the fiscal quarter ended October 3, 2021, or 6.1% of net revenue, as compared with $32.7 million for the fiscal quarter ended September 27, 2020, or 7.2% of net revenue, a decrease of $0.6 million. The decrease was primarily due to the $7.5 million up-front payment made to Quotient Limited (“Quotient”) upon the signing of a binding letter agreement in the prior year period, partially offset by increased investment in costs to develop new assays, as well as an increase in employee-related costs.

Research and development expense was $91.3 million for the fiscal nine months ended October 3, 2021, or 6.0% of net revenue, as compared with $82.1 million for the fiscal nine months ended September 27, 2020, or 6.6% of net revenue, an increase of $9.2 million. The increase was primarily due to an increased investment in costs to develop new assays, as well as an increase in employee-related costs, partially offset by the $7.5 million up-front payment made to Quotient in the prior year period.

Amortization of intangible assets

Amortization of intangible assets was $33.3 million for the fiscal quarter ended October 3, 2021 as compared with $33.1 million for the fiscal quarter ended September 27, 2020. There were no significant changes in the composition of our intangible assets in the fiscal quarter ended October 3, 2021 compared to the fiscal quarter ended September 27, 2020.

Amortization of intangible assets was $100.3 million for the fiscal nine months ended October 3, 2021 as compared with $98.7 million for the fiscal nine months ended September 27, 2020. There were no significant changes in the composition of our intangible assets in the fiscal nine months ended October 3, 2021 compared to the fiscal nine months ended September 27, 2020.

Other operating expense, net

Other operating expense, net was $9.8 million, or 1.9% of net revenue, for the fiscal quarter ended October 3, 2021, as compared with $9.5 million, or 2.1% of net revenue, for the fiscal quarter ended September 27, 2020, an increase of $0.3 million. There were no significant changes in the balance of Other operating expense, net in the fiscal quarter ended October 3, 2021 compared to the fiscal quarter ended September 27, 2020.

Other operating expense, net was $27.7 million, or 1.8% of net revenue, for the fiscal nine months ended October 3, 2021, as compared with $22.8 million, or 1.8% of net revenue, for the fiscal nine months ended September 27, 2020, an increase of $4.9 million.

The increase was primarily due to higher profit share expense in the current year due to lower manufacturing costs related to our Joint Business, partially offset by the timing of government subsidies earned.

Non-operating items

Interest expense, net

Interest expense, net was $36.1 million for the fiscal quarter ended October 3, 2021, as compared with $48.9 million for the fiscal quarter ended September 27, 2020. The decrease of $12.8 million was primarily related to lower borrowings due to the use of the net proceeds from the IPO to (i) redeem $160 million of our 2025 Notes, (ii) redeem $270 million of our 2028 Notes, and (iii) repay $892.7 million in aggregate principal amount of borrowings under our Dollar Term Loan Facility.

Interest expense, net was $112.5 million for the fiscal nine months ended October 3, 2021, as compared with $148.6 million for the fiscal nine months ended September 27, 2020. The decrease of $36.1 million was primarily related to lower borrowings due to our use of net proceeds from the IPO for debt repayment, as detailed above.

Tax indemnification (income) expense, net

Tax indemnification income was $0.2 million and $0.6 million for the fiscal quarter and nine months ended October 3, 2021, respectively. This primarily related to interest on our indemnification receivables related to certain tax matters included in our pre-acquisition audit reserves. Tax indemnification expense was $16.5 million and $11.6 million for the fiscal quarter and nine months ended September 27, 2020, respectively. This primarily related to the release of certain tax reserves upon the settlement of certain state tax matters, with an offsetting benefit recorded to income tax expense.

Other (income) expense, net

Other income, net was $2.6 million for the fiscal quarter ended October 3, 2021 comprised primarily of $0.7 million of net foreign currency gains, and fair value gains of $1.5 million in interest rate caps. Other expense, net was $50.8 million for the fiscal nine months ended October 3, 2021 and was comprised primarily of loss on early extinguishment of debt of $50.3 million, which was related to the use of proceeds from the IPO to redeem portions of our outstanding 2025 Notes, 2028 Notes and Dollar Term Loan Facility.

Other income, net was $5.9 million for the fiscal quarter ended September 27, 2020 and was comprised primarily of $5.4 million of net foreign currency gains, of which $3.9 million was unrealized, mainly related to intercompany loans denominated in currencies other than the functional currency of the affected subsidiaries, and fair value gains of $0.5 million from interest rate caps. Other expense, net was $61.1 million for the fiscal nine months ended September 27, 2020 and was comprised primarily of $49.4 million of net foreign currency losses, of which $51.1 million was unrealized, mainly related to intercompany loans denominated in currencies other than the functional currency of the affected subsidiaries, and loss on early extinguishment of the 2022 Notes of $12.6 million.

Provision for (benefit from) income taxes

During the fiscal quarter ended October 3, 2021, we reported income before provision for income taxes of $20.7 million and recognized a provision for income taxes of $6.0 million, resulting in an effective tax rate of 29.1%. During the fiscal nine months ended October 3, 2021, we incurred a loss before provision from income taxes of $20.0 million and recognized a provision for income taxes of $24.4 million, resulting in a negative effective tax rate of 122.2%. The effective tax rate for the fiscal nine months ended October 3, 2021 differs from the U.S. federal statutory rate primarily due to (i) a net cost of $27.5 million for the impacts of operating losses in certain subsidiaries not being benefited due to the establishment of valuation allowances, (ii) a net benefit of $10.9 million related to non-U.S. earnings being taxed at rates that are different than the U.S. statutory rate, and (iii) a net cost of $10.6 million for the tax expense associated with the remeasurement of deferred tax assets and liabilities due to the enactment of new tax rates, primarily in the United Kingdom.

During the fiscal quarter ended September 27, 2020, we incurred a loss before provision for income taxes of $38.8 million and recognized an income tax benefit of $10.3 million, resulting in an effective tax rate of 26.5%. During the fiscal nine months ended September 27, 2020, we incurred a loss before provision for income taxes of $173.4 million and recognized an income tax benefit of $2.4 million, resulting in an effective tax rate of 1.4%. The effective tax rate for the fiscal nine months ended September 27, 2020 differs from the U.S. federal statutory rate primarily due to (i) a net cost of $39 million for the impacts of operating losses in certain subsidiaries not being benefited due to the establishment of valuation allowances, (ii) a net benefit of $12 million related to the increase in the Company’s interest expense on prior year reserves for uncertain tax positions, and (iii) a net cost of $9.7 million due to the non-U.S. earnings being taxed at rates that are different than the U.S. statutory rate.

Use of Non-GAAP Financial Measures

Reconciliation of Net Income (Loss) to Adjusted EBITDA

We believe that our financial statements and the other financial data included in this Quarterly Report on Form 10-Q have been prepared in a manner that complies, in all material respects, with GAAP, and are consistent with current practice, with the exception of the inclusion of financial measures that differ from measures calculated in accordance with GAAP. Adjusted EBITDA consists of net income (loss) before interest expense, net, provision for (benefit from) income taxes and depreciation and amortization and eliminates (i) certain non-operating income or expense, and (ii) impacts of certain noncash, unusual or other items that are included in net income (loss) that we do not consider indicative of our ongoing operating performance.

We use these financial measures in the analysis of our financial and operating performance because they assist in the evaluation of underlying trends in our business. Additionally, Adjusted EBITDA is the basis we use for assessing the profitability of our geographic-based reportable segments and is also utilized as a basis for calculating certain management incentive compensation programs. In the case of Adjusted EBITDA, we believe that making such adjustments provides management and investors meaningful information to understand our operating performance and ability to analyze financial and business trends on a period-to-period basis. We believe that the presentation of these financial measures enhances an investor's understanding of our financial performance. We use certain of these financial measures for business planning purposes and measuring our performance relative to that of our competitors.

Other companies in our industry may calculate Adjusted EBITDA differently than we do. As a result, these financial measures have limitations as analytical and comparative tools and you should not consider these items in isolation, or as a substitute for analysis of our results as reported under GAAP. Adjusted EBITDA should not be considered as measures of discretionary cash available to us to invest in the growth of our business. In calculating these financial measures, we make certain adjustments that are based on assumptions and estimates that may prove to have been inaccurate. In addition, in evaluating these financial measures, you should be aware that in the future we may incur expenses similar to those eliminated in the presentation of these metrics included in this Quarterly Report on Form 10-Q. Our presentation of Adjusted EBITDA should not be construed as an inference that our future results will be unaffected by unusual or non-recurring items or changes in our customer base. Additionally, our presentation of Adjusted EBITDA may differ from that included in the Credit Agreement, the indenture for the 2025 Notes and the indenture for the 2028 Notes for purposes of covenant calculation.

Adjusted EBITDA has important limitations as an analytical tool and you should not consider it in isolation or as substitutes for analysis of our results as reported under GAAP. Some of these limitations include the fact that Adjusted EBITDA:

- Does not reflect the significant interest expense on our debt, including the Senior Secured Credit Facilities, the 2025 Notes and the 2028 Notes;
- eliminates the impact of income taxes on our results of operations; and
- does not reflect any cash requirements for any future replacements of assets being depreciated and amortized, although the assets being depreciated and amortized will often have to be replaced in the future.

We compensate for these limitations by relying primarily on our GAAP results and using these financial measures only as a supplement to our GAAP results.

The following tables reconcile Net income (loss) to Adjusted EBITDA for the periods presented:

(Dollars in millions)	Fiscal Quarter Ended		Fiscal Nine Months Ended	
	October 3, 2021	September 27, 2020	October 3, 2021	September 27, 2020
Net income (loss)	$ 14.7	$ (28.5)	$ (44.4)	$ (171.0)
Interest expense, net	36.1	48.9	112.5	148.6
Provision for (benefit from) income taxes	6.0	(10.3)	24.4	(2.4)
Depreciation and amortization	80.8	79.9	246.6	239.6
Stock-based compensation (a)	5.0	2.4	19.5	6.2
Restructuring and severance-related costs (b)	1.7	4.7	4.7	9.3
Loss on extinguishment of debt	—	—	50.3	12.6
Arbitration award (c)	(7.4)	—	(7.4)	—
Tax indemnification (income) expense, net	(0.2)	16.5	(0.6)	11.6
Unrealized foreign currency exchanges (gains) losses, net (d)	—	(6.3)	—	46.0
Quotient upfront payment (e)	—	7.5	—	7.5
Other adjustments (f)	2.9	4.7	14.5	14.4
Adjusted EBITDA	$ 139.6	$ 119.5	$ 420.1	$ 322.4

(a) Represents expenses related to awards granted under our 2014 Equity Incentive Plan.
(b) Represents restructuring and severance costs related to several discrete initiatives intended to strengthen operational performance and to support building our commercial capabilities.
(c) Represents an award from an arbitration proceeding related to one of our collaboration agreements of $8.5 million, partially offset by related legal fees of $1.1 million.
(d) Represents noncash unrealized gains and losses resulting from the remeasurement of transactions denominated in foreign currencies primarily related to intercompany loans. Beginning in fiscal year 2021, we initiated programs to mitigate the impact of foreign currencies related to intercompany loans in our results, and such noncash net unrealized gains were approximately $4.3 million and $38.0 million for the fiscal quarter and nine months ended October 3, 2021, respectively. We intend for these programs to mitigate the impact of foreign currency exchange rate fluctuations related to intercompany loans in current and future periods. Therefore, effective January 4, 2021, we no longer exclude non-cash unrealized gains and losses from Adjusted EBITDA.
(e) Represents an initial, non-refundable upfront payment made to Quotient, one of our partners and suppliers. See Note 9 to our unaudited consolidated financial statements for further discussion of the Quotient relationship.
(f) Represents miscellaneous other adjustments related to unusual items impacting our results, including the elimination of management fees and noncash derivative mark-to-market (gains) losses. See information below:

(Dollars in millions)	Fiscal Quarter Ended		Fiscal Nine Months Ended	
	October 3, 2021	September 27, 2020	October 3, 2021	September 27, 2020
EU medical device regulation transition costs	$ 1.1	$ 1.0	$ 2.9	$ 3.3
Principal shareholder management fee	0.8	0.8	2.3	2.3
Derivative mark-to-market (gain) loss	(0.9)	(0.5)	0.6	(0.7)
Other	2.0	3.4	8.7	9.5
Total other adjustments	$ 2.9	$ 4.7	$ 14.5	$ 14.4

Segment Results

The key indicators that we monitor are as follows:

- Net revenue — This measure is discussed in the section entitled “Results of operations.”
- Adjusted EBITDA — Adjusted EBITDA by reportable segment is used by our management to measure and evaluate the internal operating performance of our segments. It is also the basis for calculating certain management incentive compensation programs. We believe that this measurement is useful to investors as a way to analyze the underlying trends in our core business, including at the segment level, consistently across the periods presented and also to evaluate performance under management incentive compensation programs.

(Dollars in millions)	Fiscal Quarter Ended			Fiscal Nine Months Ended		
	October 3, 2021	September 27, 2020	% Change	October 3, 2021	September 27, 2020	% Change
Segment net revenue						
Americas	$ 306.5	$ 264.2	16.0%	$ 924.2	$ 755.8	22.3%
EMEA	67.2	58.6	14.6%	203.5	168.2	20.9%
Greater China	85.6	72.7	17.8%	199.1	162.3	22.6%
Other	63.2	55.6	13.7%	195.1	163.2	19.6%
Net revenue	$ 522.5	$ 451.1	15.8%	$ 1,521.8	$ 1,249.6	21.8%

(Dollars in millions)	Fiscal Quarter Ended			Fiscal Nine Months Ended		
	October 3, 2021	September 27, 2020	% Change	October 3, 2021	September 27, 2020	% Change
Segment Adjusted EBITDA						
Americas	$ 125.0	$ 116.8	7.1%	$ 394.2	$ 329.9	19.5%
EMEA	17.2	10.7	60.0%	47.7	31.4	52.0%
Greater China	42.2	41.1	2.7%	91.7	78.9	16.1%
Other	19.0	16.7	13.5%	61.4	49.9	23.0%
Corporate	(63.8)	(65.9)	(3.3)%	(174.8)	(167.8)	4.2%
Adjusted EBITDA	$ 139.6	$ 119.5	16.9%	$ 420.1	$ 322.4	30.4%

Americas

Net revenue was $306.5 million for the fiscal quarter ended October 3, 2021 compared to net revenue of $264.2 million for the fiscal quarter ended September 27, 2020, including a decrease in sales of $6.8 million from our COVID-19 antibody and antigen tests. The increase of $42.3 million, or 16.0%, which included operational net revenue growth of 15.3% and a positive impact of 0.7% from foreign currency fluctuations, was primarily due to higher reagent revenue in our Clinical Laboratories business, driven by the strong instrument placements, especially of our integrated clinical lab systems, a new customer in our Donor Screening business in the United States and an $8.5 million award from an arbitration proceeding related to one of our collaboration agreements.

Net revenue was $924.2 million for the fiscal nine months ended October 3, 2021 compared to net revenue of $755.8 million for the fiscal nine months ended September 27, 2020, including incremental sales of $3.9 million from our COVID-19 antibody and antigen tests. The increase of $168.4 million, or 22.3%, which included operational net revenue growth of 21.7% and a positive impact of 0.6% from foreign currency fluctuations, was primarily due to higher reagent revenue in our Clinical Laboratories business, higher instrument sales in our Clinical Laboratories business, a new customer in our Donor Screening business in the United States, grant revenue related to development of our COVID-19 antibody and antigen tests and an $8.5 million award from an arbitration proceeding related to one of our collaboration agreements.

Adjusted EBITDA was $125.0 million for the fiscal quarter ended October 3, 2021 compared to Adjusted EBITDA of $116.8 million for the fiscal quarter ended September 27, 2020. The increase of $8.2 million, or 7.1%, was primarily due to higher revenues, partially offset by higher operating costs.

Adjusted EBITDA was $394.2 million for the fiscal nine months ended October 3, 2021 compared to Adjusted EBITDA of $329.9 million for the fiscal nine months ended September 27, 2020. The increase of $64.3 million, or 19.5%, was primarily due to higher revenues.

EMEA

Net revenue was $67.2 million for the fiscal quarter ended October 3, 2021 compared to net revenue of $58.6 million for the fiscal quarter ended September 27, 2020, including a decrease in sales of $0.3 million from our COVID-19 antibody and antigen tests. The increase of $8.5 million, or 14.6%, which included operational net revenue growth of 13.1% and a positive impact of 1.4% from foreign currency fluctuations, was primarily due to higher reagent revenue in our Clinical Laboratories business driven by the continued recovery of testing volumes.

Net revenue was $203.5 million for the fiscal nine months ended October 3, 2021 compared to net revenue of $168.2 million for the fiscal nine months ended September 27, 2020, including incremental sales of $6.0 million from our COVID-19 antibody and antigen tests. The increase of $35.2 million, or 20.9%, which included operational net revenue growth of 14.8% and a positive impact of 6.1% from foreign currency fluctuations, was primarily due to higher reagent revenue in our Clinical Laboratories business, higher instrument sales in our Clinical Laboratories business and higher reagent revenue in our Immunohematology business.

Adjusted EBITDA was $17.2 million for the fiscal quarter ended October 3, 2021 compared to Adjusted EBITDA of $10.7 million for the fiscal quarter ended September 27, 2020. The increase of $6.4 million, or 60.0%, was primarily due to higher revenues.

Adjusted EBITDA was $47.7 million for the fiscal nine months ended October 3, 2021 compared to Adjusted EBITDA of $31.4 million for the fiscal nine months ended September 27, 2020. The increase of $16.3 million, or 52.0%, was primarily due to higher revenues.

Greater China

Net revenue was $85.6 million for the fiscal quarter ended October 3, 2021 compared to net revenue of $72.7 million for the fiscal quarter ended September 27, 2020. The increase of $12.9 million, or 17.8%, which included operational net revenue growth of 10.3% and a positive impact of 7.4% from foreign currency fluctuations, was primarily due to higher reagent revenue in our Clinical Laboratories business and higher instrument sales in our Immunohematology business.

Net revenue was $199.1 million for the fiscal nine months ended October 3, 2021 compared to net revenue of $162.3 million for the fiscal nine months ended September 27, 2020. The increase of $36.7 million, or 22.6%, which included operational net revenue growth of 13.9% and a positive impact of 8.7% from foreign currency fluctuations, was primarily due to higher reagent revenue and instrument sales in our Clinical Laboratories business and higher reagent revenue in our Immunohematology business.

Adjusted EBITDA was $42.2 million for the fiscal quarter ended October 3, 2021 compared to Adjusted EBITDA of $41.1 million for the fiscal quarter ended September 27, 2020. The increase of $1.1 million, or 2.7%, was primarily due to higher revenues, partially offset by a government subsidy received in the prior year.

Adjusted EBITDA was $91.7 million for the fiscal nine months ended October 3, 2021 compared to Adjusted EBITDA of $78.9 million for the fiscal nine months ended September 27, 2020. The increase of $12.7 million, or 16.1%, was primarily due to higher revenues.

Other

Net revenue was $63.2 million for the fiscal quarter ended October 3, 2021 compared to net revenue of $55.6 million for the fiscal quarter ended September 27, 2020. The increase of $7.6 million, or 13.7%, which included operational net revenue growth of 15.7% and a negative impact of 2.0% from foreign currency fluctuations, was primarily due to higher reagent revenue in our Clinical Laboratories business.

Net revenue was $195.1 million for the fiscal nine months ended October 3, 2021 compared to net revenue of $163.2 million for the fiscal nine months ended September 27, 2020. The increase of $31.9 million, or 19.6%, which included operational net revenue growth of 18.6% and a positive impact of 1.0% from foreign currency fluctuations, was primarily due to higher reagent revenue in our Clinical Laboratories business.

Adjusted EBITDA was $19.0 million for the fiscal quarter ended October 3, 2021 compared to Adjusted EBITDA of $16.7 million for the fiscal quarter ended September 27, 2020. The increase of $2.3 million, or 13.5%, was primarily due to higher revenues.

Adjusted EBITDA was $61.4 million for the fiscal nine months ended October 3, 2021 compared to Adjusted EBITDA of $49.9 million for the fiscal nine months ended September 27, 2020. The increase of $11.5 million, or 23.0%, was primarily due to higher revenues.

Liquidity and capital resources

As of October 3, 2021 and January 3, 2021, we had $255.9 million and $132.8 million of Cash and cash equivalents, respectively. As of October 3, 2021 and January 3, 2021, $186.2 million and $108.8 million, respectively, of these Cash and cash equivalents were maintained in non-U.S. jurisdictions, primarily held in foreign currencies. We believe our organizational structure allows us the necessary flexibility to move funds throughout our subsidiaries to meet our operational working capital needs.

Historical cash flows

The following table presents a summary of our net cash inflows (outflows) for the periods shown:

(Dollars in millions)	Fiscal Nine Months Ended	
	October 3, 2021	September 27, 2020
Net cash provided by (used in) operating activities	$ 188.2	$ (48.6)
Net cash used in investing activities	(11.7)	(27.5)
Net cash (used in) provided by financing activities	(61.9)	71.3

Fiscal nine months ended October 3, 2021

Net cash flows provided by operating activities

Net cash provided by operating activities was $188.2 million for the fiscal nine months ended October 3, 2021. Factors resulting in Cash provided by operating activities included strong collections on Accounts receivable, as well as the impact of our new receivables purchase agreement, and cash inflows from earnings before interest, taxes, depreciation and amortization expense. These increases were partially offset by the payment of interest on borrowings of $109.2 million, settlement of Accrued liabilities and increased investments in inventories of $117.3 million, which includes $82.6 million of instrument inventories that were transferred from Inventories to Property, plant and equipment, net, related to customer leased instruments.

Net cash flows used in investing activities

Net cash used in investing activities was $11.7 million for the fiscal nine months ended October 3, 2021. The primary factor resulting in Cash used in investing activities was Purchases of property, plant and equipment during the fiscal nine months ended October 3, 2021 of $27.2 million, offset by proceeds of $15.2 million related to the net settlement of our terminated cross currency swaps.

Net cash flows used in financing activities

Net cash used in financing activities was $61.9 million for the fiscal nine months ended October 3, 2021. During the fiscal nine months ended October 3, 2021, payments on long-term borrowings of $1,407.9 million and payments on short-term borrowings, net of $81.1 million, including the repayment of the outstanding balance of our Financing Program, were partially offset by net proceeds from our initial public offering of $1,426.4 million.

Fiscal nine months ended September 27, 2020

Net cash flows used in operating activities

Net cash used in operating activities was $48.6 million for the fiscal nine months ended September 27, 2020. Factors resulting in cash used in operating activities included payment of interest on borrowings of $155.5 million, settlement of accounts payable and an increased investment in inventories of $126.9 million, which includes $91.5 million of instrument inventories that were transferred from “Inventories” to “Property, plant and equipment, net,” related to customer leased instruments as well as an increase in other current and non-current assets of $27.6 million. These cash outflows were offset by cash inflows from earnings before interest, taxes, depreciation and amortization expense and other noncash items, as well as net collections of accounts receivable of $34.5 million.

Net cash flows used in investing activities

Net cash used in investing activities was $27.5 million for the fiscal nine months ended September 27, 2020. Purchases of property, plant and equipment during the fiscal nine months ended September 27, 2020 were $28.4 million. In addition, we made noncash

transfers of $91.5 million of instrument inventories from “Inventories” to “Property, plant and equipment, net,” further increasing our investment in property, plant and equipment.

Net cash flows provided by financing activities

During the fiscal nine months ended September 27, 2020, net proceeds from the issuance of the 2025 Notes, 2028 Notes and Euro Term Loan Facility of $1,421.0 million were offset by payments on the 2022 Notes of $1,347.7 million. Net payments on short-term borrowings were $2.2 million.

Debt capitalization

The following table details our debt outstanding as of October 3, 2021 and January 3, 2021:

(Dollars in millions)	October 3, 2021	January 3, 2021
Senior Secured Credit Facilities		
Dollar Term Loan Facility	$ 1,292.8	$ 2,185.5
Euro Term Loan Facility	357.2	408.9
Revolving Credit Facility	—	—
2028 Notes	405.0	675.0
2025 Notes	240.0	400.0
Accounts Receivable Financing	—	75.0
Sale and Leaseback Financing	—	20.5
Finance lease obligation	0.8	1.0
Other short-term borrowings	0.8	0.9
Other long-term borrowings	2.9	3.9
Unamortized deferred financing costs	(22.6)	(40.9)
Unamortized original issue discount	(5.6)	(11.3)
Total borrowings	2,271.3	3,718.5
Less: Current portion	(64.4)	(160.0)
Long-term borrowings	$ 2,206.9	$ 3,558.5

As of October 3, 2021 and January 3, 2021, there were no outstanding borrowings under the Revolving Credit Facility. As of October 3, 2021 and January 3, 2021, letters of credit issued under the Revolving Credit Facility totaled $45.0 million and $37.5 million, respectively, which reduced the availability under the Revolving Credit Facility. Availability under the Revolving Credit Facility was $455.0 million and $312.5 million as of October 3, 2021 and January 3, 2021, respectively. Our debt agreements contain various covenants that may restrict our ability to borrow on available credit facilities and future financing arrangements or require us to remain below a specific credit coverage threshold. We believe that we are and will continue to be in compliance with these covenants.

On February 5, 2021, we entered into a fifth amendment of our Credit Agreement (as amended, the “Credit Agreement”) governing our Senior Secured Credit Facilities, which increased the Revolving Credit Facility contained in the credit agreement by $150.0 million to an aggregate amount of $500.0 million and extended the maturity date to February 5, 2026, provided that such date may be accelerated subject to certain circumstances as set forth in the fifth amendment. To the extent that the aggregate principal amount of the Dollar Term Loan Facility and Euro Term Loan Facility (and any Refinancing Indebtedness (as defined in the Credit Agreement) with respect thereto that matures on or prior to June 30, 2025) outstanding as of March 31, 2025 exceeds $500.0 million then the maturity date with respect to the Revolving Credit Facility shall be March 31, 2025. All other terms of the Senior Secured Credit Facilities will remain substantially the same except as otherwise amended by the fifth amendment.

As of October 3, 2021 and January 3, 2021, the remaining balance of deferred financing costs related to the Dollar Term Loan Facility was $8.6 million and $17.3 million, respectively. As of October 3, 2021 and January 3, 2021, the remaining balance of deferred financing costs related to the Euro Term Loan Facility was $3.8 million and $4.6 million, respectively. As of October 3, 2021 and January 3, 2021, the remaining unamortized balance related to the Revolving Credit Facility was $3.1 million and $3.4 million, respectively. The effective interest rate of the Dollar Term Loan Facility and Euro Term Loan Facility as of October 3, 2021 is 5.76% and 3.88%, respectively.

On January 27, 2020, we issued $675.0 million aggregate principal amount of 7.250% Senior Notes due 2028, on which interest is payable semi-annually in arrears on February 1 and August 1 of each year. The 2028 Notes will mature on February 1, 2028. The 2028 Notes and the guarantees thereof are our senior unsecured obligations and the 2028 Notes and the guarantees rank equally in right of payment with all of the Lux Co-Issuer’s and U.S. Co-Issuer’s (together, the “Issuers”) and guarantors’ existing and future senior debt, including the 2025 Notes. The 2028 Notes and the guarantees thereof are effectively subordinated to any of the Issuers’ and guarantors’

existing and future secured debt, including the Senior Secured Credit Facilities, to the extent of the value of the assets securing such debt. In addition, the 2028 Notes and the guarantees thereof rank senior in right of payment to all of the Issuers' and guarantors' future subordinated debt and will be structurally subordinated to the liabilities of our non-guarantor subsidiaries. We incurred deferred financing costs of $12.9 million related to the 2028 Notes, which were capitalized as deferred financing costs and are being amortized using the effective interest method as a component of interest expense over the life of the 2028 Notes. On February 5, 2021, we used a portion of the proceeds from our IPO to redeem $270.0 million aggregate principal amount of the 2028 Notes, plus accrued interest thereon and $19.6 million of redemption premium. The redemption resulted in an extinguishment loss recognized of $24.3 million for the fiscal nine months ended October 3, 2021, which consisted of $4.7 million of unamortized deferred issuance costs and $19.6 million of the redemption premium.

Concurrent with the issuance of the 2028 Notes, we entered into a $350.0 million U.S. Dollar equivalent swap to Japanese Yen-denominated interest at a weighted average rate of 5.56%, for a five-year term. We terminated the cross currency swaps on April 1, 2021 and received $12.8 million of cash from net settlement in the fiscal nine months ended October 3, 2021.

On June 11, 2020, we issued $400.0 million aggregate principal amount of 7.375% Senior Notes due 2025 on which interest is payable semi-annually in arrears on June 1 and December 1 of each year. The 2025 Notes will mature on June 1, 2025. The 2025 Notes and the guarantees thereof are our unsecured obligations and the 2025 Notes and the guarantees thereof rank equally in right of payment with all of the Issuers' and guarantors' existing and future senior debt, including the 2028 Notes. The 2025 Notes and the guarantees thereof are effectively subordinated to any of the Issuers' and guarantors' existing and future secured debt, including the Senior Secured Credit Facilities, to the extent of the value of the assets securing such debt. In addition, the 2025 Notes and the guarantees thereof rank senior in right of payment to all of the Issuers' and guarantors' future subordinated debt and will be structurally subordinated to the liabilities of the Issuers' non-guarantor subsidiaries. We incurred deferred financing costs of $7.5 million related to the 2025 Notes, which were capitalized as deferred financing costs and are being amortized using the effective interest method as a component of interest expense over the life of the 2025 Notes. On February 5, 2021, we used a portion of the proceeds from our IPO to redeem $160.0 million aggregate principal amount of the 2025 Notes, plus accrued interest thereon and $11.8 million of redemption premium. The redemption resulted in an extinguishment loss recognized of $14.5 million for the fiscal nine months ended October 3, 2021, which consisted of $2.7 million of unamortized deferred issuance costs and $11.8 million of the redemption premium.

In September 2016, we entered into an accounts receivable financing program (the "Financing Program") with a financial institution. The Financing Program, which was fully paid off in June 2021 in connection with entry into the RPA (as defined below), was set to mature on January 24, 2022 and was secured by receivables from our U.S. business that are sold or contributed to a wholly-owned, consolidated, bankruptcy remote subsidiary. The bankruptcy remote subsidiary's sole business consists of the purchase or receipt of the receivables and subsequent granting of a security interest to the financial institution under the program, and its assets were available first to satisfy obligations and were not available to pay creditors of our other legal entities. Under the Financing Program, we could borrow up to the lower of $75.0 million or 85% of the accounts receivable borrowing base. Interest on outstanding borrowings under the Financing Program was charged based on a per annum rate equal to the London Inter-bank Offered Rate (the "LIBOR Rate") (with a floor of zero percent and as defined in the agreement) plus the LIBOR Rate margin (2.25 percentage points) if the related loan was a LIBOR Rate loan. Otherwise, the per annum rate was equal to a Base Rate (as defined in the Financing Program agreement) plus the base rate margin (1.25 percentage points). Interest was due and payable, in arrears, on the first day of each month. The Financing Program was also subject to termination under standard events of default as defined.

On June 11, 2021, Ortho-Clinical Diagnostics FinanceCo I, LLC ("Ortho FinanceCo I"), a wholly owned receivables financing subsidiary of us, entered into a receivables purchase agreement (the "RPA") with Wells Fargo, N.A., as administrative agent (the "Agent"), and certain purchasers. Under the RPA, Ortho FinanceCo I may sell receivables in amounts up to a $75.0 million limit, subject to certain conditions, including that, at any date of determination, the aggregate capital paid to Ortho FinanceCo I does not exceed a "capital coverage amount," equal to an adjusted net receivables pool balance minus a required reserve. Ortho FinanceCo I has guaranteed the prompt payment of the sold receivables, and to secure the prompt payment and performance of such guaranteed obligations, Ortho FinanceCo I has granted a security interest to the Agent, for the benefit of the purchasers, in all assets of Ortho FinanceCo I. We, in our capacity as master servicer under the RPA, are responsible for administering and collecting the receivables and have made customary representations, warranties, covenants and indemnities. We have also provided a performance guarantee for the benefit of Ortho FinanceCo I to cause the due and punctual performance by us of our obligations as master servicer. The proceeds of the RPA were used, in part, to pay off the outstanding balance of the Financing Program.

We or our affiliates, including investment funds affiliated with Carlyle, at any time and from time to time, may purchase Senior Notes or other indebtedness of the Company. Any such purchases may be made through the open market or privately negotiated transactions with third parties or pursuant to one or more tender or exchange offers or otherwise, upon such terms and at such prices, as well as with such consideration, as we, or any of our affiliates, may determine. Such purchases could result in a change to the allocation between the Issuers of the indebtedness represented by the Senior Notes and could have important tax consequences for holders of the Senior Notes.

Liquidity Outlook

Short-term liquidity outlook

We expect that our cash and cash equivalents, cash flows from operations and amounts available under the Revolving Credit Facility will be sufficient to meet debt service requirements, working capital requirements, and capital expenditures for the next 12 months from the issuance of these unaudited consolidated financial statements. Our ability to make scheduled payments of principal or interest on, or to refinance, our indebtedness or to fund working capital requirements, capital expenditures and other current obligations will depend on our ability to generate cash from operations. Such cash generation is subject to general economic, financial, competitive, legislative, regulatory and other factors that are beyond our control.

We are focused on expanding the number of instruments placed in the field and solidifying long-term contractual relationships with customers. In order to achieve this goal, in certain jurisdictions where it is permitted, we have leveraged a reagent rental model that has been recognized as more attractive to certain customers. In this model, we lease, rather than sell, instruments to our customers. Over the term of the contract, the purchase price of the instrument is embedded in the price of the assays and reagents. Going forward, we intend to increase the number of reagent rental placements in developed markets, a strategy that we believe is beneficial to our commercial goals because it lowers our customers' upfront capital costs and therefore allows purchasing decisions to be made at the lab manager level. For these same reasons, the reagent rental model also benefits our commercial strategy in emerging markets. We believe that the shift in our sales strategy will grow our installed base, thereby increasing sales of higher-margin assays, reagents and other consumables over the life of the customer contracts and enhancing our recurring revenue and cash flows. During the fiscal nine months ended October 3, 2021, we transferred $82.6 million of instrument inventories from Inventories to Property, plant and equipment, further increasing our investment in property, plant and equipment. We currently estimate that we will transfer additional instrument inventories of approximately $40 million during the remainder of fiscal year 2021.

Based on our forecasts, we believe that cash flow from operations, available cash on hand and available borrowing capacity under our Revolving Credit Facility will be sufficient to fund continuing operations for the next 12 months from the issuance of these unaudited consolidated financial statements. Our debt agreements contain various covenants that may restrict our ability to borrow on available credit facilities and future financing arrangements and require us to remain below a specific credit coverage threshold. Our credit agreement has a financial covenant (ratio of Net First Lien Secured Debt to Adjusted EBITDA not to exceed 5.5-to-1, subject to a 50 basis point step-down on September 30, 2022) that is tested when borrowings and letters of credit issued under the Revolving Credit Facility exceed 30% of the committed amount at any period end reporting date. As of October 3, 2021, we had no outstanding borrowings under our Revolving Credit Facility. Due to the current economic and business uncertainty resulting from the ongoing COVID-19 pandemic, from time to time we may borrow from our Revolving Credit Facility, if needed, for the remainder of fiscal year 2021. We believe that we will continue to comply with the financial covenant for the next 12 months. In the event we do not comply with the financial covenant of the Revolving Credit Facility, the lenders will have the right to call on all of the borrowings under the Revolving Credit Facility. If the lenders on the Revolving Credit Facility terminate their commitments and accelerate the loans, this would become a cross default to other material indebtedness. We believe that we will continue to be in compliance with these covenants. However, should it become necessary, we may seek to raise additional capital within the next 12 months through borrowings on credit facilities, other financing activities and/or the private sale of equity securities.

Long-term liquidity outlook

UK Holdco is a holding company with no business operations or assets other than cash, the capital stock of our direct and indirect subsidiaries, miscellaneous administrative costs and intercompany loan receivables. Consequently, UK Holdco is dependent on loans, dividends, interest and other payments from its subsidiaries to make principal and interest payments on our indebtedness, meet working capital requirements and make capital expenditures. As presently structured, its operating subsidiaries are the sole source of cash for such payments and there is no assurance that the cash for those interest payments will be available. We believe our organizational structure will allow the necessary flexibility to move funds throughout our subsidiaries to meet our operational working capital needs. In the future, the Issuers and borrowers under our Senior Secured Credit Facilities may also need to refinance all or a portion of the borrowings under the Senior Notes and the Senior Secured Credit Facilities on or prior to maturity. If refinancing is necessary, there can be no assurance that we will be able to secure such financing on acceptable terms, or at all.

Our ability to make payments on and to refinance our indebtedness and to fund planned capital expenditures will depend on our ability to generate cash in the future. This is subject to general economic, financial, competitive, legislative, regulatory and other factors that are beyond our control as well as the factors described in Part 1, Item 1A, "Risk factors" and "Special note regarding forward-looking statements" in our Annual Report on Form 10-K for the fiscal year ended January 3, 2021.

Recent accounting pronouncements

Information regarding new accounting pronouncements is included in *Note 3 – Recent accounting pronouncements* to the unaudited consolidated financial statements.

Critical accounting estimates and summary of significant accounting policies

Significant accounting policies are those accounting policies that can have a significant impact on the presentation of our financial condition and results of operations and that require the use of complex and subjective estimates based upon past experience and management's judgment. Because of the uncertainty inherent in such estimates, actual results may differ materially from these estimates. The policies applied preparing our interim unaudited consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q are those that management believes are the most dependent on estimates and assumptions. There have been no changes to our critical accounting estimates and significant accounting policies previously disclosed in our Annual Report on Form 10-K for the fiscal year ended January 3, 2021.

Off-balance sheet arrangements

We do not have any significant off-balance sheet arrangements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Our business and financial results are affected by fluctuations in world financial markets, including interest rates and currency exchange rates. We manage these risks through normal operating and financing activities and, when deemed appropriate, through the use of derivative financial instruments. We have policies governing our use of derivative instruments, and we do not enter into financial instruments for trading or speculative purposes.

Interest rate risk

We are subject to interest rate market risk in connection with our long-term debt. Our principal interest exposure will relate to outstanding amounts under our Senior Secured Credit Facilities. Our Senior Secured Credit Facilities provide for variable rate borrowings of up to $2,150.0 million, including up to $500.0 million under our Revolving Credit Facility. Assuming our Senior Secured Credit Facilities are fully drawn (and to the extent that LIBOR is in excess of the zero floor rate of our Senior Secured Credit Facilities), each one-eighth percentage point increase or decrease in the applicable interest rates would correspondingly change our interest expense on our Senior Secured Credit Facilities by approximately $2.7 million per year before considering the impact of derivative instruments. For further discussion of the risks related to our Senior Secured Credit Facilities, see "Risk factors—Risks related with our indebtedness—Our substantial indebtedness could adversely affect our financial condition, limit our ability to raise additional capital to fund our operations and prevent us from fulfilling our obligations under our indebtedness" in our Annual Report on Form 10-K for the fiscal year ended January 3, 2021.

We selectively use derivative instruments to reduce market risk associated with changes in interest rates. The use of derivatives is intended for hedging purposes only and we do not enter into derivative instruments for speculative purposes. As of October 3, 2021, we have an interest rate cap agreement to hedge our interest rate exposures related to our variable rate borrowings under the Senior Secured Credit Facilities with an interest rate cap amount of 3.5%, with caplets that mature through December 31, 2023.

We also have entered into an interest rate swap agreement, which fixed a portion of the variable interest due on our variable rate debt. Under the terms of the agreement, we will pay a fixed rate of 1.635% and receive a variable rate of interest based on one-month LIBOR (as defined) from the counterparty which is reset every month through December 31, 2023. As of October 3, 2021, the notional amount of the interest rate swap was $1,500 million. The notional value of this instrument is expected to be $1,000 million in fiscal 2022 and $500 million in fiscal 2023.

Foreign exchange rates risk

We are exposed to foreign currency risk by virtue of our international operations. We derived approximately 49% of our revenue for the fiscal nine months ended October 3, 2021 outside the United States. For translation of operations in non-U.S. Dollar currencies, the local currency of most entities is the functional currency. Our foreign assets and liabilities are translated into U.S. Dollars at the exchange rates existing at the respective balance sheet dates, and income and expense items are translated at the average exchange rate for each relevant period. Foreign exchange effects from the translation of our balance sheet resulted in a comprehensive loss of $13.9 million and $21.7 million for the fiscal quarter and nine months ended October 3, 2021, respectively. Foreign exchange effects from the translation of our balance sheet resulted in a comprehensive gain of $8.1 million and $1.7 million for the fiscal quarter and nine months ended September 27, 2020, respectively. Adjustments resulting from the re-measurement of transactions denominated in foreign currencies other than the functional currency of our subsidiaries are expensed as incurred.

In the majority of our jurisdictions, we earn revenue and incur costs in the currency used in such jurisdiction. We incur significant costs in foreign currencies including Brazilian Real, British Pound, Chinese Yuan/Renminbi, Euro, Indian Rupee, Japanese Yen, Mexican Peso, and the Swiss Franc. As a result, movements in exchange rates cause our revenue and expenses to fluctuate, impacting our profitability and cash flows. Future business operations and opportunities, including the continued expansion of our business outside North America, may further increase the risk that cash flows resulting from these activities may be adversely affected by changes in currency exchange rates.

Like many multi-national companies, we have exposure to the British Pound. We are negatively impacted by a lower British Pound exchange rate from translation impact when compared to the U.S. Dollar, but we also benefit from expenses denominated in British Pound, as well as some cross-border transactions at a lower exchange rate. The magnitude of the impact is dependent on our business volumes in the UK, forward contract hedge positions, cross currency volume and the exchange rate.

Additionally, in order to fund the purchase price for the assets and capital stock of certain non-U.S. entities, a combination of equity contributions and intercompany loans were utilized to capitalize certain non-U.S. subsidiaries. In many instances, the intercompany loans are denominated in currencies other than the functional currency of the affected subsidiaries. Where intercompany loans are not a component of permanently invested capital of the affected subsidiaries, increases or decreases in the value of the subsidiaries' functional currency against other currencies will affect our results of operations. During the fiscal quarter and nine months ended October 3, 2021, we recorded foreign currency exchange gains of $0.7 million and $0.3 million, respectively. During the fiscal quarter and nine months ended September 27, 2020, we recorded foreign currency exchange gains of $5.4 million and foreign currency exchange losses of $49.4 million, respectively. The foreign currency gains/losses in each period primarily consist of unrealized gains/losses related to intercompany loans denominated in currencies other than the functional currency of the affected subsidiaries. We may enter into derivative instruments to manage our foreign currency exposure on these intercompany loans in the future.

Foreign exchange risk is also managed through the use of foreign currency debt. During the fiscal quarter ended October 3, 2021, €260.0 million ($301.5 million) of our senior secured Euro Term Loan Facility has been designated as, and is effective as, economic hedges of the net investment in a foreign operation. Accordingly, foreign currency transaction gains or losses due to spot rate fluctuations on the Euro-denominated debt instruments are included in foreign currency translation adjustments within AOCI.

We have entered into foreign-currency forward contracts to manage our foreign currency exposures on foreign currency denominated firm commitments and forecasted foreign currency denominated intercompany and third-party transactions. We had forward contracts outstanding with total notional amount of $423.7 million as of October 3, 2021, with maturity dates through January 2022. Foreign-currency forward contracts that qualified and were designated for hedge accounting are recorded at their fair value as of October 3, 2021 and the unrealized loss of $1.6 million is reported as a component of other comprehensive loss, all of which is expected to be reclassified to earnings in the next 12 months. Actual gains (losses) upon settlement will be recognized in earnings, within the line item impacted, during the estimated time in which the transactions are incurred. Actual losses upon settlement of $2.7 million and gains upon settlement of $4.5 million were recognized in earnings during the fiscal nine months ended October 3, 2021 and September 27, 2020, respectively.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer ("CEO") and Chief Financial Officer ("CFO"), has evaluated the effectiveness of our disclosure controls and procedures (as that term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on such evaluation, our CEO and CFO have concluded that as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives.

Changes in Internal Control Over Financial Reporting

There has been no change in our internal control over financial reporting (as that term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the fiscal quarter ended October 3, 2021 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

We are from time to time a party to legal proceedings which arise in the normal course of business. We do not believe any pending litigation to be material, the outcome of which would, in management's judgment based on information currently available, have a material adverse effect on our results of operations or financial condition. See *Note 15 - Commitments and contingencies* to the interim unaudited consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

Item 1A. Risk Factors.

Except as set forth herein, there are no other material changes from the risk factors as previously disclosed in our Annual Report on Form 10-K for our fiscal year ended January 3, 2021 or any of our subsequently filed reports.

Our collection, use and disclosure of personal information, including health information, is subject to federal and state privacy and security regulations, as well as data privacy and security laws outside the United States, including in the European Economic Area (the "EEA"), the United Kingdom and the People's Republic of China, and our failure to comply with those laws and regulations or to adequately secure the information we hold could result in significant liability or reputational harm.

The Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and their implementing regulations (collectively referred to as "HIPAA") as well as numerous other federal and state laws and regulations, govern the collection, dissemination, use, privacy, security, confidentiality, integrity and availability of personally identifiable information ("PII"), including protected health information ("PHI"). HIPAA applies national privacy and security standards for PHI to covered entities, including certain types of health care entities and their service providers that access PHI, known as business associates. HIPAA requires covered entities and business associates to maintain policies and procedures governing PHI that is used or disclosed, and to implement administrative, physical and technical safeguards to protect PHI, including PHI maintained, used and disclosed in electronic form. These safeguards include employee training, identifying business associates with whom covered entities need to enter into HIPAA-compliant contractual arrangements and various other measures. While we undertake substantial efforts to secure the PHI we maintain, use and disclose in electronic form, a cyberattack or other intrusion that bypasses our information security systems causing an information security breach, loss of PHI, PII or other data subject to privacy laws or a material disruption of our operational systems could result in a material adverse impact on our business, along with potentially substantial fines and penalties. Ongoing implementation and oversight of these security measures involves significant time, effort and expense.

HIPAA requires covered entities and their business associates to report breaches of unsecured PHI to affected individuals without unreasonable delay and in no case later than 60 days after the discovery of the breach by the covered entity or its agents.

Notification must also be made to the U.S. Department of Health and Human Services ("HHS") and, in certain situations involving large breaches, to the media. The HIPAA rules created a presumption that all non-permitted uses or disclosures of unsecured PHI are breaches unless the covered entity establishes that there is a low probability the information has been compromised. A data breach affecting sensitive personal information, including health information, also could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business.

HIPAA also authorizes state attorney generals to bring civil actions seeking either an injunction or damages in response to violations of HIPAA privacy and security regulations that threaten the privacy of state residents. While HIPAA does not create a private right of action allowing individuals to sue us in civil court for violations of HIPAA's requirements, its standards have been used as a basis for the duty of care in state civil suits, such as those for negligence or recklessness in the handling of PHI. In addition, HIPAA mandates that the Secretary of HHS conduct periodic compliance audits of covered entities and business associates.

In addition, many states in which we operate may impose laws that are more protective of the privacy and security of PII than HIPAA. Where these state laws are more protective than HIPAA, we may have to comply with their stricter provisions. Not only may some of these state laws impose fines and penalties upon violators, but some may afford private rights of action to individuals who believe their PII has been misused.

Both state and federal laws and regulations are subject to modification or enhancement of privacy and security protections at any time. Our business will continue to remain subject to any federal and state privacy-related laws and regulations that are more restrictive than the privacy regulations issued under HIPAA. Sweeping privacy measures in certain states such as the California Consumer Privacy Act impose European-like standards for the protection of personal data and allow for a private right of action. These statutes vary and could impose additional requirements on us and more severe penalties for disclosures of confidential health information. New health and consumer information standards could have a significant effect on the manner in which we do business, and the cost of complying with new standards could be significant. We may not remain in compliance with the diverse privacy and

security requirements in all of the jurisdictions in which we do business. If we fail to comply with such state laws, we could incur substantial civil monetary or criminal penalties.

We are also subject to data privacy and security laws in jurisdictions outside of the United States. For example, in the EEA and the United Kingdom, we are subject to the General Data Protection Regulation 2016/679 (the "GDPR"), which could limit our ability to collect, control, process, share, disclose and otherwise use personal data (including health and medical information which are subject to strict requirements). Complying with the GDPR could cause our compliance costs to increase, ultimately having an adverse impact on our business. We are implementing measures to comply with these laws as part of our comprehensive compliance program with input from external advisors to address our compliance with these obligations under the GDPR. Failure to comply with the GDPR may result in fines up to the greater of €20 million or 4% of total annual revenue. In addition to the foregoing, a breach of the GDPR could result in regulatory investigations, reputational damage, orders to cease or change our processing of our data, enforcement notices or assessment notices (for a compulsory audit). We may also face civil claims including representative actions and other class action type litigation (where individuals have suffered harm), potentially amounting to significant compensation or damages liabilities, as well as associated costs, diversion of internal resources and reputational harm. In addition, beginning in 2021 when the transitional period following Brexit expires, we will be required to comply with both the GDPR and the Data Protection Act of 2018 (the "U.K. GDPR"), with each regime having the ability to fine up to the greater of €20 million (in the case of the GDPR) or £17 million (in the case of the U.K. GDPR) and 4% of total annual revenue. The relationship between the United Kingdom and the European Union in relation to certain aspects of data protection law remains unclear including, for example, how data transfers between EU member states and the United Kingdom will be treated and the role of the Information Commissioner's Office following the end of the transitional period. These changes could lead to additional costs and increase our overall risk exposure.

We are also subject to European Union rules with respect to cross-border transfers of personal data out of the EEA and the United Kingdom. Recent legal developments in Europe have created complexity and uncertainty regarding transfers of personal data from the EEA to the United States. For instance, on July 16, 2020, the Court of Justice of the European Union (the "CJEU") invalidated the EU-U.S. Privacy Shield Framework (the "Privacy Shield") under which personal data could be transferred from the EEA to U.S. entities who had self-certified under the Privacy Shield scheme.

While the CJEU did not invalidate standard contractual clauses (a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism, and potential alternative to the Privacy Shield), it made clear that reliance on them alone may not necessarily be sufficient in all circumstances. We currently rely on the standard contractual clauses among other data transfer mechanisms allowed pursuant to the GDPR to transfer personal data outside the EEA or the United Kingdom, including to the United States. These recent developments will require us to review and consider amending the legal mechanisms by which we make and receive personal data transfers to the United States and other countries outside the EEA/UK. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the standard contractual clauses cannot be used, and/or start taking enforcement action, we could suffer additional costs, complaints, regulatory investigations or fines, and if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services and the geographical location or segregation of our relevant systems and operations, which could adversely affect our financial results.

We depend on a number of third parties in relation to the operation of our business, a number of which process personal data on our behalf. With each such third party, we attempt to mitigate the associated risks of using third parties by performing applicable security assessments and detailed due diligence, entering into contractual arrangements to require that providers only process personal data according to our instructions, and that they have sufficient technical and organizational security measures in place. Where we transfer personal data outside the EEA or the United Kingdom to such third parties, we do so in compliance with the relevant data export requirements, as described above. There is no assurance that these contractual measures and our own privacy and security-related safeguards will fully protect us from the risks associated with the third-party processing. Any violation of data or security laws by our third party processors could have a material adverse effect on our business and result in the fines and penalties outlined below.

We are also subject to evolving privacy laws on cookies and e-marketing. In the European Union, regulators are increasingly focusing on compliance with requirements in the online behavioral advertising ecosystem, and current national laws that implement the ePrivacy Directive will be replaced by an EU regulation known as the ePrivacy Regulation which will significantly increase fines for non-compliance. While the text of the ePrivacy Regulation is still under development, a recent European court decision and regulators' recent guidance are driving increased attention to cookies and tracking technologies. In the United States, the Federal Trade Commission and many state laws have increasingly focused on the collection and use of behavioral data including geolocation and biometric information. As regulators start to enforce a strict approach (which has already started in Germany), this could lead to substantial costs, require significant systems changes, limit the effectiveness of our marketing activities, divert the attention of our technology personnel, adversely affect our margins, increase costs and subject us to additional liabilities.

Recently, many countries have enacted legislation to strengthen privacy laws to protect their residents' personal data. Some countries' laws have been modeled on GDPR, including fines and penalties such as Brazil's enacted data protection law and similar

pending legislation in Chile. We are currently monitoring the evolving data protection landscape so that we can comply with the requirements in the countries in which we do business.

Data compliance in other countries outside EEA, the United Kingdom and the United States are even more complex and varied making it difficult to comply with them all. China's legislation and regulation of the health care industry involves multiple pieces of legislation prescribing complex regulatory requirements governing different types of data across a continuum of care, and various supervisory authorities frequently conduct inspections and investigations. For example, under China's Cybersecurity Law, any collection, use, transfer and storage of personal information of a Chinese citizen through a network by the network operator should be based on the three principles of legitimacy, justification and necessity and requires the consent of the data subject. The rules, purposes, methods and ranges of such collection should also be disclosed to the data subject. China's data localization requirements are becoming increasingly common in sector-specific regulations. China's Cybersecurity Law requires operators of critical information infrastructure ("CIIOs") to store personal information and important data collected and generated from the critical information infrastructure within China. Failure to do so can result in fines of up to RMB 100,000 for the relevant entity as well as for the personnel directly responsible.

Building on this, China's Data Security Law ("Data Security Law") became effective on September 1, 2021. The primary purpose of the Data Security Law is to regulate data activities, safeguard data security, promote data development and usage, protect individuals and entities' legitimate rights and interests, and safeguard state sovereignty, state security and development interests. The Data Security Law applies extraterritorially, and to a broad range of activities that involve "data" (not only personal or sensitive data). Under the Data Security Law, entities and individuals carrying out data activities must abide by various data security obligations. For example, the Data Security Law proposes to classify and protect data based on the importance of data to the state's economic development, as well as the degree of harm it will cause to national security, public interests, or legitimate rights and interests of individuals or organizations when such data is tampered with, destroyed, leaked, or illegally acquired or used. The appropriate level of protective measures is required to be taken for each respective class of data. The Data Security Law also echoes the data localization requirement in the Cybersecurity Law and requires important data to be stored locally in China. Such important data may only be transferred outside of China subject to compliance with certain data transfer restrictions, such as passing a security assessment organized by the relevant authorities.

Notably, the PIPL, similar to the GDPR, applies extraterritorially. The PIPL is intended to clarify the scope of application, the definitions of personal information and sensitive personal information (which includes medical and health information), the legality of personal information processing and the basic requirements of notice and consent, among other things. The PIPL also sets out data localization requirements for CIIOs and personal information processors who process personal information above a certain threshold prescribed by the relevant authorities. The PIPL also includes a list of rules which must be complied with prior to the transfer of personal information outside of China, such as compliance with a security assessment or certification by an agency designated by the relevant authorities or entering into standard form model contracts approved by the relevant authorities with the overseas recipient. Failure to comply with PIPL can result in fines of up to RMB 50 million or 5% of the prior year's total annual revenue for the personal information processor and/or a suspension of services or data processing activities. Other potential penalties include a fine of up to RMB 1 million on the person in charge or directly responsible personnel and, in serious cases, individuals and entities may be exposed to criminal liabilities under other local Chinese law, such as the Criminal Law of the People's Republic of China. The PIPL also prohibits responsible personnel for violations of the PIPL from holding high level management or data protection officer positions in relevant enterprises.

In addition to China's Cybersecurity Law, the Data Security Law and the PIPL, the relevant government authorities of People Republic of China promulgated several regulations or released a number of draft regulations for public comments which are designed to provide further implemental guidance in accordance with the laws mentioned above.

We cannot predict what impact the new laws and regulations, in particular the Data Security Law or PIPL, or the increased costs of compliance, if any, will have on our operations in China due to their recent enactment and the limited guidance available, particularly on PIPL, which entities are awaiting further guidance on. It is also generally unclear how the laws will be interpreted and enforced in practice by the relevant government authorities as often the abovementioned laws are drafted broadly and thus leaves great discretion to the relevant government authorities to exercise.

Compliance with China's data laws mentioned above, GDPR and the various other global data privacy laws that we are subject to has required, and may continue to require, significant company resources and expenditures, and may require further changes in our products, services or business model that increase competition or reduce revenue.

We are no longer a "controlled company" within the meaning of Nasdaq rules and the rules of the SEC and may have difficulties complying with Nasdaq rules relating to the composition of our Board of Directors and certain committees.

Our ordinary shares are listed on Nasdaq. Prior to September 2021, we were a "controlled company" within the meaning of the corporate governance standards of Nasdaq. Under these rules, we were not subject to a number of corporate governance rules relating to the composition of our Board of Directors and certain committees. Following the sale of our ordinary shares by the Principal

Shareholder in September 2021, we are no longer a controlled company. Under Nasdaq rules and the rules of the SEC, we are permitted to phase into compliance with certain corporate governance requirements from which we were previously exempt, including:

- the requirement that a majority of our Board of Directors consist of "independent directors" as defined under the rules of Nasdaq;
- the requirement that we have a compensation committee that is composed entirely of directors who meet the Nasdaq independence standards for compensation committee members; and
- the requirement that our director nominations be made, or recommended to our full Board of Directors, by our independent directors or by a nominations committee that consists entirely of independent directors.

While we intend to comply with these Nasdaq rules, we may not be able to attract and retain the number of independent directors required of our Board of Directors or certain of our committees.

The Principal Shareholder will continue to have the ability to significantly influence our decisions, and their interests may not be aligned with yours.

As of September 14, 2021, the Principal Shareholder owned approximately 49.9% of our ordinary shares and continues to exercise significant influence over our affairs and policies. Pursuant to our Articles of Association, the Principal Shareholder continues to have the ability to nominate for appointment up to eight of our directors until it owns less than 35% of our ordinary shares. As a result, the Principal Shareholder and its designees to our Board of Directors currently have the ability to control: the appointment of management, the entry into mergers, sales of substantially all of our assets and other extraordinary transactions. The directors appointed have authority to issue additional shares, implement stock repurchase programs, declare interim dividends, recommend final dividends, and make other decisions. The interests of the Principal Shareholder could conflict with your interests. For example, the Principal Shareholder may also have an interest in pursuing acquisitions, divestitures, financings or other transactions that, in its judgment, could enhance its equity investments. Additionally, the Principal Shareholder is in the business of making investments in companies, and may from time to time acquire interests in businesses that directly or indirectly compete with certain portions of our business or are suppliers or customers of ours.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Number	Description	Form	File No.	Exhibit	Filing Date
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				Filed Herewith
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				Filed Herewith
32.1	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				Furnished Herewith
32.2	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				Furnished Herewith
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document				
101.SCH	Inline XBRL Taxonomy Extension Schema Document				Filed Herewith
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document				Filed Herewith
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document				Filed Herewith
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document				Filed Herewith
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document				Filed Herewith
104	Cover Page Interactive Data File—the cover page interactive data file does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document				

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 thereunto duly authorized.

Ortho Clinical Diagnostics Holdings plc

Date: November 8, 2021

By: /s/ Christopher M. Smith

Christopher M. Smith

Chairman and Chief Executive Officer

Date: November 8, 2021

By: /s/ Joseph M. Busky

Joseph M. Busky

Chief Financial Officer

Exhibit 31.1

CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Christopher M. Smith, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q, of Ortho Clinical Diagnostics Holdings plc;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. [Omitted];

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and

5. The registrant’s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: November 8, 2021

By: /s/ Christopher M. Smith

Christopher M. Smith
Chairman and Chief Executive Officer

Exhibit 31.2

CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Joseph M. Busky, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q, of Ortho Clinical Diagnostics Holdings plc;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. [Omitted];

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and

5. The registrant’s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: November 8, 2021

By: /s/ Joseph M. Busky

Joseph M. Busky
Chief Financial Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the filing of the Quarterly Report on Form 10-Q of Ortho Clinical Diagnostics Holdings plc (the "Company") for the quarterly period ended October 3, 2021 with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned Chairman and Chief Executive Officer of the Company hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 8, 2021

By: /s/ Christopher M. Smith

Christopher M. Smith
Chairman and Chief Executive Officer

Exhibit 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the filing of the Quarterly Report on Form 10-Q of Ortho Clinical Diagnostics Holdings plc (the "Company") for the quarterly period ended October 3, 2021 with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned Chief Financial Officer of the Company hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 8, 2021

By: /s/ Joseph M. Busky

Joseph M. Busky
Chief Financial Officer