Surmodics Reports Fourth Quarter and Fiscal Year 2022 Financial Results; Introduces Fiscal Year 2023 Financial Guidance

November 9, 2022 07:00 Eastern Standard Time

EDEN PRAIRIE, Minn. – Surmodics, Inc. (Nasdaq: SRDX), a leading provider of medical device and in vitro diagnostic technologies to the healthcare industry, today reported financial results for its fourth quarter and fiscal year ended September 30, 2022, and introduced its financial outlook for the fiscal year ending September 30, 2023.

Fourth Quarter 2022 Financial Summary

- Total Revenue of $26.0 million, an increase of 8% year-over-year
- GAAP Diluted EPS of $(1.06), including $(0.73) deferred tax valuation reserve, compared to $(0.02) in the prior-year period
- Non-GAAP Diluted EPS of $(0.26), compared to $(0.10) in the prior-year period

Fiscal Year 2022 Financial Summary

- Total Revenue of $100.0 million, a decrease of 5% year-over-year
- GAAP Diluted EPS of $(1.96), including $(0.73) deferred tax valuation reserve, compared to $0.30 in the prior-year period
- Non-GAAP Diluted EPS of $(0.95), compared to $0.37 in the prior-year period

Business Highlights

- On October 11, 2022, Surmodics announced that six-month data from its SWING first-in-human study of the Company's Sundance™ Sirolimus drug-coated balloon was presented at the Amputation Prevention Symposium (AMP) in Lugano, Switzerland, with *Sundance* demonstrating an excellent safety profile and the lowest binary restenosis at six months, compared to relevant below-the-knee trials.
- On October 13, 2022, Surmodics submitted a complete response to FDA comments on its application for premarket approval of the SurVeil™ drug-coated balloon.
- On October 17, 2022, Surmodics announced that it has entered into a new, five-year credit agreement with MidCap Financial, consisting of up to $100 million in term loans and a $25 million revolving credit facility.
- On November 2, 2022, Surmodics announced that 24-month data from its TRANSCEND clinical trial of the Company's SurVeil™ drug-coated balloon was presented at the Vascular InterVentional Advances (VIVA) annual conference in Las Vegas, Nevada, with *SurVeil* demonstrating sustained durability of safety and efficacy endpoints.

"We are pleased to bring fiscal 2022 to a strong conclusion, delivering revenue performance that exceeded our expectations for the fourth quarter, while continuing to invest in our business and make progress on our strategic objectives," said Gary Maharaj, President and CEO of Surmodics, Inc. "Our fourth quarter revenue performance was exclusively driven by Medical Device revenue, which increased 12% year-over-year, with stronger-than-anticipated product sales – including sales of our Pounce™ and Sublime™ products – and licensing fee revenue. From an operational standpoint, our regulatory team worked diligently to prepare a complete response to FDA comments on the PMA application for our *SurVeil* drug-coated balloon, which we are pleased to announce was submitted to the Agency on October 13th. We also made important progress with respect to the initial commercialization of our *Pounce* arterial thrombectomy and *Sublime* radial platforms, onboarding and training our recently hired territory managers, building our customer base, and generating early commercial traction."

Mr. Maharaj continued, “With an established direct sales team, recent progress with respect to our *SurVeil*, *Pounce* and *Sublime* products, and an enhanced balance sheet to support our operations and growth initiatives, we are excited about our future prospects as we enter fiscal 2023. Looking ahead, we aim to build upon the momentum gained this past year by remaining focused on driving continued execution with respect to our strategic objectives. In doing so, we will position Surmodics to achieve strong, sustainable, long-term growth and generate enhanced future value for our shareholders.”

Fourth Quarter Fiscal 2022 Financial Results

	Three Months Ended September 30,		Increase (Decrease)	
	2022	2021	$	%
Revenue:				
Medical Device	$ 19,500	$ 17,395	$ 2,105	12%
In Vitro Diagnostics	6,488	6,576	(88)	(1)%
Total revenue	$ 25,988	$ 23,971	$ 2,017	8%

Total revenue increased $2.0 million, or 8%, to $26.0 million, compared to $24.0 million in the fourth quarter of fiscal 2021.

Medical Device revenue increased $2.1 million, or 12%, to $19.5 million, compared to $17.4 million in the fourth quarter of fiscal 2021, driven by device product sales, as well as higher license fee revenue. Medical Device revenue in the fourth quarter of fiscal 2022 included $2.1 million from the Company’s Development and Distribution Agreement with Abbott Vascular, Inc. (“Abbott”) for the *SurVeil* drug-coated balloon (“DCB”), compared to $1.2 million in the prior-year period. In Vitro Diagnostics revenue decreased $0.1 million, or 1%, to $6.5 million, compared to $6.6 million in the fourth quarter of fiscal 2021, driven primarily by strong product sales offset by unfavorable order timing for distributed antigen products.

Product gross profit (defined as product sales less product costs) increased $0.4 million, or 5%, to $8.8 million, compared to $8.4 million in the fourth quarter of fiscal 2021. Product gross margin (defined as product gross profit as a percentage of product sales) was 61.1%, compared to 66.8% in the fourth quarter of fiscal 2021. Product gross margin in the fourth quarter of fiscal 2021 included a $0.5 million benefit associated with the employee retention credit under the Coronavirus Aid, Relief and Economic Security Act (the “CARES Act”). Product gross margin in the fourth quarter of fiscal 2022 was adversely impacted relative to the prior year by a higher mix of recent product introductions, which have lower product gross margins due to low production volumes.

Operating costs and expenses, excluding product costs, increased $6.7 million, or 33%, to $27.0 million, compared to $20.3 million in the fourth quarter of fiscal 2021. The increase was driven primarily by higher selling, general and administrative expenses associated with the expansion of the Company’s direct medical device salesforce. Operating costs and expenses in the fourth quarter of fiscal 2021 included a $3.1 million benefit associated with the employee retention credit under the CARES Act.

GAAP net loss was $(14.7) million, or $(1.06) per diluted share, compared to $(0.3) million, or $(0.02) per diluted share in the fourth quarter of fiscal 2021. GAAP net loss in the quarter included a non-cash tax expense of $(10.2) million, or $(0.73) per diluted share, from a full valuation reserve against the Company’s U.S. deferred tax assets. The availability of the deferred tax assets to offset future U.S. tax liabilities was unaffected by the reserve. Non-GAAP net loss was $(3.7) million, or $(0.26) per diluted share, compared to $(1.3) million, or $(0.10) per diluted share in the fourth quarter of fiscal 2021.

Adjusted EBITDA loss was $(2.5) million, compared to Adjusted EBITDA of $0.5 million in the fourth quarter of fiscal 2021.

Fiscal Year 2022 Financial Results

	Fiscal Year Ended September 30,		Increase (Decrease)	
	2022	2021	$	%
Revenue:				
Medical Device	$ 72,389	$ 78,253	$ (5,864)	(7)%
In Vitro Diagnostics	27,562	26,883	679	3%
Total revenue	$ 99,951	$ 105,136	$ (5,185)	(5)%

Total revenue decreased $5.2 million, or 5%, to $100.0 million, compared to $105.1 million in fiscal 2021.

Medical Device revenue decreased $5.9 million, or 7%, to $72.4 million, compared to $78.3 million in fiscal 2021, driven primarily by lower license fee revenue, partly offset by broad-based product sales growth. Medical Device license fee revenue in fiscal 2022 included $5.7 million from the Company's Development and Distribution Agreement with Abbott for the *SurVeil* DCB, compared to $16.0 million in the prior year. In Vitro Diagnostics revenue increased $0.7 million, or 3%, to $27.6 million, compared to $26.9 million in fiscal 2021, driven by broad-based product sales growth.

GAAP net loss was $(27.3) million, or $(1.96) per diluted share, compared to GAAP net income of $4.2 million, or $0.30 per diluted share in fiscal 2021. GAAP net loss in fiscal 2022 included a non-cash tax expense of $(10.2) million, or $(0.73) per diluted share, from a full valuation reserve against the Company's U.S. deferred tax assets. Non-GAAP net loss was $(13.2) million, or $(0.95) per diluted share, compared to Non-GAAP net income of $5.2 million, or $0.37 per diluted share in fiscal 2021.

Adjusted EBITDA loss was $(5.8) million, compared to Adjusted EBITDA of $17.9 million in fiscal 2021.

Balance Sheet Summary

As of September 30, 2022, Surmodics reported cash and investments totaling $19.0 million and $10 million in outstanding borrowings on its $25 million line of credit. Surmodics reported $2.5 million of cash used in operating activities and $0.6 million in capital expenditures in the fourth quarter of fiscal 2022.

On October 17, 2022, Surmodics entered into a new, five-year credit agreement with MidCap Financial ("MidCap"), comprised of up to $100 million in term loans and a $25 million revolving credit facility. The Company drew $25 million on the term loan and $5 million on the revolving credit facility at close. These proceeds were partially used to retire the Company's existing $25 million revolving credit facility with Bridgewater Bank, of which $10 million was outstanding. Upon closing, the Company's cash balance increased by $19.5 million.

Fiscal Year 2023 Financial Guidance

Surmodics expects fiscal year 2023 total revenue to range from $103 million to $107 million, representing an increase of 3% to 7% compared to the prior year.

The Company expects fiscal 2023 GAAP diluted loss per share to range from $(2.80) to $(2.40). Non-GAAP diluted loss per share in fiscal 2023 is expected to range from $(2.54) to $(2.14), which reflects continued investment to support the commercialization of the Company's *Pounce* thrombectomy and *Sublime* radial access products.

Surmodics has the potential to receive up to a $30 million milestone payment during fiscal 2023 pursuant to the Abbott Development and Distribution Agreement related to premarket approval ("PMA") by the U.S. Food and Drug Administration ("FDA") of the *SurVeil* DCB. The milestone payment is reduced to $27 million if PMA is received after December 31, 2022, but before June 30, 2023, and to $24 million if PMA is received on or after June 30, 2023. The Company does not expect to receive the PMA prior to January 1, 2023. The potential revenue during fiscal 2023 associated with the $30 million, $27 million or $24 million milestone payment would be approximately $27 million, $25 million or $22 million, respectively. As has been the Company's practice with past guidance, revenue from regulatory-related milestones is not included in guidance until after they are achieved.

Conference Call Today at 7:00 a.m. CT (8:00 a.m. ET)

Surmodics is hosting a live webcast at 7:00 a.m. CT (8:00 a.m. ET) today to discuss the fourth quarter and fiscal 2022 financial results and accomplishments and host a question-and-answer session. To access the webcast, navigate to upcoming events under the 'events and presentations' tab within the investor relations portion of the Company's website at https://surmodics.gcs-web.com/events-and-presentations. To listen to the live teleconference, dial 888-428-7458 (international callers may dial 862-298-0702) and provide access ID: 13733806.

An audio replay of the conference call will be available beginning at 11:00 a.m. CT on Wednesday, November 9th until 11:00 a.m. CT on Wednesday, November 23rd and can be accessed by dialing 877-660-6853 (international callers may dial 201-612-7415) and entering access ID: 13733806. In addition, the webcast and transcript will be archived on the Company's website following the call.

About Surmodics, Inc.

Surmodics is a leading provider of surface modification technologies for intravascular medical devices and chemical components for in vitro diagnostic immunoassay tests and microarrays. Surmodics is pursuing development and commercialization of highly differentiated medical devices that are designed to address unmet clinical needs and engineered to the most demanding requirements. This key growth strategy leverages the combination of the Company's expertise in proprietary surface technologies, along with enhanced device design, development, and manufacturing capabilities. The Company mission remains to improve the detection and treatment of disease. Surmodics is headquartered in Eden Prairie, Minnesota. For more information, visit www.surmodics.com. The content of Surmodics' website is not part of this press release or part of any filings that the Company makes with the Securities and Exchange Commission ("SEC").

Safe Harbor for Forward-looking Statements

This press release, and disclosures related to it, contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Statements that are not historical or current facts, including statements regarding our future prospects; statements regarding position Surmodics to achieve strong, sustainable long-term growth and generate enhanced future value for our shareholders; our revenue, expense and loss expectations for fiscal 2023 and beyond, including our fiscal 2023 financial guidance and related assumptions; our fiscal 2023 strategic objectives; the potential for receiving FDA approval of the PMA for our *SurVeil* DCB and the potential timing of that approval; the potential receipt of a PMA milestone payment from Abbott and the amount of revenue that would be recognized in fiscal 2023 on such a milestone payment; expectations regarding Abbott's commercialization plans, and the U.S. commercialization prospect, for the *SurVeil* DCB; expectation regarding the conduct, and anticipated benefits of, limited evaluations for the *Pounce* venous thrombectomy platform, as well as plans to complete process and manufacturing validation efforts to support broader commercialization efforts for the product; expectations regarding our Medical Device coating offerings and our IVD business continuing to generate meaningful operating income and support our growth initiatives in fiscal 2023; the ability of our credit facility with MidCap Financial to ensure we have the financial flexibility to support our long-term growth strategy, are forward-looking statements. Forward-looking statements involve inherent risks and uncertainties, and important factors could cause actual results to differ materially from those anticipated, including, without limitation: (1) our ability to successfully develop and commercialize our *SurVeil* DCB (including realization of the full potential benefits of our agreement with Abbott), Avess™ DCB, *Sundance* DCB, and other proprietary products; (2) whether and when the FDA grants PMA to the *SurVeil* DCB; (3) our reliance on third parties (including our customers and licensees) and their failure to successfully develop, obtain regulatory approval for, market, and sell products incorporating our technologies; (4) possible adverse market conditions and possible adverse impacts on our cash flows; (5) our ability to successfully and profitably commercialize the *Pounce* arterial thrombectomy system; (6) current and future supply chain constraints; (7) whether our increased operating expenses are effective in generating profitable revenues; and (8) the factors identified under "Risk Factors" in Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended September 30, 2021 and subsequent SEC filings. These reports are available in the Investors section of our website at https://surmodics.gcs-web.com and at the SEC website at www.sec.gov. Forward-looking statements speak only as of the date they are made, and we undertake no obligation to update them in light of new information or future events.

Use of Non-GAAP Financial Information

In addition to reporting financial results in accordance with U.S. generally accepted accounting principles, or GAAP, Surmodics is reporting non-GAAP financial results including EBITDA and Adjusted EBITDA, non-GAAP operating (loss) income, non-GAAP operating (loss) income percentage, non-GAAP (loss) income before income taxes, non-GAAP net (loss) income, and non-GAAP diluted (loss) earnings per diluted share. We believe that these non-GAAP measures, when read in conjunction with the Company's GAAP financial statements, provide meaningful insight into our operating performance excluding certain event-specific matters, and provide an alternative perspective of our results of operations. We use non-GAAP measures, including those set forth in this release, to assess our operating performance and to determine payouts under our executive compensation programs. We also are providing guidance on a range of non-GAAP diluted loss per diluted share for fiscal 2023. We believe that presentation of certain non-GAAP measures allows investors to review our results of operations from the same perspective as management and our board of directors and facilitates comparisons of our current results of operations. The method we use to produce non-GAAP results is not in accordance with GAAP and may differ from the methods used by other companies. Non-GAAP results should not be regarded as a substitute for corresponding GAAP measures but instead should be utilized as a supplemental measure of operating performance in evaluating our business. Non-GAAP measures do have limitations in that they do not reflect certain items that may have a material impact on our reported financial results. As such, these non-GAAP measures should be viewed in conjunction with both our financial statements prepared in accordance with GAAP and the reconciliation of the supplemental non-GAAP financial measures to the comparable GAAP results provided for the specific periods presented, which are attached to this release.

Surmodics, Inc. and Subsidiaries
Condensed Consolidated Statements of Operations
(in thousands, except per share data)
(Unaudited)

	Three Months Ended September 30,		Fiscal Year Ended September 30,	
	2022	2021	2022	2021
Revenue:				
Product sales	$ 14,394	$ 12,509	$ 54,621	$ 46,478
Royalties and license fees	9,510	8,874	36,248	47,056
Research, development and other	2,084	2,588	9,082	11,602
Total revenue	25,988	23,971	99,951	105,136
Operating costs and expenses:				
Product costs	5,597	4,159	20,342	17,177
Research and development	12,259	10,731	50,609	46,734
Selling, general and administrative	13,779	7,865	46,947	30,680
Acquired intangible asset amortization	966	1,117	4,150	2,793
Acquisition transaction, integration and other costs	—	588	—	1,049
Total operating costs and expenses	32,601	24,460	122,048	98,433
Operating (loss) income	(6,613)	(489)	(22,097)	6,703
Other expense, net	(179)	(73)	(396)	(357)
(Loss) income before income taxes	(6,792)	(562)	(22,493)	6,346
Income tax (expense) benefit	(7,936)	273	(4,781)	(2,109)
Net (loss) income	$ (14,728)	$ (289)	$ (27,274)	$ 4,237
Basic (loss) income per share	$ (1.06)	$ (0.02)	$ (1.96)	$ 0.31
Diluted (loss) income per share	$ (1.06)	$ (0.02)	$ (1.96)	$ 0.30
Weighted average number of shares outstanding:				
Basic	13,944	13,851	13,916	13,765
Diluted	13,944	13,851	13,916	13,989

Surmodics, Inc. and Subsidiaries
Condensed Consolidated Balance Sheets
(in thousands)
(Unaudited)

	September 30,	
	2022	**2021**
Assets		
Current Assets:		
Cash and cash equivalents	$ 18,998	$ 31,153
Available-for-sale securities	—	7,717
Accounts receivable, net	10,452	9,169
Contract assets — royalties and license fees	7,116	7,091
Inventories, net	11,819	6,760
Prepaids and other	9,202	8,365
Total Current Assets	57,587	70,255
Property and equipment, net	27,148	30,090
Available-for-sale securities	—	2,002
Deferred income taxes	—	5,867
Intangible assets, net	28,145	37,054
Goodwill	40,710	45,606
Other assets	4,769	3,718
Total Assets	$ 158,359	$ 194,592
Liabilities and Stockholders' Equity		
Current Liabilities:		
Short-term borrowings	10,000	10,000
Deferred revenue	4,160	4,647
Other current liabilities	17,919	15,168
Total Current Liabilities	32,079	29,815
Deferred revenue	5,088	10,301
Other long-term liabilities	12,800	14,391
Total Liabilities	49,967	54,507
Total Stockholders' Equity	108,392	140,085
Total Liabilities and Stockholders' Equity	$ 158,359	$ 194,592

Surmodics, Inc. and Subsidiaries
Condensed Consolidated Statements of Cash Flows
(in thousands)
(Unaudited)

	Fiscal Year Ended September 30,	
	2022	2021
Operating Activities:		
Net (loss) income	$ (27,274)	$ 4,237
Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities:		
Depreciation and amortization	9,142	8,017
Stock-based compensation	7,057	5,863
Deferred taxes	5,268	1,651
Other	860	478
Change in operating assets and liabilities:		
Accounts receivable and contract assets	(1,522)	(2,480)
Inventories	(5,060)	(818)
Prepaids and other	(665)	(2,391)
Accounts payable	1,608	264
Accrued liabilities	132	1,406
Income taxes	(1,069)	210
Deferred revenue	(5,700)	(1,048)
Net cash (used in) provided by operating activities	(17,223)	15,389
Investing Activities:		
Purchases of property and equipment	(3,370)	(5,279)
Payment for acquisition of intangible assets	—	(1,000)
Purchases of available-for-sale securities	—	(22,723)
Sales and maturities of available-for-sale securities	9,600	43,317
Purchase of business, net of acquired cash	—	(39,553)
Net cash provided by (used in) investing activities	6,230	(25,238)
Financing Activities:		
Proceeds from short-term borrowings	—	10,000
Issuance of common stock	1,246	3,128
Payments for taxes related to net share settlement of equity awards	(1,121)	(2,751)
Payments for acquisition of in-process research and development	(500)	(150)
Net cash (used in) provided by financing activities	(375)	10,227
Effect of exchange rate changes on cash	(787)	(10)
Net change in cash and cash equivalents	(12,155)	368
Cash and Cash Equivalents:		
Beginning of year	31,153	30,785
End of year	$ 18,998	$ 31,153

Surmodics, Inc. and Subsidiaries
Supplemental Segment Information
(in thousands)
(Unaudited)

	Three Months Ended September 30,		Fiscal Year Ended September 30,	
	2022	2021	2022	2021
Medical Device Revenue				
Product sales	$ 7,960	$ 6,313	$ 27,930	$ 21,777
Royalties	7,252	7,646	30,267	30,781
License fees	2,258	1,228	5,981	16,275
Research, development and other	2,030	2,208	8,211	9,420
Medical Device revenue	19,500	17,395	72,389	78,253
In Vitro Diagnostics Revenue				
Product sales	6,434	6,196	26,691	24,701
Research, development and other	54	380	871	2,182
In Vitro Diagnostics revenue	6,488	6,576	27,562	26,883
Total Revenue	$ 25,988	$ 23,971	$ 99,951	$ 105,136

	Three Months Ended September 30,		Fiscal Year Ended September 30,	
	2022	2021	2022	2021
Operating (Loss) Income:				
Medical Device	$ (6,211)	$ (797)	$ (22,923)	$ 4,683
In Vitro Diagnostics	2,811	3,363	13,073	13,770
Total segment operating (loss) income	(3,400)	2,566	(9,850)	18,453
Corporate	(3,213)	(3,055)	(12,247)	(11,750)
Total (Loss) Income from Operations	$ (6,613)	$ (489)	$ (22,097)	$ 6,703

Surmodics, Inc. and Subsidiaries
Reconciliation of GAAP Measures to Non-GAAP Amounts
Schedule of EBITDA and Adjusted EBITDA
(in thousands)
(Unaudited)

	Three Months Ended September 30,		Fiscal Year Ended September 30,	
	2022	2021	2022	2021
Net (Loss) Income	**$ (14,728)**	**$ (289)**	**$ (27,274)**	**$ 4,237**
Income tax expense (benefit)	7,936	(273)	4,781	2,109
Depreciation and amortization	2,240	2,407	9,142	8,017
Investment income, net	(26)	(28)	(99)	(123)
Interest expense	188	132	598	310
EBITDA	**(4,390)**	**1,949**	**(12,852)**	**14,550**
Adjustments:				
Stock-based compensation expense	1,859	1,545	7,057	5,863
Acquisition transaction, integration and other costs (1)	—	588	—	1,049
CARES Act Employee Retention Credit (2)	—	(3,577)	—	(3,577)
Adjusted EBITDA	**$ (2,531)**	**$ 505**	**$ (5,795)**	**$ 17,885**

Surmodics, Inc. and Subsidiaries
Guidance Reconciliation: Estimated Non-GAAP Diluted EPS
For the Fiscal Year Ending September 30, 2023
(Unaudited)

	Fiscal 2023 Full-Year Estimate	
	Low	High
GAAP Diluted EPS	$ (2.80)	$ (2.40)
Amortization of acquired intangibles per diluted share (3)	0.26	0.26
Non-GAAP Diluted EPS	$ (2.54)	$ (2.14)
Diluted weighted average shares outstanding	14,030	

Surmodics, Inc. and Subsidiaries
Net (Loss) Income and Diluted EPS GAAP to Non-GAAP Reconciliation
(in thousands, except per share data)
(Unaudited)

	For the Three Months Ended September 30, 2022					
	Revenue	Operating Loss		Loss Before Income Taxes	Net Loss (5)	Diluted EPS
GAAP	$ 25,988	$ (6,613)	(25.4)%	$ (6,792)	$ (14,728)	$ (1.06)
Adjustments:						
Amortization of acquired intangible assets (3)	—	966	3.7%	966	906	0.07
Tax expense from full valuation allowance against U.S. deferred tax assets (4)	—	—	—	—	10,151	0.73
Non-GAAP	$ 25,988	$ (5,647)	(21.7)%	$ (5,826)	$ (3,671)	$ (0.26)
Diluted weighted average shares outstanding (6)						13,944

	For the Three Months Ended September 30, 2021					
	Revenue	Operating Loss		Loss Before Income Taxes	Net Loss (5)	Diluted EPS
GAAP	$ 23,971	$ (489)	(2.0)%	$ (562)	$ (289)	$ (0.02)
Adjustments:						
Amortization of acquired intangible assets (3)	—	1,117	4.7%	1,117	1,014	0.07
Acquisition transaction, integration and other costs (1)	—	588	2.4%	588	554	0.04
CARES Act Employee Retention Credit (2)	—	(3,577)	(14.9)%	(3,577)	(2,617)	(0.19)
Non-GAAP	$ 23,971	$ (2,361)	(9.8)%	$ (2,434)	$ (1,338)	$ (0.10)
Diluted weighted average shares outstanding (6)						13,851

Surmodics, Inc. and Subsidiaries
Net (Loss) Income and Diluted EPS GAAP to Non-GAAP Reconciliation (Continued)
(in thousands, except per share data)
(Unaudited)

	Fiscal Year Ended September 30, 2022					
	Revenue	Operating Loss		Loss Before Income Taxes	Net Loss (5)	Diluted EPS
GAAP	$ 99,951	$(22,097)	(22.1)%	$ (22,493)	$ (27,274)	$ (1.96)
Adjustments:						
Amortization of acquired intangible assets (3)	—	4,150	4.1%	4,150	3,888	0.28
Tax expense from full valuation allowance against U.S. deferred tax assets (4)	—	—	—	—	10,151	0.73
Non-GAAP	$ 99,951	$(17,947)	(18.0)%	$ (18,343)	$ (13,235)	$ (0.95)
Diluted weighted average shares outstanding (6)						13,916

	Fiscal Year Ended September 30, 2021					
	Revenue	Operating Income		Income Before Income Taxes	Net Income (5)	Diluted EPS
GAAP	$ 105,136	$ 6,703	6.4%	$ 6,346	$ 4,237	$ 0.30
Adjustments:						
Amortization of acquired intangible assets (3)	—	2,793	2.7%	2,793	2,600	0.19
Acquisition transaction, integration and other costs (1)	—	1,049	1.0%	1,049	1,015	0.07
CARES Act Employee Retention Credit (2)	—	(3,577)	(3.5)%	(3,577)	(2,617)	(0.19)
Non-GAAP	$ 105,136	$ 6,968	6.6%	$ 6,611	$ 5,235	$ 0.37
Diluted weighted average shares outstanding (6)						13,989

(1) Represents expenses specifically associated with the fiscal 2021 business acquisition of Vetex Medical Limited and associated tax impact. A significant proportion of the acquisition expenses were not tax deductible.

(2) Represents the benefit recorded as a result of the employee retention credit that the Company filed for under the provisions of the Coronavirus Aid, Relief and Economic Security Act (the “CARES Act”) enacted in March 2020. The estimated tax impact reflected the combined impact of the statutory tax rate of 21% and a reduction in research and development tax credits.

(3) Represents amortization of business acquisition-related intangible assets and associated tax impact. A significant portion of the business acquisition-related amortization is not tax deductible.

(4) Represents the non-cash charge to income tax expense that resulted from the establishment of a full valuation allowance against U.S. net deferred tax assets in the fourth quarter of fiscal 2022. A valuation allowance is required to be recognized against deferred tax assets if, based on the available evidence, it is more likely than not (defined as a likelihood of more than 50%) that all or a portion of such assets will not be realized. The relevant guidance weighs available evidence such as historical cumulative taxable losses more heavily than future profitability. The valuation allowance has no impact on the availability of U.S. net deferred tax assets to offset future tax liabilities.

(5) Net (loss) income includes the effect of the above adjustments on the income tax (expense) benefit, taking into account deferred taxes and non-deductible items. Income tax impacts were estimated using the applicable statutory rate (21% in the U.S. and 12.5% in Ireland).

(6) Diluted weighted average shares outstanding used in the calculation of EPS was the same for GAAP EPS and Non-GAAP EPS. Potentially dilutive common shares resulting from dilutive common stock options and non-vested stock relating to restricted stock awards and restricted stock units have been excluded from the calculation of EPS as their effect was antidilutive for the three months ended September 30, 2022 and 2021 and for the fiscal year ended September 30, 2022 as a result of the net loss for these periods.

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