



Surmodics Reports Third Quarter of Fiscal Year 2023 Financial Results; Updates Fiscal Year 2023 Financial Guidance

August 2, 2023 07:00 a.m. ET

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 third quarter ended June 30, 2023, and updated its financial guidance for its fiscal year ending September 30, 2023.

Third Quarter Fiscal 2023 Financial Summary

- Total Revenue of \$52.5 million, an increase of 111% year-over-year
- Recognized \$24.6 million in license fee revenue upon receipt of a \$27.0 million milestone payment associated with obtaining FDA premarket approval of the SurVeil™ DCB under the company's Development and Distribution Agreement with Abbott
- GAAP Diluted EPS of \$0.52, compared to \$(0.41) in the prior-year period
- Non-GAAP Diluted EPS of \$0.52, compared to \$(0.34) in the prior-year period

Third Quarter and Recent Business Highlights

- On April 19, 2023, Surmodics announced the first successful patient use of the Sublime™ radial access microcatheter, the industry's first suite of torqueable peripheral microcatheters, designed for navigating tortuosity and crossing complex lesions and available for both transradial and transfemoral procedures.
- On April 20, 2023, Surmodics announced enrollment of the first patient in PROWL, the Pounce™ Thrombectomy System Retrospective Registry, to collect real-world efficacy and safety outcomes data for endovascular interventions using the Pounce system for the non-surgical removal of emboli and thrombi in the peripheral arterial vasculature.
- On June 14, 2023, Surmodics announced the receipt of U.S. Food and Drug Administration (FDA) 510(k) clearance for its Pounce LP (Low Profile) Thrombectomy System, which will allow for efficient clot removal in below-the-knee peripheral arteries (2 mm to 4 mm in diameter), expanding the addressable market for the Pounce platform.
- On June 20, 2023, Surmodics announced the receipt of FDA premarket approval for its SurVeil™ drug-coated balloon (DCB). The SurVeil DCB may now be marketed and sold in the U.S. by the company's exclusive distribution partner, Abbott Vascular, Inc. (Abbott). The SurVeil DCB is a next-generation device that utilizes best-in-class technology in the treatment of peripheral artery disease, includes a proprietary drug-excipient formulation for a durable balloon coating, and is manufactured using an innovative process to improve coating uniformity.

"Our third quarter was marked by a combination of strong financial performance – including total revenue growth of 111% year-over-year – and notable progress with respect to our key strategic objectives for fiscal 2023," said Gary Maharaj, President and CEO of Surmodics, Inc. "Most importantly, we obtained FDA premarket approval for the SurVeil DCB, our next-generation drug-coated balloon, secured a related \$27 million milestone payment to strengthen our balance sheet, and made progress in preparing to support its commercial launch. In addition, we expanded the commercial adoption and utilization of our Pounce arterial thrombectomy and Sublime radial access platforms, while advancing our pipeline of additional vascular intervention technologies: secured FDA 510(k) clearance for our Pounce LP Thrombectomy System, initiated the limited market evaluation of our Sublime radial access microcatheter, and continued the limited market evaluation of our Pounce Venous Thrombectomy System."

Mr. Maharaj continued, “Our impressive total revenue performance in the quarter was driven by 163% growth year-over-year in our Medical Device segment, which benefited from the aforementioned milestone payment, along with strong underlying performance – including product sales growth of 38% year-over-year fueled primarily by sales of our *Pounce* and *Sublime* products. Lastly, we made notable year-over-year improvements in our profitability profile from an operating income and adjusted EBITDA standpoint, while continuing to control our expenses and manage our cash use. Our increased guidance reflects our impressive financial and operational performance in the third quarter and latest expectations for the balance of the year. Looking ahead, we remain focused on bringing fiscal 2023 to a strong conclusion by continuing to execute against our stated strategic objectives, laying the groundwork for further growth and value creation in the years to come.”

Third Quarter Fiscal 2023 Financial Results

	Three Months Ended		Increase (Decrease)	
	June 30,		\$	%
	2023	2022		
Revenue:				
Medical Device	\$ 46,014	\$ 17,528	\$ 28,486	163%
In Vitro Diagnostics	6,469	7,326	(857)	(12)%
Total revenue	<u>\$ 52,483</u>	<u>\$ 24,854</u>	<u>\$ 27,629</u>	111%

Total revenue increased \$27.6 million, or 111%, to \$52.5 million, compared to \$24.9 million in the third quarter of fiscal 2022.

Medical Device revenue increased \$28.5 million, or 163%, to \$46.0 million, compared to \$17.5 million in the third quarter of fiscal 2022. Medical Device revenue in the third quarter of fiscal 2023 included a total of \$25.9 million in license fee revenue from the company’s Development and Distribution Agreement with Abbott for the *SurVeil* DCB – of which \$24.6 million was revenue recognized on the \$27.0 million milestone payment received in the period associated with obtaining FDA approval of the *SurVeil* DCB – compared to \$1.0 million of total license fee revenue in the prior-year period. Medical Device revenue growth was broad-based, including significant contributions from *Pounce* thrombectomy and *Sublime* radial access device platforms, as well as increased sales of performance coating reagents. In Vitro Diagnostics (“IVD”) revenue decreased \$0.9 million, or 12%, to \$6.5 million, compared to \$7.3 million in the third quarter of fiscal 2022, driven primarily by active management of inventory levels by certain customers.

Product gross profit (defined as product sales less product costs) was \$8.7 million and was unchanged compared to the third quarter of fiscal 2022. Product gross margin (defined as product gross profit as a percentage of product sales) was 55.8%, compared to 63.1% in the third quarter of fiscal 2022. The decline in product gross margin was primarily driven by the adverse mix impact from increased device product sales, which have lower product gross margins due to low production volumes during the scale-up phase following initial commercialization.

Operating costs and expenses, excluding product costs, decreased \$2.7 million, or 10%, to \$24.2 million, compared to \$26.9 million in the third quarter of fiscal 2022. The decrease was driven primarily by lower research and development expenses as the result of the spending reduction plan implemented in the second quarter of fiscal 2023. In addition, operating costs and expenses in the third quarter of fiscal 2023 included a \$0.8 million gain from the fair value adjustment of acquisition-related contingent consideration.

GAAP net income was \$7.3 million, or \$0.52 per diluted share, compared to GAAP net loss of \$(5.7) million, or \$(0.41) per diluted share in the third quarter of fiscal 2022. Non-GAAP net income was \$7.3 million, or \$0.52 per diluted share, compared to Non-GAAP net loss of \$(4.7) million, or \$(0.34) per diluted share in the third quarter of fiscal 2022.

Adjusted EBITDA was \$24.6 million, compared to Adjusted EBITDA loss of \$(3.1) million in the third quarter of fiscal 2022.

Balance Sheet Summary

As of June 30, 2023, Surmodics reported \$44.6 million in cash and cash equivalents, \$5.0 million in outstanding borrowings on its \$25.0 million revolving credit facility, and \$25.0 million in outstanding borrowings on its term loan facility. Additional draws on the term loan facility may be made in \$10.0 million minimum increments, up to a total of \$75.0 million through December 31, 2024. A third tranche of up to \$25.0 million on the term loan facility may be available through December 31, 2024 at the lender's option. Surmodics reported \$25.9 million of cash provided by operating activities and \$0.5 million in capital expenditures in the third quarter of fiscal 2023.

Fiscal Year 2023 Financial Guidance

Surmodics now expects fiscal year 2023 total revenue to range from \$130 million to \$132 million, representing an increase of 30% to 32% compared to the prior year. The company's prior guidance called for fiscal year 2023 total revenue of \$103 million to \$106 million, representing an increase of 3% to 6% compared to the prior year.

The company now expects fiscal 2023 GAAP diluted loss per share to range from \$(0.55) to \$(0.40). The company's prior guidance called for fiscal 2023 GAAP diluted loss per share of \$(2.30) to \$(2.00).

Non-GAAP diluted loss per share in fiscal 2023 is expected to range from \$(0.29) to \$(0.14). The company's prior guidance called for fiscal 2023 Non-GAAP diluted loss per share of \$(1.98) to \$(1.68).

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 third quarter of fiscal 2023 financial results and accomplishments, and to host a question-and-answer session. To access the webcast, please go to "Events & Presentations" under the "Investors" section of the company's website at <https://surmodics.gcs-web.com/events-and-presentations>, and click on the webcast icon under "Upcoming Events." To listen to the live teleconference, dial 877-407-8293 (international callers may dial 201-689-8349) and provide access ID: 13739898.

An audio replay of the conference call will be available beginning at 11:00 a.m. CT today, until 11:00 a.m. CT on Wednesday, August 16, and can be accessed by dialing 877-660-6853 (international callers may dial 201-612-7415) and entering access ID: 13739898. In addition, the webcast and transcript will be archived on the company's website following the call.

About Surmodics, Inc.

Surmodics, Inc. is a leading provider of performance coating technologies for intravascular medical devices and chemical and biological components for in vitro diagnostic immunoassay tests and microarrays. Surmodics also develops and commercializes highly differentiated vascular intervention 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 modification and drug-delivery coating technologies, along with its device design, development and manufacturing capabilities. The company's mission is to improve the detection and treatment of disease. Surmodics is headquartered in Eden Prairie, Minnesota.

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: expectations of the timing of an initial stocking order for *SurVeil* DCB products and of Abbott's commercialization of the product; being well positioned to support Abbott's commercial launch of the *SurVeil* DCB; our belief that the *SurVeil* DCB will complement and enhance Abbott's existing product portfolio; our expectation about working with the FDA to update the *SurVeil* DCB product labeling to reflect currently available paclitaxel data; our future prospects; the expected customer base for our *Sublime* radial and *Pounce* arterial thrombectomy platforms by year end and their expected year-over-year growth rate for full fiscal 2023; our expectations regarding expanding the addressable market for our *Pounce* arterial thrombectomy system with the addition of new products and clinical indications; expectations regarding the conduct and timing of limited market introductions of certain products and of commercialization of products; our expectations related to the PROWL U.S. registry study and expectation of sharing interim data therefrom; our fiscal 2023 financial guidance and related assumptions,

including assumptions in our revenue guidance provided for modeling purposes, expected revenue growth rates, expected license fee revenue related to the *SurVeil* DCB, expected product gross margins for the remainder of fiscal 2023 and factors that we expect to impact product gross margins, expected operating expenses, expected interest expense, and expected tax (expense) benefit; expected cash use for the fourth quarter of fiscal 2023; our expected cash balance at the end of fiscal 2023; our fiscal 2023 strategic objectives; and further and future growth and value creation in the years to come, 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), *A vess*[™] DCB, *Sundance*[™] DCB, and other proprietary products; (2) 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; (3) possible adverse market conditions and possible adverse impacts on our cash flows; (4) our ability to successfully and profitably commercialize our vascular intervention products; (5) supply chain constraints; (6) whether our operating expenses are effective in generating profitable revenues; (7) disruptions to our business from our plan to reduce our use of cash announced in the second quarter of fiscal 2023, the failure of such plan to achieve its objectives, or cost and expenses associated with such plan; 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, 2022 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 income (loss), non-GAAP operating income (loss) percentage, non-GAAP income (loss) before income taxes, non-GAAP net income (loss), and non-GAAP income (loss) 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 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 June 30,		Nine Months Ended June 30,	
	2023	2022	2023	2022
Revenue:				
Product sales	\$ 15,667	\$ 13,919	\$ 45,251	\$ 40,227
Royalties and license fees	34,153	8,795	52,347	26,738
Research, development and other	2,663	2,140	7,016	6,998
Total revenue	52,483	24,854	104,614	73,963
Operating costs and expenses:				
Product costs	6,921	5,141	17,926	14,745
Research and development	11,232	12,975	36,899	38,350
Selling, general and administrative	12,874	12,854	39,077	33,159
Acquired intangible asset amortization	879	1,024	2,659	3,184
Restructuring expense	—	—	1,282	—
Contingent consideration (gain) expense	(835)	3	(829)	9
Total operating costs and expenses	31,071	31,997	97,014	89,447
Operating income (loss)	21,412	(7,143)	7,600	(15,484)
Other expense, net	(763)	(38)	(2,324)	(217)
Income (loss) before income taxes	20,649	(7,181)	5,276	(15,701)
Income tax (expense) benefit	(13,303)	1,530	(13,506)	3,155
Net income (loss)	\$ 7,346	\$ (5,651)	\$ (8,230)	\$ (12,546)
Basic net income (loss) per share	\$ 0.52	\$ (0.41)	\$ (0.59)	\$ (0.90)
Diluted net income (loss) per share	\$ 0.52	\$ (0.41)	\$ (0.59)	\$ (0.90)
Weighted average number of shares outstanding:				
Basic	14,050	13,929	14,020	13,907
Diluted	14,072	13,929	14,020	13,907

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

	June 30, 2023	September 30, 2022
	(Unaudited)	(See Note)
Assets		
Current Assets:		
Cash and cash equivalents	\$ 44,579	\$ 18,998
Accounts receivable, net	11,752	10,452
Contract assets — royalties and license fees	7,678	7,116
Inventories, net	14,610	11,819
Prepays and other	7,231	9,202
Total Current Assets	85,850	57,587
Property and equipment, net	26,571	27,148
Intangible assets, net	27,798	28,145
Goodwill	43,844	40,710
Other assets	4,838	4,769
Total Assets	<u>\$ 188,901</u>	<u>\$ 158,359</u>
Liabilities and Stockholders' Equity		
Current Liabilities:		
Short-term borrowings	\$ —	\$ 10,000
Deferred revenue	4,328	4,160
Income tax payable	11,953	—
Other current liabilities	15,767	17,919
Total Current Liabilities	32,048	32,079
Long-term debt, net	29,353	—
Deferred revenue	3,492	5,088
Other long-term liabilities	11,596	12,800
Total Liabilities	76,489	49,967
Total Stockholders' Equity	112,412	108,392
Total Liabilities and Stockholders' Equity	<u>\$ 188,901</u>	<u>\$ 158,359</u>

Note: Derived from audited financial statements as of the date indicated.

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

	Nine Months Ended June 30,	
	2023	2022
Operating Activities:		
Net loss	\$ (8,230)	\$ (12,546)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization	6,365	6,902
Stock-based compensation	5,662	5,198
Deferred taxes	(187)	(2,996)
Other	217	636
Change in operating assets and liabilities:		
Accounts receivable and contract assets	(1,825)	(847)
Inventories	(2,790)	(4,167)
Prepays and other	(961)	(1,998)
Accounts payable	(669)	349
Accrued liabilities	(2,474)	(1,039)
Income taxes	15,583	(676)
Deferred revenue	(1,427)	(3,539)
Net cash provided by (used in) operating activities	<u>9,264</u>	<u>(14,723)</u>
Investing Activities:		
Purchases of property and equipment	(2,170)	(2,798)
Maturities of available-for-sale securities	—	7,600
Net cash (used in) provided by investing activities	<u>(2,170)</u>	<u>4,802</u>
Financing Activities:		
Payments of short-term borrowings	(10,000)	—
Proceeds from issuance of long-term debt	29,664	—
Payments of debt issuance costs	(614)	—
Issuance of common stock	803	763
Payments for taxes related to net share settlement of equity awards	(888)	(936)
Payments for acquisition of in-process research and development	(978)	(500)
Net cash provided by (used in) financing activities	<u>17,987</u>	<u>(673)</u>
Effect of exchange rate changes on cash	500	(485)
Net change in cash and cash equivalents	<u>25,581</u>	<u>(11,079)</u>
Cash and Cash Equivalents:		
Beginning of period	18,998	31,153
End of period	<u>\$ 44,579</u>	<u>\$ 20,074</u>

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

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2023	2022	2023	2022
Medical Device Revenue				
Product sales	\$ 9,299	\$ 6,741	\$ 25,593	\$ 19,970
Royalties	8,220	7,771	23,702	23,015
License fees	25,933	1,024	28,645	3,723
Research, development and other	2,562	1,992	6,799	6,181
Medical Device revenue	46,014	17,528	84,739	52,889
In Vitro Diagnostics Revenue				
Product sales	6,368	7,178	19,658	20,257
Research, development and other	101	148	217	817
In Vitro Diagnostics revenue	6,469	7,326	19,875	21,074
Total Revenue	\$ 52,483	\$ 24,854	\$ 104,614	\$ 73,963

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2023	2022	2023	2022
Operating income (loss):				
Medical Device	\$ 21,777	\$ (7,308)	\$ 7,483	\$ (16,712)
In Vitro Diagnostics	2,866	3,387	9,450	10,262
Total segment operating income (loss)	24,643	(3,921)	16,933	(6,450)
Corporate	(3,231)	(3,222)	(9,333)	(9,034)
Total operating income (loss)	\$ 21,412	\$ (7,143)	\$ 7,600	\$ (15,484)

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

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2023	2022	2023	2022
Net income (loss)	\$ 7,346	\$ (5,651)	\$ (8,230)	\$ (12,546)
Income tax expense (benefit)	13,303	(1,530)	13,506	(3,155)
Depreciation and amortization	2,151	2,206	6,365	6,902
Interest expense, net	884	145	2,594	410
Investment income, net	(182)	(22)	(531)	(73)
EBITDA	23,502	(4,852)	13,704	(8,462)
Adjustments:				
Stock-based compensation expense	1,915	1,799	5,662	5,198
Restructuring expense (1)	—	—	1,282	—
Contingent consideration fair value adjustment (2)	(829)	—	(829)	—
Adjusted EBITDA	\$ 24,588	\$ (3,053)	\$ 19,819	\$ (3,264)

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	\$ (0.55)	\$ (0.40)
Per diluted share:		
Amortization of acquired intangible assets (3)	0.23	0.23
Restructuring expense (1)	0.09	0.09
Contingent consideration fair value adjustment (2)	(0.06)	(0.06)
Non-GAAP Diluted EPS	\$ (0.29)	\$ (0.14)
Diluted weighted average shares outstanding	14,030	

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

Three Months Ended June 30, 2023						
	Revenue	Operating Income		Income Before Income Taxes	Net Income (4)	Diluted EPS
GAAP	\$ 52,483	\$ 21,412	40.8%	\$ 20,649	\$ 7,346	\$ 0.52
Adjustments:						
Amortization of acquired intangible assets (3)	—	879	1.7%	879	813	0.06
Contingent consideration fair value adjustment (2)	—	(829)	(1.6)%	(829)	(829)	(0.06)
Non-GAAP	\$ 52,483	\$ 21,462	40.9%	\$ 20,699	\$ 7,330	\$ 0.52
Diluted weighted average shares outstanding (5)						14,072

Three Months Ended June 30, 2022						
	Revenue	Operating Loss		Loss Before Income Taxes	Net Loss (4)	Diluted EPS
GAAP	\$ 24,854	\$ (7,143)	(28.7)%	\$ (7,181)	\$ (5,651)	\$ (0.41)
Adjustments:						
Amortization of acquired intangible assets (3)	—	1,024	4.1%	1,024	930	0.07
Non-GAAP	\$ 24,854	\$ (6,119)	(24.6)%	\$ (6,157)	\$ (4,721)	\$ (0.34)
Diluted weighted average shares outstanding (5)						13,929

Nine Months Ended June 30, 2023						
	Revenue	Operating Income		Income Before Income Taxes	Net Loss (4)	Diluted EPS
GAAP	\$ 104,614	\$ 7,600	7.3%	\$ 5,276	\$ (8,230)	\$ (0.59)
Adjustments:						
Amortization of acquired intangible assets (3)	—	2,659	2.5%	2,659	2,467	0.18
Restructuring expense (1)	—	1,282	1.2%	1,282	1,282	0.09
Contingent consideration fair value adjustment (2)	—	(829)	(0.8)%	(829)	(829)	(0.06)
Non-GAAP	\$ 104,614	\$ 10,712	10.2%	\$ 8,388	\$ (5,310)	\$ (0.38)
Diluted weighted average shares outstanding (5)						14,020

Nine Months Ended June 30, 2022						
	Revenue	Operating Loss		Loss Before Income Taxes	Net Loss (4)	Diluted EPS
GAAP	\$ 73,963	\$(15,484)	(20.9)%	\$ (15,701)	\$ (12,546)	\$ (0.90)
Adjustments:						
Amortization of acquired intangible assets (3)	—	3,184	4.3%	3,184	2,893	0.21
Non-GAAP	\$ 73,963	\$(12,300)	(16.6)%	\$ (12,517)	\$ (9,653)	\$ (0.69)
Diluted weighted average shares outstanding (5)						13,907

- (1) Restructuring expense consists of severance and related costs specifically associated with a workforce restructuring implemented in the second quarter of fiscal 2023.
- (2) Represents accounting adjustments to state acquisition-related contingent consideration liabilities at their estimated fair value as of the period end date, including adjustments to the liabilities' fair values related to changes in the timing and/or probability of achieving milestones and accretion expense for the passage of time.
- (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) Net income (loss) includes the effect of the above adjustments on income tax (expense) benefit, taking into account deferred taxes net of valuation allowances, as well as non-deductible items. Income tax impacts were estimated using the applicable statutory rate (21% in the U.S. and 12.5% in Ireland).
- (5) Diluted weighted average shares outstanding used in the calculation of EPS was the same for GAAP EPS and Non-GAAP EPS.

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