

Surmodics Reports Second Quarter Fiscal 2019 Results

May 1, 2019

Updates Fiscal 2019 Guidance

EDEN PRAIRIE, Minn.--(BUSINESS WIRE)--May 1, 2019-- Surmodics, Inc. (Nasdaq: SRDX), a leading provider of medical device and in vitro diagnostic technologies to the healthcare industry, today announced results for its fiscal 2019 second quarter ended March 31, 2019, and updated its financial outlook for fiscal 2019.

Summary of Second Quarter and Recent Highlights

- Revenue of \$22.7 million, an increase of 19% year-over-year
- GAAP EPS of \$0.09, non-GAAP EPS of \$0.07
- TRANSCEND clinical trial enrollment 75% complete
- FDA Clearance of Sublime™ guide sheath for radial access

"Our second quarter performance marked our fourth consecutive quarter of double-digit year-over-year revenue growth as both our Medical Device and IVD businesses continued to generate meaningful top-line gains," said Gary Maharaj, President and CEO of Surmodics. "Despite the current uncertainty related to paclitaxel-coated devices, we have appropriately adjusted our TRANSCEND trial to respond to the FDA's recommendations and are pleased to have many of our trial sites actively enrolling and randomizing patients. In addition, we continue to make progress on our key strategic initiatives including the recent FDA 510(k) clearance of our *Sublime* guide sheath for radial access to the peripheral arteries."

Second Quarter Fiscal 2019 Financial Results

Total revenue for the second quarter of fiscal 2019 was \$22.7 million, as compared with \$19.1 million in the prior-year period. Medical Device revenue was \$17.3 million in the second quarter of fiscal 2019, as compared with \$14.1 million in the year-ago period, an increase of 23%, and includes \$1.6 million from our SurVeil™ agreement with Abbott, as compared with \$0.5 million in the prior-year quarter. In Vitro Diagnostics revenue was \$5.4 million for the second quarter of fiscal 2019 as compared with \$5.0 million in the same prior-year quarter, an increase of 7%.

Diluted GAAP earnings per share in the second quarter of fiscal 2019 was \$0.09 as compared with \$0.11 in the year-ago period. On a non-GAAP basis, earnings per share were \$0.07 in the second quarter of fiscal 2019, as compared with \$0.07 in the year-ago period.

As of March 31, 2019, cash and investments were \$46.5 million. Surmodics generated \$1.5 million of cash from operating activities in the second quarter of fiscal 2019. Capital expenditures totaled \$1.0 million for the second quarter of fiscal 2019.

Fiscal 2019 Guidance Revised

Although we continue to enroll patients in our TRANSCEND trial, the current uncertainty related to utilization of paclitaxel-coated devices has and is expected to continue to impact our recognition of *SurVeil* revenue and TRANSCEND clinical trial expense. We are updating our full-year revenue and earnings guidance for fiscal 2019 to account for this impact, as well as our strong operating performance in the first half of our fiscal year. We are lowering our fiscal 2019 revenue expectations by \$5.5 million to a range of \$88.5 million to \$91.5 million, from our previous revenue range of \$94 million to \$97 million. We are increasing our fiscal 2019 diluted GAAP EPS to a range of \$0.14 to \$0.24 per share compared with our previous expectations of a diluted loss in the range of (\$0.22) to a loss of (\$0.02) per share. Diluted non-GAAP EPS is now expected to be in the range of \$0.26 to \$0.36 per share compared with previous expectations of \$0.02 to \$0.22 per share.

Conference Call

Surmodics will host a webcast at 4 p.m. CT (5 p.m. ET) today to discuss second quarter results. To access the webcast, go to the investor relations portion of the Company's website at https://surmodics.gcs-web.com and click on the webcast icon. The webcast will be archived on the Company's website for 90 days. A replay of the second quarter conference call will be available by dialing 888-203-1112 and entering conference call ID passcode 7350230. The audio replay will be available beginning at 7 p.m. CT on Wednesday, May 1, 2019, until 7 p.m. CT on Wednesday, May 8, 2019.

About Surmodics, Inc.

Surmodics is the global leader in surface modification technologies for intravascular medical devices and a leading provider of chemical components for in vitro diagnostic (IVD) immunoassay tests and microarrays. Surmodics is pursuing highly differentiated whole-product solutions that are designed to address unmet clinical needs for its medical device customers 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 fillings that the company makes with the SEC.

Safe Harbor for Forward-Looking Statements

This press release contains forward-looking statements. Statements that are not historical or current facts, including statements about beliefs and expectations regarding the Company's performance in the near- and long-term, including our revenue and earnings expectations for fiscal 2019, our *SurVeil DCB* and other proprietary products, and the TRANSCEND clinical trial 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 (1) our ability to successfully develop, timely complete clinical trials for, obtain regulatory approval for and, if approved, commercialize our *SurVeil* DCB (including realization of the full potential benefits of our agreement with Abbott), 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, and (4) 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, 2018, and updated in our subsequent reports filed with the SEC. 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, non-GAAP income before income taxes, non-GAAP net income, and non-GAAP diluted earnings per share, and the non-GAAP effective income tax rate. 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 payout under our executive compensation programs. 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.

Three Months Ended Six Months Ended

Surmodics, Inc. and Subsidiaries

Condensed Consolidated Statements of Operations

(in thousands, except per share data)

(Unaudited)

	March 31,	illis Ended	March 31,					
	2019	2018	2019	2018				
	(Unaudite	d)	(Unaudite	ed)				
Revenue:								
Product sales	\$ 9,887	\$8,686	\$19,638	\$16,774				
Royalties and license fees	9,932	8,428	20,028	15,504				
Research, development and other	2,857	1,944	5,251	3,793				
Total revenue	22,676	19,058	44,917	36,071				
Operating costs and expenses:								
Product costs	3,093	2,913	6,616	5,804				
Research and development	13,555	10,774	25,041	18,605				
Selling, general and administrative	4,876	6,440	10,825	11,628				
Acquired intangible asset amortization	604	636	1,210	1,254				
Contingent consideration gain	(317)	(2,230)	(352)	(1,112)				
Total operating costs and expenses	21,811	18,533	43,340	36,179				
Operating income (loss)	865	525	1,577	(108)				
Other income (loss), net	235	(211)	657	(99)				
Income (loss) before income taxes	1,100	314	2,234	(207)				
Income tax benefit	162	1,220	338	185				
Net income (loss)	\$ 1,262	\$ 1,534	\$2,572	\$ (22)				
Basic income (loss) per share:	\$ 0.09	\$ 0.12	\$0.19	\$(0.00)				
Diluted income (loss) per share:	\$ 0.09	\$ 0.11	\$0.19	\$(0.00)				
Weighted average number of shares outstanding:	40.005	10.105	40.075	40.076				
Basic	13,390	13,102	13,379	13,078				
Diluted	13,785	13,465	13,816	13,078				

Surmodics, Inc. and Subsidiaries

Condensed Consolidated Balance Sheets

(in thousands)

(Unaudited)

Assets Current Assets:	March 31, 2019 (Unaudited	20	eptember 30, 018
Cash and cash equivalents	\$ 22,470	\$	23,318
Restricted cash	_		350
Available-for-sale securities	24,023		41,352
Accounts receivable, net	9,312		8,877
Contract assets - royalties and license fees	7,065		_
Inventories, net	4,345		4,016
Prepaids and other	4,302		3,614
Total Current Assets	71,517		81,527
Property and equipment, net	29,512		30,143
Deferred tax assets	5,301		6,304
Intangible assets, net	16,020		17,683
Goodwill	26,549		27,032
Other assets	2,081		1,446
Total Assets	\$ 150,980	\$	164,135
Liabilities and Stockholders' Equity			
Current Liabilities:			
Contingent consideration, current portion	3,009		11,041
Deferred revenue	6,385		9,646
Other current liabilities	10,950		14,446
Total Current Liabilities	20,344		35,133
Contingent consideration, less current portion	_		3,425
Deferred revenue, less current portion	10,470		11,247
Other long-term liabilities	4,853		5,720
Total Liabilities	35,667		55,525
Total Stockholders' Equity	115,313		108,610
Total Liabilities and Stockholders' Equity	\$150,980	\$	164,135

Surmodics, Inc. and Subsidiaries

Supplemental Segment Information

(in thousands)

(Unaudited)

	Three Months Ended March 31,											
	2019		2018									
Revenue:		% of Total		% of Total	% Change							
Medical Device	\$ 17,301	76.3%	\$14,052	73.7%	23.1%							
In Vitro Diagnostics	5,375	23.7%	5,006	26.3%	7.4%							
Total revenue	\$ 22,676		\$19,058		19.0%							

Six Months Ended March 31,

	2019		2018		
Revenue:		% of Total		% of Total	% Change
Medical Device	\$ 34,559	76.9%	\$ 26,826	74.4%	28.8%
In Vitro Diagnostics	10,358	23.1%	9,245	25.6%	12.0%
Total revenue	\$ 44,917		\$ 36,071		24.5%
	Three Mo	nths Ended	Six Mont	ns Ended	
	March 31	,	March 31	,	
	2019	2018	2019	2018	
Operating income (loss):					
Medical Device	\$ (23)	\$ 232	\$ 334	\$ (157)
In Vitro Diagnostics	2,915	2,423	5,370	4,093	
Total segment operating income	2,892	2,655	5,704	3,936	
Corporate	(2,027)	(2,130)	(4,127)	(4,044)
Total operating income (loss)	\$ 865	\$ 525	\$1,577	\$ (108)

Surmodics, Inc. and Subsidiaries

Reconciliation of GAAP Measures to Non-GAAP Amounts

Schedule of EBITDA, Adjusted EBITDA and Cash Flows from Operations

(in thousands)

(Unaudited)

	Three Mo	nths Ended	Six Months Ended						
	March 31	,	March 31,						
	2019	2018	2019 2018						
Net income (loss)	\$1,262	\$ 1,534	\$2,572 \$(22)					
Income tax benefit	(162)	(1,220)	(338) (185))					
Depreciation and amortization	1,819	1,586	3,575 3,106						
Investment income, net	(265)	(142)	(581) (263)					
Interest expense	37	_	74 —						
EBITDA	2,691	1,758	5,302 2,636						
Adjustments:									
Contingent consideration gain (1)	(317)	(2,230)	(352) (1,112))					
Foreign exchange loss (gain) (2)	_	353	(126) 539						
Gain on strategic investment (4)	_	_	(7) (177))					
Claim settlement (6)	(650)	1,000	(650) 1,000						
Adjusted EBITDA	\$ 1,724	\$ 881	\$4,167 \$2,886						

Net Cash Provided by (Used In) Operating Activities \$1,467 \$26,817 \$(3,938) \$27,431

Estimated Non-GAAP Net Earnings per Common Share Guidance Reconciliation

For the Fiscal Year Ended September 30, 2019

(Unaudited)

	Full Fiscal	l Year Estimate
	Low	High
GAAP results	\$ 0.14	\$ 0.24
Contingent consideration adjustments (1)	0.01	0.01
Foreign exchange gain on contingent consideration (2)	(0.01) (0.01)

Non-GAAP results	\$ 0.26	\$	0.36	
Claim settlement (6)	(0.04)	(0.04)
Amortization of acquired intangibles (3)	0.16		0.16	

Surmodics, Inc., and Subsidiaries

Net Income (Loss) and Diluted EPS GAAP to Non-GAAP Reconciliation

(in thousands, except per share data)

Claim settlement (6)

Non-GAAP

(Unaudited)

	For the T	hree Mon	ths	Ended Marc	ch 3	31, 2019				
				Incom						
				Operating		Before				
	Total	Operatir	ng	Income		Income	Net	Diluted	Effective	е
	Revenue	Income		Percentage	9	Taxes	Income (7)	EPS	tax rate	
GAAP	\$ 22,676	\$ 865		3.8	%	\$1,100	\$ 1,262	\$ 0.09	(14.7	%)
Adjustments:										
Contingent consideration gain (1)	_	(317)	(1.4)	(317)	(317)	(0.02)		
Amortization of acquired intangible assets (3)	_	604		2.7		604	559	0.04		
Gain on strategic investment (4)	_	_		_		_	_	_		

(650)

% \$737

(514

\$ 990

) (0.04)

\$ 0.07

(34.3

%)

For the Three Months Ended March 31, 2018

	Total Revenue	Operating Income	Operating Income Percentage	a	Income Before Income Taxes	Net Income (7)	Diluted EPS	Effective	e
GAAP	\$ 19,058	` '	2.8	%	\$314	\$ 1,534	\$ 0.11	(388.5	%)
Adjustments:									
Contingent consideration gain (1)	_	(2,230	(11.7)	(2,230)	(2,230)	(0.17)		
Foreign exchange loss on contingent consideration (2)	_	_	_		338	338	0.03		
Amortization of acquired intangible assets (3)	_	636	3.3		636	584	0.04		
Claim settlement (6)	_	1,000	5.2		1,000	755	0.06		
Non-GAAP	\$ 19,058	\$ (69	(0.4	%)	\$ 58	\$ 981	\$ 0.07	(1591.4	%)

) (2.9

2.2

(650

\$22,676 \$ 502

Surmodics, Inc., and Subsidiaries

Net Income (Loss) and Diluted EPS GAAP to Non-GAAP Reconciliation - Continued

(in thousands, except per share data)

(Unaudited)

For the Six Months Ended March 31, 2019

						Income						
					Operating		Before					
	Total	Operating		Income		Income	Ν	et		Diluted	Effective	е
	Revenue	Income		Percentage	•	Taxes	Ir	ncome (7	')	EPS	tax rate	
GAAP	\$ 44,917	\$ 1,577		3.5	%	\$ 2,234	\$	2,572		\$ 0.19	(15.1	%)
Adjustments:												
Contingent consideration gain (1)	_	(352)	(0.8)	(352)		(352)	(0.03)		
Foreign exchange gain (2)	_	_		_		(126)		(126)	(0.01)		

Amortization of acquired intangible assets (3)	_	1,210	2.7		1,210	1,121		0.08	
Gain on strategic investment (4)	_	_	_		(7)	(7)	(0.00)	
Claim settlement (6)	_	(650)	(1.4)	(650)	(514)	(0.04)	
Non-GAAP	\$44.917 \$	1.785	4.0	% \$	\$ 2.309 \$	2.694	\$	0.19 (16.7	%)

For the Six Months Ended March 31, 2018

	Total Revenue	Operating (Loss) Income	J	Operating (Loss) Income Percentage	•	Income Before Income Taxes	et (Loss) come (7)		Diluted EPS	Effectiv	
GAAP	\$ 36,071	\$ (108)	(0.3	%)	\$ (207)	\$ (22)	\$ (0.00)	89.4	%
Adjustments:											
Contingent consideration gain (1)	_	(1,112)	(3.1)	(1,112)	(1,112)	(0.08)		
Foreign exchange loss (2)	_	_		_		518	518		0.04		
Amortization of acquired intangible assets (3)	_	1,254		3.5		1,254	1,150		0.09		
Gain on strategic investment (4)	_			_		(177)	(177)	(0.01)		
Tax reform impact (5)	_			_		_	1,246		0.09		
Claim settlement accrual (6)	_	1,000		2.8		1,000	755		0.06		
Non-GAAP	\$ 36,071	\$ 1,034		2.9	%	\$1,276	\$ 2,358		\$ 0.18	(84.8	%)

Represents accounting adjustments to state acquisition-related contingent consideration liabilities at their estimated fair value, including accretion for the passage of time as well as adjustments to the liabilities' fair values related to changes in the timing and/or probability of achieving

- (1) milestones. The tables include contingent consideration liability adjustments in each respective historical period and do not include in futureperiod fair value changes, other than estimated accretion expense as determined at the end of the current quarter. These amounts are not taxable or tax deductible.
- Foreign exchange gains and losses are related to marking non-U.S. dollar contingent consideration to period-end or settlement date exchange (2) rates. The tables include foreign currency exchange loss or gain recorded in each respective historical period and do not include forecasted currency fluctuations in future periods. These gains and losses are not taxable or tax deductible.
- Amortization of acquisition-related intangible assets and associated tax impact. A significant portion of the acquisition-related amortization is not (3)tax deductible.
- Represents the gain recognized on the sale of a strategic investment which was not tax-affected as it was offset by previously recognized capital (4) losses.
- Income tax expense from the re-measurement of net deferred tax assets recognized after the enactment of the Tax Cuts and Jobs Act in December 2017.
- Represents a royalty-related customer claim accrued at \$1.0 million in the second quarter of fiscal 2018, settled in the second quarter of 2019 for \$0.4 million.
- Net income (loss) includes the effect of the above adjustments on the income tax provision, taking into account deferred taxes and non-deductible (7) items. Effective rates of 21% (fiscal 2019) and 24.5% (fiscal 2018) were used to estimate the income tax impact of the adjustments, except that

expenses occurring in Ireland have not been tax-affected as all tax benefits are offset by a full valuation allowance.

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Source: Surmodics, Inc.

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