

Surmodics Reports Fourth Quarter Fiscal 2018 Results and Issues Fiscal 2019 Guidance

November 9, 2018

EDEN PRAIRIE, Minn.--(BUSINESS WIRE)--Nov. 9, 2018-- 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 2018 fourth quarter ended September 30, 2018, and provided its financial outlook for fiscal 2019.

Summary of Fourth Quarter Fiscal 2018 Highlights and Fiscal 2019 Guidance

- Revenue of \$23.0 million, an increase of 15% year-over-year
- GAAP EPS of (\$0.13), non-GAAP EPS of \$0.05
- Submitted application for first in-human study for arteriovenous (AV) access drug coated balloon (DCB)
- Fiscal 2019 revenue outlook of \$92.0 to \$97.0 million, GAAP EPS outlook of (\$0.32) to (\$0.02)

"We continue to drive strong revenue growth and solid operational performance as we execute on our strategic objectives," said Gary Maharaj, President & CEO of Surmodics. "The positive twelve-month data recently presented from PREVEIL, the early feasibility study of our SurVeil[®] DCB and the recent submission for first in-human study for our AV access DCB, AVess[™], demonstrate meaningful progress towards our whole-products solutions initiatives."

Fourth Quarter Fiscal 2018 Financial Results

Total revenue for the fourth quarter of fiscal 2018 was \$23.0 million, as compared with \$20.1 million in the prior-year period. Medical Device revenue was \$17.0 million in the fourth quarter of fiscal 2018, as compared with \$14.7 million in the year-ago period, an increase of 15.4%, and includes \$2.2 million from our *SurVeil* agreement with Abbott. In Vitro Diagnostics revenue was \$6.1 million for the fourth quarter of fiscal 2018 as compared with \$5.3 million in the same prior-year quarter, an increase of 13.4%.

Diluted GAAP loss per share in the fourth quarter of fiscal 2018 was \$(0.13) as compared with diluted GAAP earnings per share of \$0.03 in the year-ago period. On a non-GAAP basis, earnings per share were \$0.05 in the fourth quarter of fiscal 2018, as compared with \$0.18 in the year-ago period.

As of September 30, 2018, cash and investments were \$65.0 million. Surmodics generated cash from operating activities of \$34.1 million in fiscal 2018. Capital expenditures totaled \$9.0 million for fiscal 2018.

Fiscal 2019 Outlook

Surmodics expects fiscal year 2019 revenue to range from \$92 million to \$97 million. The Company expects diluted EPS in the range of (\$0.32) to (\$0.02) per share, which reflects the Company's continued investment in research and development to further its whole-product solutions strategy. Non-GAAP diluted EPS is expected to be in the range of (\$0.07) to \$0.23 per share.

Conference Call

Surmodics will host a webcast at 7:30 a.m. CT (8:30 a.m. ET) today to discuss fourth 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 fourth quarter conference call will be available by dialing 888-203-1112 and entering conference call ID passcode 1123199. The audio replay will be available beginning at 10:30 a.m. CT on Friday, November 9, 2018, until 10:30 a.m. CT on Friday, November 16, 2018.

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 <u>www.surmodics.com</u>. The content of Surmodics' website is not part of this press release or part of any filings 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, and our *SurVeil* DCB and other proprietary products 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, obtain regulatory approval for, and 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, 2017, 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 (loss) 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.

Surmodics, Inc. and Subsidiaries

Condensed Consolidated Statements of Operations (in thousands, except per share data) (Unaudited)

	Three Mor Septembe 2018	nths Ended r 30, 2017	Years Ended September 30, 2018 2017			
	(Unaudite	d)	(Unaudited	d)		
Revenue:						
Product sales	\$ 10,704	\$ 8,826	\$ 37,953	\$32,790		
Royalties and license fees	10,323	9,223	35,424	31,787		
Research, development and other	2,011	2,009	7,959	8,535		
Total revenue	23,038	20,058	81,336	73,112		
Operating costs and expenses:						
Product costs	4,089	3,317	13,997	11,422		
Research and development	12,591	9,713	40,973	31,817		
Selling, general and administrative	6,505	5,307	24,111	20,478		
Acquired in-process research and development	—	—	7,888	—		
Acquired intangible asset amortization	613	629	2,491	2,419		
Contingent consideration expense (gain)	1,681	676	675	(127)		
Total operating costs and expenses	25,479	19,642	90,135	66,009		
Operating (loss) income	(2,441)	416	(8,799)	7,103		
Other income (loss), net	411	(224)	1,267	(70)		
(Loss) income from operations before income taxes	(2,030)	192	(7,532)	7,033		
Income tax benefit (provision)	277	208	3,075	(3,107)		
Net (loss) income	\$ (1,753)	\$ 400	\$(4,457)	\$3,926		
Basic (loss) income per share:	\$ (0.13)	\$ 0.03	\$(0.34)	\$0.30		
Diluted (loss) income per share:	\$ (0.13)	\$ 0.03	\$(0.34)	\$0.29		
Weighted average number of shares outstanding:						
Basic	13,279	13,041	13,157	13,153		
Diluted	13,279	13,365	13,157	13,389		

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

> September 30, 2018 2017

Assets	(Unaudited)						
Current Assets:							
Cash and cash equivalents	\$23,318	\$16,534					
Restricted cash	350	—					
Available-for-sale securities	41,352	31,802					
Accounts receivable, net	8,877	7,211					
Inventories, net	4,016	3,516					
Prepaids and other	3,614	1,820					
Total Current Assets	81,527	60,883					
Property and equipment, net	30,143	22,942					
Deferred tax assets	6,304	4,027					
Intangible assets, net	17,683	20,562					
Goodwill	27,032	27,282					
Other assets	1,446	897					
Total Assets	\$164,135	\$136,593					
Liabilities and Stockholders' Equity							
Current Liabilities:							
Contingent consideration, current portion	11,041	1,750					
Deferred revenue	9,646	62					
Other current liabilities	14,446	7,991					
Total Current Liabilities	35,133	9,803					
Contingent consideration, less current portion	3,425	13,114					
Deferred revenue	11,247	181					
Other long-term liabilities	5,720	1,938					
Total Liabilities	55,525	25,036					
Total Stockholders' Equity	108,610	111,557					
Total Liabilities and Stockholders' Equity	\$ 164,135	\$136,593					

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

	Three Mo 2018	onths Ended	30		
Revenue:		% of Total		% of Total	% Change
Medical Device	\$ 16,986	73.7%	\$ 14,723	73.4%	15.4%
In Vitro Diagnostics	6,052	26.3%	5,335	26.6%	13.4%
Total revenue	\$ 23,038		\$20,058		14.9%
	Years En 2018				
Revenue:		% of Total		% of Total	% Change
Medical Device	\$60,513	74.4%	\$ 53,983	73.8%	12.1%
In Vitro Diagnostics	20,823	25.6%	19,129	26.2%	8.9%
Total revenue	\$81,336		\$73,112		11.2%
	Three Mo	onths Ended	Years En		

September 30, September 30,

	2018	2017	2018	2017
Operating (loss) income:				
Medical Device	\$(2,127)	\$ 276	\$(8,478)	\$ 6,902
In Vitro Diagnostics	2,350	2,371	8,619	8,293
Total segment operating income	223	2,647	141	15,195
Corporate	(2,664)	(2,231) (8,940)	(8,092
Total (loss) income from operations	\$(2,441)	\$ 416	\$(8,799)	\$ 7,103

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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)

	Septemb		•	Years Ended September 30,				
	2018		2017		2018	-	2017	
Net (loss) income	\$ (1,753)	\$ 400		\$(4,457)) (\$3,926	
Income tax (benefit) provision	(277)	(208)	(3,075)	3,107	
Depreciation and amortization	1,720		1,549		6,431		5,555	
Investment income, net	(285)	(116)	(851)	(390)
EBITDA	(595)	1,625		(1,952))	12,19	8
Adjustments:								
Contingent consideration expense (gain) (1)	1,681		676		675		(127)
Foreign exchange (gain) loss (2)	(74)	347		(148)	474	
Gain on strategic investment (4)	_		(43)	(177)	(43)
Claim settlement accrual (6)	_				1,000		_	
Acquired in-process research and development (7)	_				7,888		_	
Asset impairment (8)	_		427		_		427	
Adjusted EBITDA	\$ 1,012		\$ 3,032		\$7,286	ç	\$ 12,92	9
Net Cash Provided by Operating Activities	\$ 4,830		\$ 6,397		\$34,052	(\$14,05	3
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Estimated Non-GAAP Net Earnings per Common Share Guidance Reconciliation For the Fiscal Year Ended September 30, 2019

(Unaudited)

	Fiscal 2019 Full-Year Estimate									
	Lo	w								
GAAP results	\$	(0.32)	\$	(0.02)				
Contingent consideration adjustments (1)		0.08			0.08					
Amortization of acquired intangibles (3)		0.17			0.17					
Non-GAAP results	\$	(0.07)	\$	0.23					

Surmodics, Inc., and Subsidiaries

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

For the Three Months Ended September 30, 2018

Total	Operating	Operating	(Loss) Income	Net	Diluted	Effective
Revenue	(Loss)	(Loss) Income	Before	(Loss)	EPS	tax rate
	Income	Percentage	Income Taxes	Income (10)		

GAAP	\$ 23,038	\$ (2,441) (10.6)% \$ (2,030) \$ (1,753) \$ (0.13) 13.6	%
Adjustments:							
Contingent consideration expense (1)	_	1,681	7.3	1,681	1,681	0.13	
Foreign exchange gain (2)	—	—	—	(74) (74) (0.01)	
Amortization of acquired intangible assets (3)	—	613	2.7	613	561	0.04	
Tax reform impact (5)	—	—	—	—	327	0.02	
Dilutive effect of outstanding stock awards (9)	—	—	—	—	—	(0.01)	
Non-GAAP	\$ 23,038	\$ (147) (0.6)% \$ 190	\$ 742	\$ 0.05 (290.5)%

For the Three Months Ended September 30, 2017

	Total Revenue	Operating Income	Operating Income Percentage					Income Before Income Taxes						let ncome 10)		Diluted EPS	Effectiv tax rate	-
GAAP	\$ 20,058	\$ 416	2.1	%	\$	192	\$	400	\$	6 0.03	(108.3)%						
Adjustments:																		
Contingent consideration expense (1)	_	676	3.4			676		676		0.05								
Foreign exchange loss (2)	_	—	—			347		347		0.03								
Amortization of acquired intangible assets (3)	—	629	3.1			629		550		0.04								
Gain on strategic investment (4)	_	_	_			(43)	(43)	(0.00)								
Asset impairment (8)	_	427	2.1			427		427		0.03								
Non-GAAP	\$ 20,058	\$ 2,148	10.7	%	\$	2,228	\$	2,357	\$	6 0.18	(5.8)%						

For the Year Ended September 30, 2018

	Total Revenue	Operating (Loss) Income	Operating (Loss) Income Percentage		(Loss) Income Before Income Tax	es	Net (Loss) Income (10)		Diluted EPS	Effectiv tax rate	
GAAP	\$ 81,336	\$ (8,799)	(10.8)%	\$ (7,532)	\$ (4,457) \$ (0.34)	40.8	%
Adjustments:											
Contingent consideration expense (1)	_	675	0.8		675		675		0.05		
Foreign exchange gain (2)	_	—	_		(148)	(148	2) (0.01)		
Amortization of acquired intangible assets (3)	—	2,491	3.1		2,491		2,282		0.17		
Gain on strategic investment (4)	_	_	_		(177)	(177) (0.01)		
Tax reform impact (5)	_	_	_		_		1,573		0.12		
Claim settlement accrual (6)	—	1,000	1.2		1,000		755		0.06		
Acquired in-process research and development (7)	_	7,888	9.7		7,888		6,232		0.47		
Dilutive effect of outstanding stock awards (9) Non-GAAP	— \$ 81,336	 \$ 3,255	4.0	%	 \$ 4,197		 \$ 6,735		(0.02) \$ 0.49	(60.5)%

For the Year Ended September 30, 2017

	Total Revenue	Operating Income	Operating Income Percentage		Income Before Income Taxes	Net Income (10)	Diluted EPS	Effectiv tax rate	
GAAP Adjustments:	\$ 73,112	\$ 7,103	9.7	%	\$ 7,033	\$ 3,926	\$ 0.29	44.2	%
Contingent consideration gain (1)	_	(127)	(0.2)	(127) (127) (0.01)	1	
Foreign exchange loss (2)	—	—	—		474	474	0.04		
Amortization of acquired intangible assets (3)	—	2,419	3.3		2,419	2,105	0.16		
Gain on strategic investment (4)	_	—	_		(43) (43) (0.00)	1	
Asset impairment (8)	_	427	0.6		427	427	0.03		
Non-GAAP	\$ 73,112	\$ 9,822	13.4	%	\$ 10,183	\$ 6,762	\$ 0.51	33.6	%

(1) 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 milestones. The tables include contingent consideration liability adjustments in each respective historical period and do not include in future-period 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 exchange rates. The tables
- (2) 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.
- (3) Amortization of acquisition-related intangible assets and associated tax impact. A significant portion of the acquisition-related amortization is not tax deductible.
- (4) Represents the gain recognized on the sale of a strategic investment which was not tax-affected as it was offset by previously recognized capital losses.
- (5) 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.
- (6) Represents an estimated royalty-related customer claim settlement accrued in the second quarter of fiscal 2018 and associated tax impact.
- (7) Represents the acquisition of the Embolitech in-process research and development assets during the third quarter of fiscal 2018 and associated tax impact.
- (8) Impairment of indefinite-lived intangible assets which were not tax deductible. Options to purchase common stock as well as unvested restricted stock and performance stock units are considered to be potentially dilutive common shares but have been excluded from the calculation of GAAP net loss per share as their effect is anti-dilutive for three months and year
- (9) ended September 30, 2018 as a result of the net loss for those periods on a GAAP basis. However, as the Non-GAAP adjustments result in Non-GAAP net income, the dilutive effect of these options and other outstanding stock awards have been included in the calculation of Non-GAAP earnings per share. Accordingly, Diluted EPS includes these adjustments. Net (loss) income includes the effect of the above adjustments on the income tax provision, taking into account deferred taxes and
- (10) non-deductible items. Effective rates of 24.5% (fiscal 2018) and between 34-35% (fiscal 2017) 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 and acquired in-process research and development, which will be deductible at a 21% statutory tax rate.

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Source: Surmodics, Inc.

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