



## Surmodics Reports Fourth Quarter Fiscal 2016 Results

November 16, 2016

- **GAAP Revenue of \$18.2 Million, up 5%**
- **GAAP EPS of \$0.20, Non-GAAP EPS of \$0.26**
- **Core Business Performs Well as Key Strategic Growth Priorities Advance**
- **Fiscal 2017 Revenue and EPS Guidance Outlined**

EDEN PRAIRIE, Minn.--(BUSINESS WIRE)--Nov. 16, 2016-- 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 2016 fourth quarter, ended September 30, 2016.

"The fourth quarter marked the continuation of the outstanding execution by the Surmodics team in fiscal 2016. I am proud of our accomplishments as we surpassed our fiscal 2016 financial goals and successfully integrated the Creagh Medical and NorMedix teams with Surmodics. We have also made significant progress on all key strategic growth priorities," said Gary Maharaj, president and chief executive officer. "Most notably, we have frozen the design of our first 510(k) product and completed an interim look at the data from the investigational device exemption (IDE) study of our SurVeil® drug-coated balloon platform."

### Fourth Quarter Revenue and Earnings Summary

GAAP revenue for the fiscal 2016 fourth quarter totaled \$18.2 million, compared with \$17.4 million a year earlier. Fourth quarter fiscal 2016 revenue included \$1.3 million from Surmodics' fiscal 2016 acquisitions.

Diluted GAAP earnings per share in the fourth quarter of fiscal 2016 were \$0.20 compared with \$0.10 a year ago. GAAP earnings per share were impacted by increased research and development investments, accretion and amortization from acquisitions, and included a \$0.04 per share tax benefit related to the adoption of a new accounting standard related to accounting for income taxes associated with stock-based compensation. On a non-GAAP basis, earnings per share were \$0.26 in the fourth quarter of fiscal 2016 versus \$0.34 last year.

### Medical Device Segment

This segment, which includes hydrophilic coatings, device drug delivery technologies and balloon catheter products, posted revenue of \$13.7 million in the fourth quarter of fiscal 2016, an increase of 5% compared to the year-ago period. The gain stems from higher reagent product sales and revenue from our fiscal 2016 acquisitions. Fiscal fourth quarter 2016 hydrophilic coating royalty and license fee revenue totaled \$8.0 million, a decrease of 13% percent compared to the year-earlier period, reflecting the impact of the November 2015 expiration of U.S. patents covering Surmodics' third-generation hydrophilic coatings. The Medical Device business unit generated \$4.2 million of operating income in the fourth quarter compared to \$4.7 million in the prior-year quarter. Planned increases in research and development expense, as well as acquisition-related amortization and accretion expenses partly offset by higher revenue, accounted for the change in operating income.

### Update on SurVeil Drug-Coated Balloon

Surmodics has completed an interim look at the data from its early feasibility study of the SurVeil drug-coated balloon. This study is part of the Company's strategy to move its medical device business from being solely a provider of coatings to offering differentiated whole-product solutions to leading medical device customers. "The SurVeil drug-coated balloon is performing well in the early feasibility study," said Kenneth Rosenfield, M.D., M.H.C.D.S., at Massachusetts General Hospital in Boston, Mass. and Chairman of the Surmodics Clinical Advisory Board, "I look forward to the next steps as Surmodics advances this important technology on behalf of patients."

### In Vitro Diagnostics Segment

Revenue for the fourth quarter of fiscal 2016 grew 5% to \$4.5 million compared to the year-ago period. The IVD business unit operating income increased to \$1.8 million versus \$1.3 million in the prior-year quarter. Operating income benefited from improved operating leverage due to higher revenue and lower expenses.

### Balance Sheet, Cash Flow, EBITDA and Capital Allocation

As of September 30, 2016, the Company had \$46.9 million of cash and investments. Cash flows from operating activities aggregated \$25.2 million in fiscal 2016. Earnings before interest, taxes, depreciation and amortization (EBITDA), adjusted for certain discrete or non-operations items, totaled \$26.5 million for fiscal 2016, an increase of 4.0% from fiscal 2015. Capital expenditures totaled \$8.2 million for fiscal 2016. In addition, the Company used \$25.9 million of net cash to acquire Creagh Medical and NorMedix in fiscal 2016.

### Fiscal 2017 Outlook

"In fiscal 2016 we completed our three priorities: complete an acquisition to accelerate our transformation to providing whole-product solutions to our medical device customers, move ahead with a drug-coated balloon first-in-human clinical trial, and continue to deliver differentiated innovation and service in our core medical device and in vitro diagnostics businesses for current and prospective customers," said Maharaj. "We are very excited about the current status of our whole-product solutions strategy and will build on this foundation in fiscal 2017 to make Surmodics a more valuable and relevant partner to our customers, thereby delivering long-term shareholder value. Our capital allocation in fiscal 2017 to invest in research and development is a well-thought-through execution of our whole-product solutions strategy."

The Company estimates GAAP revenue for fiscal 2017 to be in the range of \$63.0 million to \$67.0 million. Surmodics anticipates diluted GAAP earnings (loss) to be in the range of (\$0.15) to \$0.05 per share. The Non-GAAP earnings range is expected to be from \$0.15 to \$0.35 per share. The Company's earnings per share guidance includes an increase of approximately 50% in research and development investment over fiscal 2016 levels, primarily to accelerate whole-product solutions development initiatives. This investment in growth will likely be more heavily weighted to the second half of fiscal 2017 and reflects the expected continued funding of the *SurVeil* drug-coated balloon technology for above-the-knee clinical studies.

Surmodics' GAAP earnings per share guidance excludes the impact of gains and losses from strategic investment and foreign currency translation adjustments related to the Company's Euro denominated contingent consideration associated with the fiscal 2016 Creagh Medical acquisition. Capital expenditures for fiscal 2017 are projected to range between \$7.0 million and \$8.0 million versus \$8.2 million in fiscal 2016. The outlook assumes 13.5 million diluted shares outstanding and income tax expense of \$2.0 million to \$3.0 million. While dependent on market conditions and corporate development initiatives, the Company may buy back common shares under its \$30.0 million repurchase authorization; the guidance excludes any shares Surmodics may repurchase.

### **Live Webcast**

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 [www.surmodics.com](http://www.surmodics.com) and click on the webcast icon. A replay of the fourth quarter conference call will be available by dialing 888-203-1112 and entering conference call ID passcode 8067923. The audio replay will be available beginning at 10:30 a.m. CT today until 10:30 a.m. CT on Wednesday, November 23, 2016. In addition, the conference call audio and transcript will be archived on the Company's website following the call.

### **About Surmodics *SurVeil* Drug-Coated Balloon**

The *SurVeil* drug-coated balloon incorporates Surmodics' decades of experience as a leading supplier of surface modification technologies to the medical device industry. It includes a Surmodics-proprietary drug-excipient formulation for the balloon coating, and a new and proprietary manufacturing process for the coating applications. It also includes the Surmodics Serene™ low-friction, low-particulate hydrophilic coating on the catheter shaft. The *SurVeil* drug-coated balloon is not available for sale in the US and is for investigational use only. We completed an interim look at the data from the first-in-human clinical trial using Surmodics *SurVeil* drug-coated balloon in the quarter ended September 30, 2016.

### **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) tests and microarrays. Following two recent acquisitions of Creagh Medical and NorMedix, the Company is executing a key growth strategy for its medical device business by expanding to offer total intravascular product solutions to its medical device customers. The combination of proprietary surface technologies, along with enhanced device design, development and manufacturing capabilities, enables Surmodics to significantly increase the value it offers with highly differentiated intravascular solutions designed and engineered to meet the most demanding requirements. With this focus on offering total product solutions, Surmodics' mission remains to improve the detection and treatment of disease by using its technology to provide solutions to difficult medical device and diagnostic challenges. Surmodics is headquartered in Eden Prairie, Minnesota. For more information about the Company, visit [www.surmodics.com](http://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 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, earnings and cash flow expectations for fiscal 2017, our fiscal 2017 priorities, our strategy to become a provider of whole-product solutions, such as those relating to our *SurVeil* drug-coated balloon and other proprietary products being developed, 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* drug-coated balloon product; (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) our ability to successfully identify, acquire, and integrate target companies, and achieve expected benefits from acquisitions that are consummated; (4) possible adverse market conditions and possible adverse impacts on our cash flows, and (5) 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, 2015, and updated in our subsequent reports filed with the SEC. These reports are available in the Investors section of our website at [www.surmodics.com](http://www.surmodics.com) and at the SEC website at [www.sec.gov](http://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 generally accepted accounting principles, or GAAP, Surmodics is reporting non-GAAP financial results including adjusted EBITDA, non-GAAP operating income, non-GAAP income before income taxes, non-GAAP net income, and non-GAAP diluted net income per share, and the non-GAAP effective 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 Income

(in thousands, except per share data)

	Three Months Ended		Years Ended	
	September 30,		September 30,	
	2016	2015	2016	2015
	(Unaudited)			
Revenue:				
Product sales	\$ 8,133	\$ 6,844	\$ 30,999	\$ 24,925
Royalties and license fees	7,996	9,197	33,203	31,763
Research, development and other	2,025	1,323	7,164	5,210
Total revenue	18,154	17,364	71,366	61,898
Operating costs and expenses:				
Product costs	2,839	2,588	10,908	8,619
Research and development	5,303	4,326	18,498	16,165
Selling, general and administrative	5,011	3,519	18,000	14,906
Acquisition transaction, integration and other costs	—	—	3,187	—
Acquired intangible asset amortization	482	165	2,422	619
Contingent consideration accretion expense	436	—	1,492	—
Claim settlement	—	2,500	—	2,500
Total operating costs and expenses	14,071	13,098	54,507	42,809
Operating income	4,083	4,266	16,859	19,089
Other income (loss), net	17	(1,493 )	89	(848 )
Income from operations before income taxes	4,100	2,773	16,948	18,241
Income tax provision	(1,456 )	(1,415 )	(6,963 )	(6,294 )
Net income	\$ 2,644	\$ 1,358	\$ 9,985	\$ 11,947
Basic income per share:	\$ 0.20	\$ 0.10	\$ 0.77	\$ 0.92
Diluted income per share:	\$ 0.20	\$ 0.10	\$ 0.76	\$ 0.90
Weighted average number of shares outstanding:				
Basic	13,088	12,934	12,998	13,029
Diluted	13,408	13,190	13,219	13,289

## Surmodics, Inc. and Subsidiaries Condensed Consolidated Balance Sheets

(in thousands)

	September 30,	
	2016	2015
	(Unaudited)	
Assets		
Current Assets:		
Cash and cash equivalents	\$ 24,987	\$ 55,588
Available-for-sale securities	21,954	—
Accounts receivable, net	6,869	7,478
Inventories	3,579	2,979
Prepays and other	1,169	1,744
Total Current Assets	58,558	67,789
Property and equipment, net	19,601	12,968
Deferred tax assets	5,027	6,704
Intangible assets, net	22,525	2,760
Goodwill	26,555	8,010
Other assets	628	479
Total Assets	\$ 132,894	\$ 98,710
Liabilities and Stockholders' Equity		
Current Liabilities	10,135	4,700
Contingent consideration, less current portion	13,592	—

Other long-term liabilities	2,334	2,137
Total Liabilities	26,061	6,837
Total Stockholders' Equity	106,833	91,873
Total Liabilities and Stockholders' Equity	\$ 132,894	\$ 98,710

**Surmodics, Inc. and Subsidiaries**  
**Supplemental Segment Information**

(in thousands)

(Unaudited)

**Three Months Ended September 30,**  
**2016**                      **2015**

%

Revenue:	% of Total		% of Total		Change
Medical Device	\$ 13,702	75.5 %	\$ 13,118	75.5 %	4.5 %
In Vitro Diagnostics	4,452	24.5 %	4,246	24.5 %	4.9 %
Total revenue	\$ 18,154		\$ 17,364		4.6 %

**Twelve Months Ended September 30,**  
**2016**                      **2015**

%

Revenue:	% of Total		% of Total		Change
Medical Device	\$ 53,202	74.5 %	\$ 45,944	74.2 %	15.8 %
In Vitro Diagnostics	18,164	25.5 %	15,954	25.8 %	13.9 %
Total revenue	\$ 71,366		\$ 61,898		15.3 %

**Three Months Ended**    **Years Ended**  
**September 30,**        **September 30,**  
**2016**    **2015**        **2016**    **2015**

Operating income:				
Medical Device	\$ 4,150	\$ 4,687	\$ 16,975	\$ 21,192
In Vitro Diagnostics	1,817	1,264	7,115	4,484
Total segment operating income	5,967	5,951	24,090	25,676
Corporate	(1,884 )	(1,685 )	(7,231 )	(6,587 )
Total income from operations	\$ 4,083	\$ 4,266	\$ 16,859	\$ 19,089

**Surmodics, Inc. and Subsidiaries**  
**Reconciliation of GAAP Measures to Non-GAAP Amounts**  
**Schedule of Adjusted EBITDA**

(in thousands)

	<b>Three Months Ended</b>		<b>Years Ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	<b>2016</b>	<b>2015</b>	<b>2016</b>	<b>2015</b>
	<b>(Unaudited)</b>		<b>(Unaudited)</b>	
Net Income	\$ 2,644	\$ 1,358	\$ 9,985	\$ 11,947
Income tax provision	1,456	1,415	6,963	6,294
Depreciation and Amortization	1,170	723	4,875	2,805
EBITDA	5,270	3,496	21,823	21,046

Adjustments:

Acquisition transaction, integration and other costs (1)	—	—	3,187	—
Contingent consideration expense (2)	436	—	1,492	—
Foreign exchange loss (3)	146	—	481	—
Impairment charge (4)	—	1,500	—	1,500
Claim settlement (5)	—	2,500	—	2,500
Gain on strategic investments (6)	(136 )	—	(497 )	(523 )
Adjusted EBITDA	\$ 5,716	\$ 7,496	\$ 26,486	\$ 25,523

Net Cash Provided by Operating Activities	\$ 6,671	\$ 2,990	\$ 25,166	\$ 15,066
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**Reconciliation of Estimated GAAP to Non-GAAP**

**Net Income (Loss) per Common Share**

Fiscal 2017 Guidance

	Year ending	
	September 30, 2017	
	Estimated Diluted EPS	
	Low	High
<b>GAAP results</b>	\$ (0.15 )	\$ 0.05
Contingent consideration expense (2)	0.15	0.15
Amortization of acquired intangibles (7)	0.15	0.15
<b>Non-GAAP results</b>	\$ 0.15	\$ 0.35

- (1) Represents acquisition-related costs, including due diligence and integration expenses. Due diligence and other fees include legal, tax, investment banker and other expenses associated with acquisitions that can be highly variable and not representative of on-going operations. Contingent consideration expense represents accounting adjustments to state acquisition related contingent consideration liabilities at their estimated fair value. There is no impact for taxes in the net income (loss) per share reconciliation as this expense is not deductible for income tax purposes.
- (2) Foreign exchange loss related to marking non-U.S. dollar contingent consideration to period end exchange rates.
- (3) To exclude an impairment charge associated with a strategic investment in CeloNova BioSciences, Inc.
- (4) To exclude the settlement of a customer claim.
- (5) Represents the gain recognized on the sale of a strategic investment.
- (6) Amortization of acquisition-related intangible assets, net of applicable tax.

**Surmodics, Inc., and Subsidiaries**

**Net Income and Diluted EPS GAAP to Non-GAAP Reconciliation**

(in thousands, except per share data)

(unaudited)

For the Three Months Ended September 30, 2016

		Income				
		Operating	Before			
Total	Operating	Income	Income	Net	Diluted	Effective
Revenue	Income	Percentage	Taxes	Income (7)	EPS	tax rate

<b>GAAP</b>	\$ 18,154	\$ 4,083	22.5	%	\$ 4,100	\$ 2,644	\$ 0.20	35.5	%
Adjustments:									
Contingent consideration accretion expense (1)	—	436	2.4		436	436	0.03	(3.4)	)
Foreign exchange loss (2)	—	—	—		146	146	0.01	(1.0)	)
Amortization of acquired intangible assets (3)	—	482	2.7		482	392	0.03	(1.2)	)
Gain on strategic investments (4)	—	—	—		(136 )	(136 )	(0.01)	0.8	)
<b>Non-GAAP</b>	\$ 18,154	\$ 5,001	27.6	%	\$ 5,028	\$ 3,482	\$ 0.26	30.7	%

**For the Three Months Ended September 30, 2015**

	Income								
	Operating			Before					
	Total	Operating	Income	Income	Net	Diluted	Effective		
	Revenue	Income	Percentage	Taxes	Income (7)	EPS	tax rate		
<b>GAAP</b>	\$ 17,364	\$ 4,266	24.6	%	\$ 2,773	\$ 1,358	\$ 0.10	51.0	%
Adjustments:									
Amortization of acquired intangible assets (3)	—	165	0.9		165	107	0.01	(1.3)	)
Impairment loss on strategic investment (5)	—	—	—		1,500	1,500	0.11	(16.5)	)
Claim settlement (6)	—	2,500	14.4		2,500	1,617	0.12	0.8	)
<b>Non-GAAP</b>	\$ 17,364	\$ 6,931	39.9	%	\$ 6,938	\$ 4,582	\$ 0.34	34.0	%

- (1) Represents accounting adjustments to state acquisition-related contingent consideration liabilities at their estimated fair value. No income tax deductions were generated from these expenses as they are considered a part of purchase price for income tax purposes.
- (2) Foreign exchange loss related to marking non-U.S. dollar contingent consideration liabilities to period-end exchange rates. These losses are not deductible for income tax purposes.
- (3) Amortization of acquisition-related intangible assets and associated tax impact. No income tax deductions were generated from a significant portion of fiscal 2016 amortization expense as it was offset by a net operating loss carryforward valuation allowance.
- (4) Represents the gain recognized on the sale of strategic investments. The strategic investment gains did not generate an income tax expense as there was an offsetting release of a capital loss valuation allowance.
- (5) Represents an impairment charge associated with a strategic investment in CeloNova BioSciences, Inc. This loss was not deductible for income tax purposes as the Company is in a capital loss carryforwards position.
- (6) Represents a customer claim settlement.
- (7) Net income includes the effect of the above adjustments on the income tax provision, taking into account deferred taxes and non-deductible items. An effective rate between 34-35% was used to estimate the income tax impact of the adjustments.

**Surmodics, Inc., and Subsidiaries**

**Net Income and Diluted EPS GAAP to Non-GAAP Reconciliation**

(in thousands, except per share data)

(unaudited)

**For the Year Ended September 30, 2016**

	Income						
	Operating			Before			
	Total	Operating	Income	Income	Income	Diluted	Effective

	Revenue	Income	Percentage	Taxes	(10)	EPS	tax rate
<b>GAAP</b>	\$ 71,366	\$ 16,859	23.6 %	\$ 16,948	\$ 9,985	\$ 0.76	41.1 %
Adjustments:							
Acquisition transaction, integration and other costs (1)	—	3,187	4.5	3,187	2,860	0.22	(4.9 )
Contingent consideration expense (2)	—	1,492	2.1	1,492	1,492	0.11	(2.5 )
Foreign exchange loss (3)	—	—	—	481	481	0.03	(0.7 )
Research and development tax credit (4)	—	—	—	—	(222 )	(0.02)	1.0
Amortization of acquired intangible assets (5)	—	2,422	3.4	2,422	2,047	0.15	(1.9 )
Gain on strategic investment (6)	—	—	—	(497 )	(497 )	(0.04)	0.7
<b>Non-GAAP</b>	\$ 71,366	\$ 23,960	33.6 %	\$ 24,033	\$ 16,146	\$ 1.21	32.8 %

**For the Year Ended September 30, 2015**

	Income						
	Total	Operating	Income	Before	Net	Diluted	Effective
<b>GAAP</b>	\$ 61,898	\$ 19,089	30.8 %	\$ 18,241	\$ 11,947	\$ 0.90	34.5 %
Adjustments:							
Amortization of acquired intangible assets (5)	—	619	1.1	619	401	0.02	(0.0 )
Gain on strategic investment (6)	—	—	—	(523 )	(523 )	(0.04)	1.0
Impairment loss on strategic investment (7)	—	—	—	1,500	1,500	0.11	(2.7 )
Claim settlement (8)	—	2,500	4.0	2,500	1,617	0.12	0.3
Research and development tax credit (9)	—	—	—	—	(201 )	(0.02)	0.9
<b>Non-GAAP</b>	\$ 61,898	\$ 22,208	35.9 %	\$ 22,337	\$ 14,741	\$ 1.09	34.0 %

- (1) Represents acquisition-related costs, including due diligence and integration expenses. Due diligence and other fees include legal, tax, investment banker and other expenses associated with acquisitions that can be highly variable and not representative of on-going operations.
- (2) Represents accounting adjustments to state acquisition-related contingent consideration liabilities at their estimated fair value. No income tax deductions were generated from these expenses as they are considered a part of purchase price for income tax purposes.
- (3) Foreign exchange loss related to marking non-U.S. dollar contingent consideration to period end exchange rates. These losses are not deductible for income tax purposes.
- (4) Represents a discrete income tax benefit associated with the December 2015 signing of the Protecting Americans from Tax Hikes Act of 2015, which retroactively reinstated federal R&D income tax credits for calendar 2015.
- (5) Amortization of acquisition-related intangible assets and associated tax impact. No income tax deductions were generated from a significant portion of fiscal 2016 amortization expense as it was offset by a net operating loss carryforward valuation allowance.
- (6) Represents the gain recognized on the sale and contingent consideration received from strategic investments. The strategic investment gains did not generate an income tax expense as there was an offsetting release of a capital loss valuation allowance.
- (7) Represents a fourth-quarter impairment charge associated with a strategic investment in Celonova BioSciences, Inc. This loss was not deductible for income tax purposes as the Company is in a capital loss carryforwards position.
- (8) Represents a fourth-quarter customer claim settlement.
- (9) Represents a discrete income tax benefit associated with the December 2014 signing of the Tax Increase Prevention Act of 2014, which retroactively reinstated federal R&D income tax credits for calendar 2014.
- (10) Net income includes the effect of the above adjustments on the income tax provision, taking into account deferred taxes and non-deductible items. An effective rate between 34-35% was used to estimate the income tax impact of the adjustments.

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Source: Surmodics, Inc.

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