Align Technology is a publicly traded medical device company engaged in the design, manufacture and marketing of the Invisalign® system, the world's leading invisible orthodontic product, and the iTero® Intraoral scanning systems and services. Align Technology went public on the NASDAQ market under the trading symbol ALGN in January 2001.

# Align Technology Announces Record 2018 Financial Results

January 29, 2019

- 2018 revenues up 33.5% to a record \$2.0 billion
- 2018 Invisalign volume of 1.2 million cases up 31.9% and iTero scanner volume up 77.2%
- 2018 operating margin of 23.7% and diluted EPS of \$4.92
- 2018 Invisalign volume in Americas and International regions up 24.2% and 45.0%, respectively
- Q4 total revenues up 26.7% year-over-year to a record \$534.0 million, and diluted EPS of \$1.20
- Q4 Invisalign volume up 30.9% year-over-year to 333.8 thousand cases
- Q4 scanner and services revenues up 54.8% year-over-year to \$88.4 million
- Q4 operating income up 9.9% year-over-year to \$120.5 million or operating margin of 22.6%

SAN JOSE, Calif., Jan. 29, 2019 (GLOBE NEWSWIRE) -- Align Technology, Inc. (Nasdaq: ALGN) today reported financial results for the fourth quarter (Q4'18) and year ended December 31, 2018 (FY 2018). Q4'18 Invisalign volume was 333.8 thousand cases, up 30.9% year-over-year. For the Americas and International regions, Q4'18 Invisalign volume was up 21.7% and 45.3% year-over-year, respectively. Q4'18 Invisalign volume for teenage patients was 87.1 thousand cases, up 37.3% year-over-year. Q4'18 total revenues were \$534.0 million, up 26.7% year-over-year, and Q4'18 scanner and services revenues were \$88.4 million, up 54.8% year-over-year. Q4'18 operating income of \$120.5 million was up 9.9% year-over-year resulting in an operating margin of 22.6%. Q4'18 net profit was \$97.4 million, or \$1.20 per diluted share.

For 2018, record Invisalign revenues were \$1.7 billion, up 29.4% year-over-year with Invisalign case shipments of 1.2 million, up 31.9% year-over-year. 2018 iTero revenues were \$275.0 million, up 67.5% year-over-year with record volume, up 77.2% year-over-year. 2018 Invisalign cases for teenage patients were 333.1 thousand, up 40.3% year-over-year. For 2018, total revenues were \$2.0 billion, up 33.5% year-over-year, and net profit was \$400.2 million, or \$4.92 per diluted share.

Commenting on Align's Q4 and 2018 results, Align Technology President and CEO Joe Hogan said, "Our fourth quarter was a strong finish to a great year. Q4 revenues were better than expected reflecting higher Invisalign ASPs and volume growth of 31% year-over-year, as well as another record quarter for our iTero scanners with revenue up 55% year-over-year. Q4 sequential growth was driven by a strong quarter for EMEA with record growth from teens, as well as continued traction with Invisalign Go. Q4 operating margin of 22.6% reflects higher doctor training and manufacturing costs, as well as higher legal fees than anticipated, partially offset by a sequential improvement in Invisalign ASPs."

Hogan continued, "We achieved record revenues of nearly \$2.0 billion for the year and had over 1.2 million people start treatment with Invisalign clear aligners the first time, resulting in our 6th millionth Invisalign patient – a teenager from China. These results reflect record revenues and volumes for both Invisalign and iTero across customer channels and country markets, and continued strength from teens, which grew 40.3%. The total number of teenagers treated with Invisalign this year was over 333 thousand representing 27.1% of our volume. Finally, in 2018, we trained a record number of new Invisalign doctors – nearly 20 thousand worldwide – and more than half of them were international doctors."

## GAAP Summary Financial Comparisons Fourth Quarter Fiscal 2018

	Q4'18	Q3'18	Q4'17	Q/Q Change	Y/Y Change
Invisalign Case Shipments <sup>1</sup>	333,800	319,345	255,030	+4.5%	+30.9%
Net Revenues	\$534.0M	\$505.3M	\$421.3M	+5.7%	+26.7%
Clear Aligner <sup>2</sup>	\$445.6M	\$427.1M	\$364.2M	+4.3%	+22.4%
Scanner & Services	\$88.4M	\$78.2M	\$57.1M	+13.0%	+54.8%
Net Profit	\$97.4M	\$100.9M	\$10.3M	(3.4)%	+848.9%
Diluted EPS <sup>3</sup>	\$1.20	\$1.24	\$0.13	\$(0.04)	\$1.07
Fiscal 2018					
		2018		2017	Y/Y Change
Invisalign Case Shipments <sup>1</sup>		1,228,065		931,045	+31.9%
Net Revenues		\$1,966.5M	\$	1,473.4M	+33.5%
Clear Aligner <sup>2</sup>		\$1,691.5M	\$	1,309.3M	+29.2%
Scanner & Services		\$275.0M	\$	164.2M	+67.5%

Note: Changes and percentages are based on actual values and may affect totals due to rounding

As of December 31, 2018, Align had \$744.5 million in cash, cash equivalents and marketable securities compared to \$761.5 million as of December 31, 2017. During Q4'18, we repurchased \$50.0 million of our stock against our stock buy-back authorizations and have \$500.0 million still available for repurchase under the May 2018 Repurchase Program.

\$400.2M

\$4.92

\$231.4M

\$2.83

+72.9%

+\$2.09

# 2018 Business Highlights

Net Profit

The following list highlights Align's key announcements over the past year:

Invisalign and iTero Intraoral Scanner

- Launched Invisalign treatment with mandibular advancement in the U.S. for teen Class II treatment following FDA approval.
- Introduced Invisalign First clear aligners worldwide for treatment of growing children.
- Expanded the Invisalign product portfolio with new options and greater flexibility for a broader range of patients.
- Launched the new Invisalign Go product with a more user-friendly iTero chair side experience
- Announced multiple industry awards for iTero Element 2 and iTero Element Flex scanners, including 2018 DrBicuspid.com Dental Excellence Award and 2018 GOOD DESIGN® Award.
- Entered into multi-year agreements with both Aspen Dental and Heartland Dental for iTero Element scanners in their U.S. locations.
- Expanded the iTero Element portfolio with the launch of the iTero Element 2 and the iTero Element Flex scanners, along with new functionality connectivity to exocad and
- Began marketing the iTero Element intraoral scanner in China.
- Announced the commercial availability of Vivera Retainers with Precision Bite Ramps, the first retainers in the market that can be customized to provide additional support

Invisalian shipment figures do not include SmileDirectClub alianers

<sup>&</sup>lt;sup>2</sup> Clear aligner revenue includes revenues from Invisalign clear aligners and SmileDirectClub aligners

<sup>&</sup>lt;sup>3</sup> Q4'17 includes deemed repatriation tax impact of \$1.06

after deep bite correction.

## Invisalign Experience Program

- Expanded the interactive brand experience program that was piloted in late 2017, and added eight new stores in major U.S. cities in the fourth quarter of 2018 to end the year with twelve stores in the U.S.
- Announced the Invisalign Experience Branded Practice Pilot (doctor owned pilot). In late 2018, Align partnered with a few Invisalign doctors in select U.S. cities to pilot
  Invisalign Experience branded practices to test new ways to reach consumers and connect them directly with doctors to start Invisalign treatment.

## Patient Milestones

- · Reached 6th millionth Invisalign patient milestone with a teenage patient from China.
- Announced the one millionth Invisalign case for the Europe, Middle East and Africa (EMEA) region.

## International Expansion

- Opened the first Invisalign treatment planning facility in Europe, located in Cologne, Germany.
- Launched a new digital treatment planning facility and education center in Madrid, Spain.

### Research and Awards

- Announced eleven recipients of research grants under Align's 2018 Research Award Program, and opened the 2019 Research Award Program to support clinical and scientific dental research in universities across the globe.
- Launched the Orthodontic Aligner Fellowship Certificate Program, in collaboration with DentalXP, a global dental education provider on August 6, 2018.

#### Corporate

- Announced entering into an accelerated stock repurchase agreement to repurchase \$50.0 million of Align's common stock as part of Align's \$600.0 million stock repurchase program announced on May 23, 2018.
- Announced that on August 22, 2018, the United States Court of Appeals for the Federal Circuit vacated the Patent Trial and Appeal Board's decision invalidating certain
  claims of Align's patent no. 6,699,037, entitled "Method and System for Incrementally Moving Teeth."

## Q1 2019 Business Outlook

For the first quarter of 2019 (Q1'19), Align provides the following guidance:

- Net revenues in the range of \$525.0 million to \$535.0 million, up approximately 20% to 22% over the same period a year ago.
- Invisalign case shipments in the range of 340 thousand to 345 thousand, up approximately 25% to 27% over the same period a year ago.
- Operating margin in the range of 15.1% to 16.1%.
- Diluted EPS in the range of \$0.78 to \$0.84.

## Align Web Cast and Conference Call

Align will host a conference call today, January 29, 2019 at 4:30 p.m. ET, 1:30 p.m. PT, to review its fourth quarter and year ended 2018 results, discuss future operating trends and the business outlook. The conference call will also be web cast live via the Internet. To access the webcast, go to the "Events & Presentations" section under Company Information on Align's Investor Relations web site at <a href="http://investor.aligntech.com">http://investor.aligntech.com</a>. To access the conference call, please dial 201-689-8261. An archived audio web cast will be available beginning approximately on hour after the call's conclusion and will remain available for approximately 12 months. Additionally, a telephonic replay of the call can be accessed by dialing 877-660-6853 with conference number 13685779 followed by #. For international callers, please dial 201-612-7415 and use the same conference number referenced above. The telephonic replay will be available through 5:30 p.m. ET on February 12, 2019.

# About Align Technology, Inc.

Align Technology designs and manufactures the Invisalign® system, the most advanced clear aligner system in the world, and iTero® intraoral scanners and services. Align's products help dental professionals achieve the clinical results they expect and deliver effective, cutting-edge dental options to their patients. Visit <a href="www.aligntech.com">www.aligntech.com</a> for more information.

For additional information about the Invisalign system or to find an Invisalign doctor in your area, please visit <a href="https://www.invisalign.com">www.invisalign.com</a>. For additional information about iTero digital scanning system, please visit <a href="https://www.invisalign.com">www.invisalign.com</a>. For additional information about iTero digital scanning system, please visit <a href="https://www.invisalign.com">www.invisalign.com</a>. For additional information about iTero digital scanning system, please visit <a href="https://www.invisalign.com">www.invisalign.com</a>. For additional information about iTero digital scanning system, please visit <a href="https://www.invisalign.com">www.invisalign.com</a>.

# Forward-Looking Statement

This news release, including the tables below, contains forward-looking statements, including statements regarding certain business metrics for the first quarter of 2019, including, but not limited to, anticipated net revenues, gross margin, operating expenses, operating profit, diluted earnings per share, tax rate and case shipments. Forward-looking statements contained in this news release and the tables below relating to expectations about future events or results are based upon information available to Align as of the date hereof. Readers are cautioned that these forward-looking statements are only predictions and are subject to risks, uncertainties and assumptions that are difficult to predict. As a result, actual results may differ materially and adversely from those expressed in any forward-looking statement. Factors that might cause such a difference include, but are not limited to, difficulties predicting customer and consumer purchasing behavior, Align's ability to protect its intellectual property rights, continued compliance with regulatory requirements, competition from existing and new competitors, the willingness and ability of our customers to maintain and/or increase product utilization in sufficient numbers, the possibility that the development and release of new products does not proceed in accordance with the anticipated timeline, the possibility that the market for the sale of these new products may not develop as expected, or that the expected benefits of new or existing business relationships will not be achieved as anticipated, the risks relating to Align's ability to sustain or increase profitability or revenue growth in future periods while controlling expenses, growth related risks, including excess or constrained capacity at our manufacturing and treat operations facilities and pressure on our internal say result of, among other things, prevailing economic conditions, levels of employment, salaries and wages and consumer demand for our existing and new products, changes in consumer s

# ALIGN TECHNOLOGY, INC. UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS\* (in thousands, except per share data)

	Three Months End December 31,	led	Year Ended December 31,			
	2018	2017	2018	2017		
Net revenues	\$ 534,020	\$ 421,323	\$ 1,966,492	\$ 1,473,413		
Cost of net revenues	150,924	103,406	518,625	356,466		
Gross profit	383,096	317,917	1,447,867	1,116,947		
Operating expenses: Selling, general and administrative Research and development	226,819 35,804	182,141 26,170	852,404 128,899	665,777 97,559		

Total operating expenses	262,623		208,311	981,303		7	763,336
Income from operations Interest income Other income (expense), net	120,473 2,249 (730	)	109,606 2,486 95	466,564 8,576 (8,489	)	6	353,611 6,948 4,240
Net income before provision for income taxes and equity in losses of investee	121,992		112,187	466,651		3	364,799
Provision for income taxes** Equity in losses (gains) of investee, net of tax	22,517 2,083		103,654 (1,731 )	57,723 8,693			130,162 3,219
Net income	\$ 97,392	\$	10,264	\$ 400,235	,	\$ 2	231,418
Net income per share: Basic Diluted	\$ 1.22 \$ 1.20		0.13 0.13	5 5.00 5 4.92			2.89 2.83
Shares used in computing net income per share: Basic Diluted	79,891 80,943		80,080 81,863	80,064 81,357			80,085 81,832

<sup>\*</sup> During Q1'18, we adopted the ASC 606, "Revenues from Contracts with Customers" using the full retrospective method. The adoption of ASC 606 did not have a material impact on our Condensed Consolidated Statements of Operations presented herein.

ALIGN TECHNOLOGY, INC.
UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS\*
(in thousands)

ASSETS	Dec 201	cember 31, 8	Dec 201	cember 31, 17
Current assets: Cash and cash equivalents Marketable securities, short-term Accounts receivable, net Inventories Prepaid expenses and other current assets Total current assets	\$	636,899 98,460 439,009 55,641 72,470 1,302,479	\$	449,511 272,031 324,189 31,688 80,948 1,158,367
Marketable securities, long-term Property, plant and equipment, net Equity method investments Goodwill and intangible assets, net Deferred tax assets Other assets	\$	9,112 521,329 45,913 81,949 64,689 26,987	\$	39,948 348,793 54,606 89,068 49,334 43,893
LIABILITIES AND STOCKHOLDERS' EQUITY				
Current liabilities: Accounts payable Accrued liabilities Deferred revenues Total current liabilities	\$	64,256 234,679 393,138 692,073	\$	36,776 195,562 267,713 500,051
Income tax payable Other long-term liabilities Total liabilities		78,008 29,486 799,567		114,091 15,579 629,721
Total stockholders' equity		1,252,891		1,154,288
Total liabilities and stockholders' equity	\$	2,052,458	\$	1,784,009

<sup>\*</sup> During Q1'18, we adopted the ASC 606, "Revenues from Contracts with Customers" using the full retrospective method. Condensed Consolidated Balance Sheet as of December 31, 2017 has been recasted to comply with the adoption.

ALIGN TECHNOLOGY, INC. UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS\* (in thousands)

<sup>\*\*</sup> During Q4'17, the U.S. Tax Cuts and Jobs Act was enacted into law and we recorded the tax impacts in our provision for income taxes.

CASH FLOWS FROM OPERATING ACTIVITIES  Net cash provided by operating activities	\$ 554,681	\$ 438,539	
CASH FLOWS FROM INVESTING ACTIVITIES  Net cash provided by (used in) investing activities	6,927	(251,477	)
CASH FLOWS FROM FINANCING ACTIVITIES  Net cash used in financing activities  Effect of foreign exchange rate changes on cash, cash equivalents, and restricted cash  Net decrease in cash, cash equivalents, and restricted cash  Cash, cash equivalents, and restricted cash at beginning of the period  Cash, cash equivalents, and restricted cash at end of the period	(369,434 (4,733 187,441 450,125 \$ 637,566	) (135,500 ) 5,544 57,106 393,019 \$ 450,125	)

<sup>\*</sup>During Q1'18, we adopted ASU 2016-18, "Statement of Cash Flows - Restricted Cash" on a retrospective basis. Condensed Consolidated Statement of Cash Flows for the year ended December 31, 2017 has been recasted to comply with the adoption.

ALIGN TECHNOLOGY, INC. INVISALIGN BUSINESS METRICS\*

	Q4 2017		Fiscal 2017		Q1 2018		Q2 2018		Q3 2018		Q4 2018		Fiscal 2018	
Invisalign Average Selling Price (ASP):														
Worldwide ASP	\$ 1,305		\$ 1,295		\$ 1,310		\$ 1,315		\$ 1,230		\$ 1,235		\$ 1,270	
International ASP	\$ 1,400		\$ 1,375		\$ 1,435		\$ 1,425		\$ 1,340		\$ 1,295		\$ 1,370	
Invisalign Cases Shipped by Geography:														
Americas	155,625		586,205		166,665		181,425		190,615		189,410		728,115	
International	99,405		344,840		105,570		121,260		128,730		144,390		499,950	
Total Cases Shipped	255,030		931,045		272,235		302,685		319,345		333,800		1,228,065	
YoY % growth	34.2	%	31.4	%	30.8	%	30.5	%	35.3	%	30.9	%	31.9	%
QoQ % growth	8.0	%			6.7	%	11.2	%	5.5	%	4.5	%		
Number of Invisalign Doctors Cases Were Shipped To:														
Americas	26,480		38,230		27,105		28,280		28,890		29,215		42,000	
International	18,505		26,175		19,700		21,805		23,270		25,475		36,040	
Total Doctors Cases Shipped To	44,985		64,405		46,805		50,085		52,160		54,690		78,040	
Invisalign Doctor Utilization Rates**:														
North America	6.0		15.8		6.3		6.6		6.9		6.7		18.2	
North American Orthodontists	14.0		46.6		15.3		16.4		17.4		16.5		56.7	
North American GP Dentists	3.3		8.2		3.4		3.6		3.5		3.6		9.1	
International	5.4		13.2		5.4		5.6		5.5		5.7		13.9	
Total Utilization Rates	5.7		14.5		5.8		6.0		6.1		6.1		15.7	
Number of Invisalign Doctors Trained***:														
Americas	1,760		6,615		1,630		1,880		2,085		2,290		7,885	
International	2,400		10,215		2,645		3,300		2,845		2,980		11,770	
Total Doctors Trained Worldwide	4,160		16,830		4,275		5,180		4,930		5,270		19,655	
Total to Date Worldwide	132,300		132,300		136,575		141,755		146,685		151,955		151,955	

Note: Historical public data may differ due to rounding. Additionally, rounding may effect totals. Effective Q1'18, Americas region includes North America and LATAM. International region includes EMEA and APAC. We have recasted historical data to reflect the change.

ALIGN TECHNOLOGY, INC. STOCK-BASED COMPENSATION (in thousands)

	Q4	Fiscal	Q1	Q2	Q3	Q4	Fiscal
	2017	2017	2018	2018	2018	2018	2018
Stock-based Compensation (SBC)							
SBC included in Gross Profit	\$ 804	\$ 3,330	\$ 881	\$ 900	\$ 966	\$ 948	\$ 3,695
SBC included in Operating Expenses	14,026	55,524	14,949	15,990	18,232	17,897	67,068
Total SBC Expense	\$ 14,830	\$ 58,854	\$ 15,830	\$ 16,890	\$ 19,198	\$ 18,845	\$ 70,763

<sup>\*</sup> Invisalign business metrics exclude SmileDirectClub aligners.

<sup>\*\* #</sup> of cases shipped / # of doctors to whom cases were shipped. LATAM utilization rate is not separately disclosed, but included in the total utilization rates.

<sup>\*\*\*2018</sup> and 2017 adjusted to reflect Americas doctors trained for Invisalign iGo

The outlook figures provided below and elsewhere in this press release are approximate in nature since Align's business outlook is difficult to predict. Align's future performance involves numerous risks and uncertainties and the company's results could differ materially from the outlook provided. Some of the factors that could affect Align's future financial performance and business outlook are set forth under "Forward Looking Information" above in this press release.

## **Financial Outlook**

(in millions, except per share amounts and percentages)

	Q1'19 Guidance
	GAAP
Net Revenues	\$525.0 - \$535.0
Gross Margin	70.3% - 71.0%
Operating Expenses	\$289.8 - \$293.8
Operating Margin	15.1% - 16.1%
Net Income per Diluted Share	\$0.78 - \$0.84
Business Metrics:	Q1'19
Case Shipments Capital Expenditure Depreciation & Amortization Diluted Shares Outstanding Stock Based Compensation Expense Effective Tax Rate	340.0K - 345.0K \$60M - \$65M \$19M - \$20M 80.9M (2) \$19.9M ~16% (1)

- (1) Includes excess tax benefits related to share-based compensation expense pursuant to ASU 2016-09
- (2) Excludes any stock repurchases during the quarter

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Source: Align Technology, Inc.