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 Second Quarter 2018 Financial Results

July 25, 2018

- Q2 revenues up 37.5% year-over-year to a record \$490.3 million, and diluted EPS of \$1.30
- Q2 operating income up 46.8% year-over-year to \$122.7 million, operating margin of 25.0%
- Q2 total Invisalign case shipments up 30.5% year-over-year to 302.7 thousand
- Q2 Invisalign cases for teenage patients up 42.1% year-over-year to 78.4 thousand
- Q2 iTero scanner and services revenues up 60.9% year-over-year to \$57.0 million

SAN JOSE, Calif., July 25, 2018 (GLOBE NEWSWIRE) -- Align Technology, Inc. (Nasdaq:ALGN) today reported financial results for the second quarter ended June 30, 2018. Invisalign case shipments in the second quarter of 2018 (G2/18) were 302.7 thousand, up 30.5% year-over-year. Americas and International region case shipments were up year-over-year 22.2% and 45.4%, respectively. Q2'18 Invisalign cases for teenage patients were 78.4 thousand, up 42.1% year-over-year. Q2'18 revenues were \$490.3 million, up 37.5% year-over-year and Q2'18 operating income was \$122.7 million, up 48.8% year-over-year resulting in an operating margin of 25.0%. Net profit was \$106.1 million, or \$1.30 per diluted share, up \$0.45 year-over-year.

Commenting on Align's Q2 2018 results, Align Technology President and CEO Joe Hogan said, "I'm pleased to report another better than expected quarter for Align. Our second quarter results reflect strong growth across our customer channels with record volume in all regions and in almost every country market. Year-over-year revenue growth of 37.5% was driven by continued momentum from Invisalign doctors and increased adoption of Invisalign treatment for teenage patients which grew 42.1%. Q2 Invisalign volume growth of 30.5% year-over-year reflects increased utilization and expansion of our customer base, which was over 50,000 for the first time and included more than 5,000 new Invisalign-trained doctors. We also saw momentum from the iTero scanner and services business which includes the continued rollout of Tero scanner across Heartland Dental's installed base, as well as the first iTero scanner shipments to China."

GAAP Summary Financial Comparisons Second Quarter Fiscal 2018

	Q2'18	Q1'18	Q2'17	Q/Q Change	Y/Y Change
Invisalign Case Shipments ¹	302,685	272,235	231,890	+11.2%	+30.5%
Net Revenues	\$490.3M	\$436.9M	\$356.5M	+12.2%	+37.5%
Clear Aligner ²	\$433.3M	\$385.5M	\$321.0M	+12.4%	+35.0%
Scanner & Services	\$57.0M	\$51.4M	\$35.4M	+10.9%	+60.9%
Net Profit	\$106.1M	\$95.9M	\$69.2M	+10.7%	+53.4%
Diluted EPS	\$1.30	\$1.17	\$0.85	+\$0.13	+\$0.45

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

¹ Invisalign shipment figures do not include SmileDirectClub aligners

² Clear aligner revenue includes revenues from Invisalign clear aligners and SmileDirectClub aligners

As of June 30, 2018, Align had \$720.7 million in cash, cash equivalents and marketable securities compared to \$673.0 million as of March 31, 2018. In May 2018, we announced an additional \$600 million stock buy-back authorization. We also have \$100 million remaining under the April 2016 repurchase program, which we expect to utilize during the remainder of 2018.

Announcements and Highlights

 Today, Align issued a separate press release announcing that the Company has opened new facilities in Costa Rica to support continued long term growth. The Company hosted a grand opening celebration on Friday, July 20 attended by Costa Rican President Carlos Alvarado Quesada and local government officials. Today, the Company also announced that it has received Certificate of Medical Device Registration and Certificate of Production from the China Food and Drug Administration (CFDA) to manufacture the iTero Element intraoral scanner in China. Align had previously announced in April that it had received approval from the CFDA to market the iTero Element intraoral scanner in China.

Q2 2018 Company Highlights. During the second quarter Align announced the following:

- The One Millionth Invisalign case for the Europe, Middle East and Africa ("EMEA") region. This is a significant milestone for the Company with more than 34 thousand Invisalign-trained orthodontists and general dentists in the region and reflects accelerating adoption of Invisalign clear aligner therapy in EMEA.
- Eleven recipients of research grants under the Company's Annual Research Award Program. Now in its ninth year of funding, nearly \$300,000 has been awarded for 2018 to researchers at universities in the Americas, Europe, and Asia Pacific regions.
- The grand opening of the first Invisalign treatment planning facility in Europe, located in Cologne, Germany. The Cologne facility is one of only three Invisalign treatment planning facilities in the world and reflects the rapid growth and expansion of Align globally. It serves as a training facility for Invisalign doctors within the German-speaking market, providing clinical education and support in local language for doctors in Germany, Austria, Switzerland and Lichtenstein.
- The extension of the Invisalign product family with Invisalign First clear aligners, designed with features specifically for younger patients with early mixed dentition (mixture of primary/baby and permanent teeth). Phase 1 treatment is early interceptive orthodontic treatment for young patients, traditionally done through arch expanders, or partial metal braces, before all permanent teeth have erupted typically at ages 6 through 10 years. Invisalign First clear aligners are designed specifically to address a broad range of younger patients' malocclusions, including shorter clinical crowns, management of erupting dentition, and predictable dental arch expansion.
- A new expanded Invisalign product portfolio that includes new options and greater flexibility to treat a broader range of patients. The new Invisalign product portfolio offers doctors more choices by extending desirable features across the entire portfolio and creating new Invisalign Treatment Packages, as well as new options to treat young patients with early mixed dentition. The new end-to-end Invisalign portfolio now includes clear aligner product offerings for almost every patient age group and case complexity to make it easier for doctors to tailor treatment planning to the needs of each unique patient.
- The new Invisalign Go product with a more user-friendly iTero digital chairside experience and greater flexibility to treat a wider range of mild to moderate cases such as crowded or gap teeth that require teeth straightening prior to restorative treatments. Invisalign Go also incorporates new data-driven clinical protocols for predictable tooth movement and automated case assessments that leverage over 5.5 million Invisalign patients treated to date. These improvements make it easier for dentists to tailor their treatment plans to the individual needs of each patient.
- The commercial availability of Vivera Retainers with Precision Bite Ramps, the first retainers in the market that can be customized to provide additional support after deep bite correction. First introduced in 2014 with Invisalign G5 Innovations, Precision Bite Ramps are designed to disocclude the posterior teeth or "open the bite" for improved efficiency in deep bite Invisalign treatments.

- The expansion of the iTero Element portfolio with the launch of the iTero Element 2 and the iTero Element Flex scanners. These additions build on the existing high precision, full-color imaging and fast scan times of the iTero Element portfolio. The next-generation iTero Element 2 is designed for greater performance with 2X faster start-up and 25% faster scan processing time compared to the iTero Element.
- Regulatory approval from the China Food and Drug Administration (CFDA) to market the iTero Element intraoral scanner in China.

Q3 2018 Business Outlook

For the third quarter of 2018 (Q3'18), Align provides the following guidance:

- Net revenues in the range of \$493 million to \$503 million, up approximately 28% to 31% over the same period a year ago
- Invisalign case shipments in the range of 302 thousand to 307 thousand, up approximately 28% to 30% over the same period a year ago
- Operating margin in the range of 24.2% to 24.9%
- Diluted EPS in the range of \$1.13 to \$1.18

Align Web Cast and Conference Call

Align will host a conference call today, July 25, 2018 at 4:30 p.m. ET, 1:30 p.m. PT, to review its second quarter 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 http://investor.aligntech.com. To access the conference call, please dial 201-689-8261. An archived audio web cast will be available beginning approximately one 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 13681104 followed by #. For international callers, please dial 201-612-7415 and use the same conference above. The telephonic replay will be available through 5:30 p.m. ET on August 8, 2018.

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 <u>www.aligntech.com</u> for more information.

For additional information about the Invisalign system or to find an Invisalign doctor in your area, please visit <u>www.invisalign.com</u>. For additional information about iTero digital scanning system, please visit <u>www.itero.com</u>.

Forward-Looking Statement

This news release, including the tables below, contains forward-looking statements, including statements regarding certain business metrics for the third guarter of 2018, including, but not limited to. anticipated net revenues, gross margin, operating expenses, operating profit, diluted earnings per share, tax rate including the financial impact of recent U.S. Tax Cuts and Jobs Act 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, risks relating to international sales, which are increasingly a larger portion of our total revenues, 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 capacity constraints and pressure on our internal systems and personnel, the security of customer and/or patient data is compromised for any reason, continued customer demand for our existing and new products, changes in consumer spending habits as a result of, among other things, prevailing economic conditions, levels of employment, salaries and wages and consumer confidence, the timing of case submissions from our doctors within a quarter, acceptance of our products by consumers and dental professionals, changes to our interpretation of the U.S. Tax Cuts and Jobs Act which may change as we receive additional clarification and implementation guidance, possibly materially, foreign operational, political and other risks relating to Align's international manufacturing operations, litigation risks, uncertainties involved in any contract dispute resolution and the possibility of Align choosing to settle the litigation for business or other reasons. Align's ability to develop and successfully introduce new products and product enhancements and the loss of key personnel. These and other risks are detailed from time to time in Align's periodic reports filed with the Securities and Exchange Commission, including, but not limited to, its Annual Report on Form 10-K for the year ended December 31, 2017, which was filed with the Securities and Exchange Commission (SEC) on February 28, 2018. Align undertakes no obligation to revise or update publicly any forward-looking statements for any reason.

ALIGN TECHNOLOGY, INC.

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS* (in thousands, except per share data)

	Three Months End June 30, 2018	led 2017	Six Months Endec June 30, 2018	2017
Net revenues	\$ 490,259	\$ 356,482	\$ 927,183	\$ 666,823
Cost of net revenues	124,677	85,565	234,193	160,281
Gross profit	365,582	270,917	692,990	506,542
Operating expenses: Selling, general and administrative Research and development Total operating expenses	212,087 30,804 242,891	162,964 24,384 187,348	411,712 60,395 472,107	314,112 47,188 361,300
Income from operations Interest income Other income (expense), net	122,691 1,917 (7,099)	83,569 1,441 1,771	220,883 4,093 (6,922)	145,242 2,636 2,221
Net income before provision for income taxes and equity in losses of investee	117,509	86,781	218,054	150,099
Provision for income taxes Equity in losses of investee, net of tax	7,703 3,701	15,387 2,215	10,605 5,478	8,164 3,336
Net income	\$ 106,105	\$ 69,179	\$ 201,971	\$ 138,599
Net income per share: Basic Diluted	\$ 1.32 \$ 1.30	\$ 0.86 \$ 0.85	\$ 2.52 \$ 2.48	\$ 1.73 \$ 1.70
Shares used in computing net income per share: Basic Diluted	80,216 81,471	80,188 81,631	80,127 81,575	80,047 81,668

* 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)

	Ju 20	ne 30, 18	De 201	ember 31, 7	
ASSETS					
Current assets:					
Cash and cash equivalents	\$	547,993	\$	449,511	
Marketable securities, short-term		164,629		272,031	
Accounts receivable, net		374,371		324,189	
Inventories		47,252		31,688	
Prepaid expenses and other current assets		126,754		80,948	
Total current assets		1,260,999		1,158,367	
Marketable securities, long-term		8,061		39,948	
Property, plant and equipment, net		447,933		348,793	
Equity method investments		49,128		54,606	
Goodwill and intangible assets, net		85,307		89,068	
Deferred tax assets		45,859		49,334	
Other assets		19,302		43,893	
Total assets	\$	1,916,589	\$	1,784,009	
LIABILITIES AND STOCKHOLDERS' EQUITY					
Current liabilities:					
Accounts payable	\$	48,744	\$	36,776	
Accrued liabilities		196,754		195,562	
Deferred revenues		321,148		267,713	
Total current liabilities		566,646		500,051	
Income tax payable		115,701		114,091	
Other long-term liabilities		15,283		15,579	
Total liabilities		697,630		629,721	
Total stockholders' equity		1,218,959		1,154,288	
Total liabilities and stockholders' equity	\$	1,916,589	\$	1,784,009	

* 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)

	Six Months End June 30, 2018	ed 2017	
CASH FLOWS FROM OPERATING ACTIVITIES Net income	\$ 201,971	\$ 138,599	
Net cash provided by operating activities	217,121	158,088	
CASH FLOWS FROM INVESTING ACTIVITIES Net cash provided by (used in) investing activities	54,003	(111,718)
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 increase (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	(170,745 (1,923 98,456 450,125 \$ 548,581) (84,240) 3,640 (34,230 393,019 \$ 358,789)

*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 six months ended June 30, 2017 has been recasted to comply with the adoption.

	Q1 2017		Q2 2017		Q3 2017		Q4 2017		Fiscal 2017		Q1 2018		Q2 2018	
Invisalign Average Selling Price (ASP):														
Worldwide ASP	\$ 1,270		\$ 1,285		\$ 1,310		\$ 1,305		\$ 1,295		\$ 1,310		\$ 1,315	
International ASP	\$ 1,345		\$ 1,340		\$ 1,395		\$ 1,400		\$ 1,375		\$ 1,435		\$ 1,425	
Invisalign Cases Shipped by Geography:														
Americas	134,450		148,470		147,660		155,625		586,205		166,665		181,425	
International	73,610		83,420		88,405		99,405		344,840		105,570		121,260	
Total Cases Shipped	208,060		231,890		236,065		255,030		931,045		272,235		302,685	
YoY % growth	27.1	%	31.0	%	32.8	%	34.2	%	31.4	%	30.8	%	30.5	%
QoQ % growth	9.5	%	11.5	%	1.8	%	8.0	%			6.7	%	11.2	%
Number of Invisalign Doctors Cases Were Shipped To:														
Americas	24,595		25,570		25,865		26,480		38,230		27,105		28,280	
International	14,270		15,695		16,740		18,505		26,175		19,700		21,805	
Total Doctors Cases Shipped To	38,865		41,265		42,605		44,985		64,405		46,805		50,085	
Invisalign Doctor Utilization Rates**:														
North America	5.6		5.9		5.8		6.0		15.8		6.3		6.6	
North American Orthodontists	12.6		13.6		13.8		14.0		46.6		15.3		16.4	
North American GP Dentists	3.1		3.3		3.1		3.3		8.2		3.4		3.6	
International	5.2		5.3		5.3		5.4		13.2		5.4		5.6	
Total Utilization Rates	5.4		5.6		5.5		5.7		14.5		5.8		6.0	
Number of Invisalign Doctors Trained:														
Americas	1,040		1,820		1,740		1,685		6,285		1,605		1,795	
International	2,220		3,055		2,540		2,400		10,215		2,645		3,300	
Total Doctors Trained Worldwide	3,260		4,875		4,280		4,085		16,500		4,250		5,095	
Total to Date Worldwide	118,730		123,605		127,885		131,970		131,970		136,220		141,315	

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.

* Invisalign business metrics exclude SmileDirectClub aligners.

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

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

	Q1 2017	Q2 2017	Q3 2017	Q4 2017	Fiscal 2017	Q1 2018	Q2 2018
Stock-based Compensation (SBC)							
SBC included in Gross Profit	\$ 925	\$ 768	\$ 833	\$ 804	\$ 3,330	\$ 881	\$ 900
SBC included in Operating Expenses	13,887	13,477	14,134	14,026	55,524	14,949	15,990
Total SBC Expense	\$ 14,812	\$ 14,245	\$ 14,967	\$ 14,830	\$ 58,854	\$ 15,830	\$ 16,890

ALIGN TECHNOLOGY, INC. BUSINESS OUTLOOK SUMMARY (unaudited)

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.

\$60M - \$65M

Financial Outlook

Capital Expenditure

(in millions, except per share amounts and percentages)

	Q3'18 Guidance	
	GAAP	
Net Revenues	\$493 - \$503	
Gross Margin	74.0% - 74.4%	
Operating Expenses	\$245 - \$249	
Operating Margin	24.2% - 24.9%	
Net Income per Diluted Share	\$1.13 - \$1.18	(1, 2)
Business Metrics:	Q3'18	
Case Shipments	302K - 307K	

Depreciation & Amortization	\$10M - \$11M	
Diluted Shares Outstanding	81.6M	(2)
Stock Based Compensation Expense	\$18.8M	
Effective Tax Rate	~21%	(1)

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

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Primary Logo

Source: Align Technology, Inc.