

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 First Quarter 2020 Financial Results

April 29, 2020

Achieves 2 Millionth Invisalign Teen Patient Milestone

- Q1 total revenues of \$551.0 million, compared to \$549.0 million in Q1'19
- Q1 GAAP earnings per diluted share (EPS) of \$19.21, Q1 non-GAAP EPS of \$0.73
- Q1 Invisalign volume of 359.4 thousand cases, compared to 349.2 thousand cases in Q1'19
- Q1 Invisalign cases for teenage patients of 104.0 thousand cases, 29% of total volume, compared to 97.4 thousand cases, up 1 point vs. Q1'19
- Q1 scanner and services revenues of \$69.4 million, compared to \$79.8 million in Q1'19

SAN JOSE, Calif., April 29, 2020 (GLOBE NEWSWIRE) -- Align Technology, Inc. (Nasdaq: ALGN) today reported financial results for the first quarter (Q1'20). Q1'20 total revenues were \$551.0 million, up 0.4% year-over-year. Q1'20 clear aligner revenues were \$481.6 million, up 2.6% year-over-year and Q1'20 scanner and services revenues were \$69.4 million, down 13.1% year-over-year. Q1'20 Invisalign volume was 359.4 thousand cases, up 2.9% year-over-year. For the Americas and International regions, Q1'20 Invisalign volume was up 5.2% and down 0.2% year-over-year, respectively. Q1'20 Invisalign volume for teenage patients was 104,000 cases, up 6.8% year-over-year. Q1'20 operating income of \$69.9 million was down 20.3% year-over-year resulting in an operating margin of 12.7%. Q1'20 GAAP net income was \$1.5 billion, or \$19.21 per diluted share. On a non-GAAP basis, Q1'20 net income was \$57.9 million, or \$0.73 per diluted share.

Commenting on Align's Q1'20 results, Align Technology President and CEO Joe Hogan said, "For Q1'20, total revenues were \$551 million, down 15.2% sequentially and unchanged year-over-year, reflecting significantly lower than expected sales of Invisalign clear aligners and iTero scanners due to the COVID-19 pandemic. Revenues from clear aligners were \$481.6 million and iTero scanner & services were \$69.4 million. Clear aligner shipments were 359.4 thousand cases. Notwithstanding the impact of COVID-19, shipment volumes were up 2.9% year-over-year, reflecting solid growth from non-comprehensive products driven by the Invisalign Go system across all regions, as well as Invisalign Moderate. This was offset by a lower mix of comprehensive products due primarily to the shortfall in China."

Hogan added the following comments regarding Align's first quarter results, "Through early March, China was progressing in line with our original guidance and our other regions were performing ahead of our outlook. However, the situation quickly changed in mid-March as most governments in EMEA and North America closed non-essential businesses and initiated stay at home orders. As a result, the vast majority of Invisalign practices shut down and stopped seeing patients and our business fell off sharply. At the same time, while EMEA, North America, and other parts of APAC fell off in March, we began to see improvements in China as the country started to open up again."

Summary Financial Comparisons First Quarter Fiscal 2020

	Q1'20	Q4'19	Q1'19	Q/Q Change	Y/Y Change
GAAP					
Invisalign Case Shipments ¹	359,440	413,715	349,195	(13.1)%	+2.9%
Net Revenues	\$551.0M	\$649.8M	\$549.0M	(15.2)%	+0.4%
Clear Aligner ²	\$481.6M	\$543.6M	\$469.2M	(11.4)%	+2.6%
Scanner & Services	\$69.4M	\$106.2M	\$79.8M	(34.7)%	(13.1)%
Net Profit	\$1,518.1B	\$121.3M	\$71.8M	+1,152%	+2,013%
Diluted EPS	\$19.21	\$1.53	\$0.89	+\$17.68	+\$18.32
Non-GAAP					
Net Profit	\$57.9M	\$139.4M	\$100.5M	(58.4)%	(42.4)%
Diluted EPS	\$0.73	\$1.76	\$1.25	\$(1.03)	\$(0.52)

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

¹ Invisalign shipments do not include SmileDirectClub ("SDC") aligners.

² Clear aligner revenues include Invisalign clear aligners and SDC aligners. The supply agreement with SDC terminated December 31, 2019 and was not renewed.

As of March 31, 2020, Align had \$790.7 million in cash, cash equivalents and marketable securities compared to \$868.6 million as of December 31, 2019. On April 1, 2020, we acquired privately held exocad Global Holdings GmbH (exocad) for a cash purchase price of approximately \$430 million. Additionally, we have \$100.0 million remaining available for repurchase of our common stock under our May 2018 Repurchase Program.

Align Announcement Highlights:

Corporate

- Announced the following contributions towards relief efforts in response to COVID-19:
 - Pledged RMB 1 million donation to the Chinese Red Cross Foundation to support its ongoing prevention and control efforts for the outbreak in China.
 - The Align Technology Foundation, Align's donor-advised fund through Fidelity Charitable, pledged US \$1 million donation to support relief efforts globally. In addition, Align will donate personal protective equipment (PPE) such as N95 masks, working with partners to source supplies for any additional PPE to help hospitals and healthcare providers treating patients with COVID-19. As the world's largest manufacturer of custom 3D-printed materials, Align will also reach out to public and private sector organizations to offer its technology expertise and counsel on ways to reduce the scarcity of parts and materials for public health needs. Additionally, Align will explore options to convert its custom manufacturing and tooling equipment to help meet critical needs.
- Announced the acquisition of privately held exocad, a global leader in the dental CAD/CAM software market that offers fully integrated workflows to dental labs and dental practices via a broad customer base of partners and resellers in over 150 countries. The acquisition of exocad broadens Align's digital platform reach by adding technology that addresses restorative needs in an end-to-end digital platform workflow to facilitate ortho-restorative and comprehensive dentistry. The acquisition brings exocad's expertise in restorative dentistry, implantology, guided surgery, and smile design to the Align technology portfolio.
- Announced the creation of a combined product innovation and marketing organization to further extend its lead in digital orthodontics and dentistry by enabling greater organizational speed, agility and impact across customer channels and consumers. The new Product, Innovation, and Marketing organization led by Raj Pudipeddi, Align senior vice president and chief marketing, product and business development officer, combines IT and R&D with Product Management and Global Marketing under one integrated organization responsible for the entire product lifecycle, from customer insights and ideation, to product innovation designing delightful customer and consumer experiences on the Align digital platform, to commercialization and go-to-market strategy.

Product

- Launched ClinCheck® "In-Face" visualization tool for the Invisalign Go system, Align's innovative tooth movement system designed for general dentists. The ClinCheck In-Face Visualization tool enhances the digital treatment planning experience for doctors and their patients by incorporating a front-facing smile image of a patient's face

into their ClinCheck treatment plan.

- Received U.S. Food and Drug Administration (FDA) 510(K) clearance for the award-winning iTero Element 5D Imaging System for commercial availability in the United States. The iTero Element 5D Imaging System expands the suite of existing high-precision, full-color imaging and fast scan times of the iTero Element intraoral scanner portfolio with a new clinical approach, optimized orthodontic and restorative dental workflows, and an improved doctor experience.

Business Outlook

Due to the uncertain scope and duration of the pandemic, and uncertain timing of the global recovery and economic normalization, we cannot at this time estimate the future impact on our operations and financial results. Accordingly, we are not providing guidance for the second quarter of fiscal year 2020 and are withdrawing our full year 2020 guidance.

Align Web Cast and Conference Call

Align will host a conference call today, April 29, 2020 at 4:30 p.m. ET, 1:30 p.m. PT, to review its first quarter 2020 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 one month. Additionally, a telephonic replay of the call can be accessed by dialing 877-660-6853 with conference number 13701221 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 May 13, 2020.

About Non-GAAP Financial Measures

To supplement our condensed consolidated financial statements, which are prepared and presented in accordance with generally accepted accounting principles in the United States ("GAAP"), we may provide investors with certain non-GAAP financial measures including, non-GAAP gross profit, gross margin, operating expenses, income from operations, operating margin, interest income and other income (expense), net, provision for (benefit from) income taxes, effective tax rate, net income and diluted EPS, which exclude certain items that may not be indicative of our fundamental operating performance including discrete cash and non-cash charges or gains that are included in the most directly comparable GAAP measure. Non-GAAP measures will exclude the effects of stock-based compensation, non-cash deferred tax assets and associated amortization related to intra-entity transfer of non-inventory assets, acquisition related costs, impairments and other (gains) charges, and litigation settlement gains, and, if applicable, any associated tax impacts.

We use non-GAAP financial measures for financial and operational decision-making and as a means to evaluate period-to-period comparisons. Our management believes that these non-GAAP financial measures provide meaningful supplemental information regarding our recurring core operating performance. We believe that both management and investors benefit from referring to these non-GAAP financial measures in assessing our performance and when planning, forecasting and analyzing future periods. These non-GAAP financial measures also facilitate management's internal evaluation of period-to-period comparisons. We believe these non-GAAP financial measures are useful to investors both because (1) they allow for greater transparency with respect to key metrics used by management in its financial and operational decision-making and (2) they will be provided to and used by our institutional investors and the analyst community to help them analyze the performance of our business.

There are limitations to using non-GAAP financial measures, though, because they are not prepared in accordance with GAAP and may be different from non-GAAP financial measures used by other companies. The non-GAAP financial measures are limited in value because they exclude certain items that may have a material impact upon our reported financial results. In addition, they are subject to inherent limitations as they reflect the exercise of judgments by management about which charges are excluded from the non-GAAP financial measures. We compensate for these limitations by analyzing current and future results on a GAAP as well as a non-GAAP basis and also by providing GAAP measures in our public disclosures. The presentation of non-GAAP financial information is meant to be considered in addition to, not as a substitute for or in isolation from, the directly comparable financial measures prepared in accordance with GAAP. We urge investors to review the reconciliation of our GAAP financial measures to the comparable Non-GAAP financial measures included in this presentation, and not to rely on any single financial measure to evaluate our business. For more information on these non-GAAP financial measures, please see the table captioned "Unaudited GAAP to Non-GAAP Reconciliation."

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 www.aligntech.com for more information.

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

Forward-Looking Statements

This news release, including the tables below, contains forward-looking statements, including quotations from management, statements in the paragraphs under Align Announcement Highlights regarding COVID-19 relief efforts, the acquisition of exocad and its expected impact, and new product releases and clearances. 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:

- the impact of the COVID-19 pandemic on the health and safety of our employees, customers, patients, and our suppliers as well as the physical and economic impacts of the various recommendations, orders and protocols issued by local and national governmental agencies in light of the evolving situation;
- the ability to (i) realize expected benefits in connection with the acquisition of exocad within the expected timeframes or at all, (ii) timely, cost-efficiently and effectively integrate exocad's business without adversely impacting operations of either Align or exocad, and (iii) avoid or mitigate uncertainties or liabilities in connection with the acquisition or its impacts on the value of our stock;
- difficulties predicting customer and consumer purchasing behavior and changes in consumer spending habits as a result of, among other things, prevailing economic conditions, levels of employment, salaries and wages and consumer confidence;
- expectations regarding the continued growth or declines of our domestic and/or international markets;
- increasing competition from existing and new competitors;
- rapidly evolving and groundbreaking advances that are fundamentally changing the dental industry and the way new and existing participants market and provide products and services to consumers;
- the ability to protect our intellectual property rights;
- continued compliance with regulatory requirements;
- our expectations regarding sales of our intra-oral scanners domestically and internationally and our belief that technology features and functionality of the iTero scanners and exocad technology will increase adoption of Invisalign and increase sales of our intra-oral scanners;
- 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 or enhancements to existing products do not proceed in accordance with the anticipated timeline or may themselves contain bugs or errors requiring remediation and that the market for the sale of these new or enhanced products may not develop as expected;
- a tougher consumer demand environment in China generally, especially for manufacturers and service providers whose headquarters or primarily operations are not based in China;
- the risks relating to our ability to sustain or increase profitability or revenue growth in future periods (or minimize declines) while controlling expenses;
- the impact of excess or constrained capacity at our manufacturing and treat operations facilities and pressure on our internal systems and personnel;
- the compromise of customer and/or patient data for any reason;
- the timing of case submissions from our doctors within a quarter as well as an increased manufacturing costs per case;
- foreign operational, political and other risks relating to our international manufacturing operations; and
- the loss of key personnel or work stoppages.

The foregoing and other risks are detailed from time to time in our periodic reports filed with the Securities and Exchange Commission, including, but not limited to, our Annual Report on Form 10-K for the year ended December 31, 2019, which was filed with the Securities and Exchange Commission (SEC) on February 28, 2020. We undertake no obligation to revise or update publicly any forward-looking statements for any reason.

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

	Three Months Ended March 31,	
	2020	2019
Net revenues	\$ 550,963	\$ 548,971
Cost of net revenues	156,607	146,875
Gross profit	394,356	402,096
Operating expenses:		
Selling, general and administrative	282,906	247,110
Research and development	41,532	37,503
Impairments and other charges	-	29,782
Total operating expenses	324,438	314,395
Income from operations	69,918	87,701
Interest income and other income (expense), net:		
Interest income	1,986	2,633
Other income (expense), net	(18,549)	(5,746)
Total interest income and other income (expense), net	(16,563)	(3,113)
Net income before provision for (benefit from) income taxes and equity in losses of investee	53,355	84,588
Provision for (benefit from) income taxes	(1,464,776)	8,796
Equity in losses of investee, net of tax	-	3,944
Net income	<u>\$ 1,518,131</u>	<u>\$ 71,848</u>
Net income per share:		
Basic	<u>\$ 19.32</u>	<u>\$ 0.90</u>
Diluted	<u>\$ 19.21</u>	<u>\$ 0.89</u>
Shares used in computing net income per share:		
Basic	<u>78,592</u>	<u>79,860</u>
Diluted	<u>79,028</u>	<u>80,687</u>

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

	March 31, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 790,696	\$ 550,425
Marketable securities, short-term	-	318,202
Accounts receivable, net	533,004	550,291
Inventories	120,977	112,051
Prepaid expenses and other current assets	131,848	102,450
Total current assets	1,576,525	1,633,419
Property, plant and equipment, net	663,491	631,730
Operating lease right-of-use assets, net	70,366	56,244
Goodwill and intangible assets, net	73,751	75,692
Deferred tax assets	1,551,141	64,007
Other assets	29,566	39,610
Total assets	<u>\$ 3,964,840</u>	<u>\$ 2,500,702</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 72,690	\$ 87,250

Accrued liabilities	259,459	319,958
Deferred revenues	578,537	563,762
Total current liabilities	910,686	970,970
Income tax payable	109,128	102,794
Operating lease liabilities	53,745	43,463
Other long-term liabilities	38,292	37,306
Total liabilities	1,111,851	1,154,533
Total stockholders' equity	2,852,989	1,346,169
Total liabilities and stockholders' equity	\$ 3,964,840	\$ 2,500,702

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

	Three Months Ended March 31,	
	2020	2019
CASH FLOWS FROM OPERATING ACTIVITIES		
Net cash provided by operating activities	\$ 9,784	\$ 117,207
CASH FLOWS FROM INVESTING ACTIVITIES		
Net cash provided by (used in) investing activities	276,211	(74,418)
CASH FLOWS FROM FINANCING ACTIVITIES		
Net cash used in financing activities	(34,733)	(92,762)
Effect of foreign exchange rate changes on cash, cash equivalents, and restricted cash	(11,007)	1,089
Net increase (decrease) in cash, cash equivalents, and restricted cash	240,255	(48,884)
Cash, cash equivalents, and restricted cash at beginning of the period	551,134	637,566
Cash, cash equivalents, and restricted cash at end of the period	\$ 791,389	\$ 588,682

ALIGN TECHNOLOGY, INC.
INVISALIGN BUSINESS METRICS*

	Q1 2019	Q2 2019	Q3 2019	Q4 2019	Fiscal 2019	Q1 2020
Invisalign Average Selling Price (ASP):						
Worldwide ASP	\$ 1,245	\$ 1,230	\$ 1,260	\$ 1,240	\$ 1,245	\$ 1,255
International ASP	\$ 1,330	\$ 1,305	\$ 1,330	\$ 1,300	\$ 1,315	\$ 1,340
Invisalign Cases Shipped by Geography:						
Americas	202,935	211,360	215,355	225,925	855,575	213,505
International	146,260	165,785	170,005	187,790	669,840	145,935
Total Cases Shipped	349,195	377,145	385,360	413,715	1,525,415	359,440
YoY % growth	28.3%	24.6%	20.7%	23.9%	24.2%	2.9%
QoQ % growth	4.6%	8.0%	2.2%	7.4%		-13.1%
Number of Invisalign Doctors Cases Were Shipped To:						
Americas	30,200	31,445	31,975	33,130	47,130	32,315
International	26,510	28,970	30,980	33,720	48,650	28,535
Total Doctors Cases Shipped To	56,710	60,415	62,955	66,850	95,780	60,850
Invisalign Doctor Utilization Rates**:						
North America	7.0	7.0	7.0	7.2	19.4	6.9
North American Orthodontists	18.3	18.9	19.1	19.3	65.0	18.9
North American GP Dentists	3.6	3.6	3.5	3.8	9.5	3.6
International	5.5	5.7	5.5	5.6	13.8	5.1
Total Utilization Rates	6.2	6.2	6.1	6.2	15.9	5.9
Number of Invisalign Doctors Trained:						
Americas	1,840	3,070	2,760	2,095	9,765	2,035
International	2,410	3,520	3,135	3,445	12,510	2,600
Total Doctors Trained Worldwide	4,250	6,590	5,895	5,540	22,275	4,635
Total to Date Worldwide	156,205	162,795	168,690	174,230	174,230	178,865

* 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 2019	Q2 2019	Q3 2019	Q4 2019	Fiscal 2019	Q1 2020
Stock-based Compensation (SBC)						
SBC included in Gross Profit	\$ 1,112	\$ 1,278	\$ 1,354	\$ 1,410	\$ 5,154	\$ 1,347
SBC included in Operating Expenses	19,932	21,189	22,822	19,087	83,030	21,580
Total SBC	<u>\$ 21,044</u>	<u>\$ 22,467</u>	<u>\$ 24,176</u>	<u>\$ 20,497</u>	<u>\$ 88,184</u>	<u>\$ 22,927</u>

ALIGN TECHNOLOGY, INC.
UNAUDITED GAAP TO NON-GAAP RECONCILIATION
(in thousands except per share data)

	Three Months Ended March 31,	
	2020	2019
GAAP gross profit	\$ 394,356	\$ 402,096
Stock-based compensation	1,347	1,112
Non-GAAP gross profit	\$ 395,703	\$ 403,208
GAAP gross margin	71.6%	73.2%
Non-GAAP gross margin	71.8%	73.4%
GAAP income from operations	\$ 69,918	\$ 87,701
Stock-based compensation	22,927	21,044
Acquisition related costs ⁽¹⁾	1,339	-
Impairments and other charges ⁽²⁾	-	29,782
Non-GAAP income from operations	\$ 94,184	\$ 138,527
GAAP operating margin	12.7%	16.0%
Non-GAAP operating margin	17.1%	25.2%
GAAP interest income and other income (expense), net	\$ (16,563)	\$ (3,113)
Acquisition related costs ⁽¹⁾	9,175	-
Non-GAAP interest income and other income (expense), net	\$ (7,388)	\$ (3,113)
GAAP net income before provision for (benefit from) income taxes and equity in losses of investee	\$ 53,355	\$ 84,588
Stock-based compensation	22,927	21,044
Acquisition related costs ⁽¹⁾	10,514	-
Impairments and other charges ⁽²⁾	-	29,782
Non-GAAP net income before provision for (benefit from) income taxes and equity in losses of investee	\$ 86,796	\$ 135,414
GAAP provision for (benefit from) income taxes	\$ (1,464,776)	\$ 8,796
Tax impact on non-GAAP adjustments	136	22,134
Tax related non-GAAP items	1,493,494	-
Non-GAAP provision for (benefit from) income taxes	\$ 28,854	\$ 30,930
GAAP effective tax rate	(2,745.3)%	10.4%
Non-GAAP effective tax rate	33.2%	22.8%
GAAP net income	\$ 1,518,131	\$ 71,848
Stock-based compensation	22,927	21,044
Acquisition related costs ⁽¹⁾	10,514	-
Impairments and other charges ⁽²⁾	-	29,782
Tax impact on non-GAAP adjustments	(136)	(22,134)
Tax related non-GAAP items ⁽³⁾	(1,493,494)	-
Non-GAAP net income	\$ 57,942	\$ 100,540
GAAP diluted net income per share	\$ 19.21	\$ 0.89
Non-GAAP diluted net income per share	\$ 0.73	\$ 1.25

Shares used in computing diluted net income per share

79,028

80,687

Notes:

⁽¹⁾ Includes certain incremental expenses related to the business acquisition of exocad to close in Q2'20 including third party advisory, legal, tax, accounting, banking, valuation, and other professional or consulting fees and foreign exchange losses related to a forward contract for the purchase commitment.

⁽²⁾ Q1'19 includes \$29.8 million of impairments and other charges as a result of closing our Invisalign Stores due to the arbitrator's decision regarding SDC including operating lease right-of-use asset impairments, store leasehold improvement and fixed asset impairments and employee severance and other charges.

⁽³⁾ Related to a one-time net tax benefit recorded for the deferred tax asset and certain costs associated with the intra-entity transfer of certain intellectual property rights and assets to our Swiss subsidiary.

Refer to "About Non-GAAP Financial Measures" section of press release.



Source: Align Technology, Inc.