UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 23, 2020

ALIGN TECHNOLOGY INC

(Exact name of registrant as specified in its charter)

Delaware (State or Other Jurisdiction of Incorporation) 0-32259 (Commission File Number) 94-3267295 (I.R.S. Employer Identification No.)

2820 Orchard Parkway

San Jose, California 95134 (Address of Principal Executive Offices) (Zip Code)

(408) 470-1000

(Registrant's telephone number, including area code)

Not applicable

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

□ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

□ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

□ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

□ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|----------------------------------|-------------------|---|
| Common Stock, \$0.0001 par value | ALGN | The NASDAQ Stock Market LLC |
| | | (NASDAQ Global Market) |

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company \Box

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. \Box

Item 7.01. Regulation FD Disclosure.

As previously announced on November 18, 2020, Align Technology, Inc. ("Align") is holding a virtual Investor Day today, November 23, 2020. During the virtual Investor Day, members of Align's executive management team will make presentations regarding Align, its historical and future business activities, strategies, markets, financial performance and other topics relevant to its business. The presentations will be webcast live via the Investor Relations section of Align's website at http://investor.aligntech.com.

Presentation slides will be made available prior to or concurrently with the management virtual presentations in the investor relations section of Align's website at investor.aligntech.com and an archived replay will remain on the website for approximately three months.

In advance of the event, Align issued a press release relating to matters to be discussed at the event on November 23, 2020. The full text of the press release is furnished as Exhibit 99.1 to this Form 8-K.

This information shall not be deemed "filed" for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.Description99.1Press Release of Align Technology, Inc. dated November 23, 2020 entitled, "Align Technology Hosts 2020 Virtual Investor Day"104Cover Page Interactive Data File (embedded within the Inline XBRL document)

Forward-Looking Statements

This Form 8-K, the furnished press release and the Investor Day presentations and replays of the event referred to herein contain forward-looking statements that involve a number of risks and uncertainties. Words such as "believes," "anticipates," "plans," "intends," "expects," "seeks," "estimates," and similar expressions are intended to identify forward-looking statements, but other statements that are not historical facts may also be deemed to be forward-looking statements. Important factors that could cause actual results to differ materially from those indicated by forward-looking statements include risks and uncertainties relating to: the markets for Align's products, its beliefs concerning the digital transformation of dentistry and Align's strategic priorities, its business momentum, products and product mix, the COVID-19 pandemic and its impacts on Align's business and results of operations, Align's expectations for digital adoption in dentistry and the potential impact of its products in the transition, and Align's expectations for investments in its business, including sales, marketing, development and manufacturing. Forward-looking statements 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.

Risks relating to the matters discussed above are detailed in Align's press release and Investor Day presentations and are in addition to other risks detailed from time to time by Align in its 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, 2019, which was filed with the Securities and Exchange Commission (SEC) on February 28, 2020 and its latest Quarterly Report on Form 10-Q for the quarter ended September 30, 2020, which was filed with the SEC on October 30, 2020. Align undertakes no obligation to revise or update publicly any forward-looking statements for any reason.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ALIGN TECHNOLOGY INC

Date: November 23, 2020

By: <u>/s/ John F. Morici</u> John F. Morici

Chief Financial Officer and Senior Vice President, Global Finance

Exhibit No. Description

99.1Press Release of Align Technology, Inc. dated November 23, 2020 entitled, "Align Technology Hosts 2020 Virtual Investor Day"104Cover Page Interactive Data File (embedded within the Inline XBRL document)

Align Technology Hosts 2020 Virtual Investor Day

Shares Vision to Bring Digital Orthodontics to the Masses Through Invisalign Doctors

- Huge global market opportunity of 15M annual orthodontic case starts with an incremental 500 million potential through Align's doctor-driven model and its digital platform
- Strategic priorities drive Align's 5-year revenue CAGR of more than 20%
- iTero scanner installed base of more than 35K enables more than 1M scans per month and drives Invisalign adoption

SAN JOSE, Calif., Nov. 23, 2020 (GLOBE NEWSWIRE) -- Align Technology, Inc. (NASDAQ: ALGN) announced that it is hosting a Virtual Investor Day today focused on the Align digital platform that is enabling doctors to deliver the benefits of digital orthodontics to more than 9 million patients and counting. Align Technology CEO Joe Hogan will share Align's vision and strategy of successful disruptive innovation that is accelerating a wave of digital orthodontics, bringing doctor-delivered Invisalign clear aligner treatment to more people around the world.

"Align's global Invisalign brand is vastly underpenetrated into the existing orthodontic market which we now estimate to be approximately 15 million case starts each year, 3 million more than our prior estimate, as a result of establishing and increasing our direct presence in several new markets including Brazil, Russia, Turkey, Middle East and Africa, India and Southeast Asia," said Joe Hogan, Align Technology president and CEO. "We believe digital orthodontics is inevitable and an incremental 500 million potential consumers can benefit from Invisalign treatment. Align is well positioned to enable over 189 thousand Invisalign doctors to capture this market using our products, services and digital platform. We will continue investing in resources to drive utilization and scale the Align digital platform to meet the needs of consumers, patients, and doctors globally."

Align's 2020 Virtual Investor Day will highlight the company's strategic priorities and growth drivers, including the Align digital platform, and how Invisalign treatment, iTero scanner and services, and exocad CAD/CAM software are key to unlocking the potential 500 million consumers. Align's executive team will address the company's many strengths and advantages including its global scale and operational expertise, sales and marketing initiatives, and its demand creation and customer segmentation strategies that are driving utilization and helping doctors convert more consumers into Invisalign patients. The company will also provide an update to its fourth quarter commentary.

"The strong momentum we experienced across the business in October has continued into November," said John Morici, Align Technology CFO. "Similar to the third quarter, we are continuing to see a higher mix of new Invisalign cases as compared to additional aligner cases as doctors continue to ramp up their practices. We remain committed to supporting our doctors and their practices through this recovery and beyond. Our prior investments have helped drive adoption and top line growth and we are encouraged by the return on our investments. Therefore, we are adding significant investments in sales, marketing, innovation and manufacturing capacity to continue to drive momentum and penetrate the huge market opportunity. At the same time, there continues to be uncertainty around the pandemic and the global environment, and any additional lockdowns, change in consumer behavior or practice closures could impact our operations and financial results."

To register for the 2020 Align Virtual Investor Day starting at 8:00 a.m. Eastern time today, please use the following link:

https://event.webcasts.com/starthere.jsp?ei=1398581&tp_key=8aa7c31f94

To register in advance to listen to the **live Q&A session** starting at 1:00 p.m. Eastern time today with the Align executive team, please use the following link to attend the Zoom webinar:

https://aligntech-us00.zoom.us/webinar/register/WN_CsIXkvgQTBu3WjYRxPovXw

After registering, you will receive a confirmation email with information about how to join the webinar.

Q&A session attendees will be able to submit written questions via the Q&A window.

Forward Looking Statement

This press release includes forward looking statements that involve a number of risks and uncertainties. Words such as "believes," "anticipates," "plans," "intends," "expects," "seeks," "estimates," and similar expressions are intended to identify forward-looking statements, but other statements that are not historical facts may also be deemed to be forward-looking statements. Important factors that could cause actual results to differ materially from those indicated by forward-looking statements include risks and uncertainties relating to: the markets for Align's products, its beliefs concerning the digital transformation of dentistry and Align's strategic priorities, its business momentum, products and product mix, the COVID-19 pandemic and its impacts on Align's business and results of operations, Align's expectations for digital adoption in dentistry and the potential impact of its products in the transition, and Align's expectations for investments in its business, including sales, marketing, development and manufacturing. Forward-looking statements 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, including any reimplementation of preventative measures;
- difficulties predicting customer and consumer purchasing behavior and changes in consumer spending habits as a result of, among other things, the COVID-prev19 pandemic, 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 and its latest Quarterly Report on Form 10-Q for the quarter ended September 30, 2020, which was filed with the SEC on October 30, 2020. Align undertakes no obligation to revise or update publicly any forward-looking statements for any reason.

About Align Technology, Inc.

Align Technology designs and manufactures the Invisalign® system, the most advanced clear aligner system in the world, iTero® intraoral scanners and services, and CAD/CAM software. Align has helped treat over 9 million patients with the Invisalign system and is driving the evolution in digital dentistry with the iTero intraoral scanner and exocad® CAD/CAM software – modernizing today's practices by enabling enhanced digital orthodontic and restorative workflows to improve patient outcomes and practice efficiencies. 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 the iTero digital scanning system, please visit <u>www.itero.com</u>. For additional information about exocad dental CAD/CAM offerings and a list of exocad reseller partners, please visit <u>www.exocad.com</u>.

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