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): February 7, 2022

ALIGN TECHNOLOGY, INC.

(Exact Name of Registrant as Specified in Charter)

000-32259

94-3267295 (I.R.S. Employer Identification No.)

Delaware

(State or Other Jurisdiction of Incorporation)

(Commission File Number)

410 North Scottsdale Road, Suite 1300, Tempe, Arizona 85281

(Address of Principal Executive Offices) (Zip Code)

(602) 742-2000

(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 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 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2). Emerging growth company

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.

Item 7.01 Regulation FD Disclosure.

On February 7, 2022, Align Technology, Inc., a Delaware corporation (the "Company") issued a press release entitled "Align Technology Announces Settlement of Outstanding Litigation with 3Shape A/S." 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.	Description
<u>99.1</u>	<u>Press Release of Align Technology, Inc. entitled "Align Technology Announces Settlement of</u> <u>Outstanding Litigation with 3Shape A/S</u>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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.

By: /s/ Julie Coletti

Julie Coletti Senior Vice President, Chief Legal and Regulatory Officer

Date: February 7, 2022

align

<u>Align Technology</u> Madelyn Valente (408) 470-1180 mvalente@aligntech.com Zeno Group Sarah Johnson (828) 551-4201 sarah.johnson@zenogroup.com

ALIGN TECHNOLOGY ANNOUNCES SETTLEMENT OF OUTSTANDING LITIGATION WITH 3SHAPE A/S

TEMPE, Ariz., February 7, 2022 -- Align Technology, Inc. (Nasdaq: ALGN), a leading global medical device company that designs, manufactures, and sells the Invisalign system of clear aligners, iTero intraoral scanners, and exocad CAD/CAM software for digital orthodontics and restorative dentistry, today announced that it has settled its longstanding patent infringement and antitrust litigation with 3Shape A/S which began in November of 2017.

The litigation included patent infringement claims pending in federal courts in the District of Delaware and the Eastern District of Texas, as well as petitions to invalidate patents before the United States Patent Trial and Appeal Board brought by both parties. In addition, 3Shape had an antitrust claim pending against Align in Delaware District Court.

The terms of the settlement are confidential, and the settlement is not expected to have a material effect on Align's ongoing operations and financial results. Following the settlement, Invisalign customers may continue current practices of using scans from 3Shape Trios 2 and Trios 3 scanners for Invisalign case submissions in certain countries and territories outside the United States, China and Japan subject to Align's terms and conditions for Invisalign case submissions, the settlement and other applicable agreements.

"Align Technology is pleased to have resolved these disputes with 3Shape," stated Julie Coletti, senior vice president, Chief Legal and Regulatory Officer. "We will continue our focus on innovation, including technologies such as the award-winning iTero Element 5D imaging system which aids in the detection and monitoring of interproximal caries lesions above the gingiva without using harmful radiation."*

*Data on file at Align Technology

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 exocad[®] CAD/CAM software. These technology building blocks enable enhanced digital orthodontic and restorative workflows to improve patient outcomes and practice efficiencies for over 212 thousand doctor customers and is key to accessing Align's 500 million consumer market opportunity worldwide. Align has helped doctors treat over 12.2 million patients with the Invisalign system and is driving the evolution in digital dentistry through the Align Digital Platform, our integrated suite of unique, proprietary technologies and services delivered as a seamless, end-to-end solution for patients and consumers, orthodontists and GP dentists, and lab/partners. 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>.

Forward-Looking Statements

This news release contains forward-looking statements, including the company's expectations regarding the terms and conditions of the settlement with 3Shape A/S. Forward-looking statements contained in this news release 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 reflect our best judgments based on currently known facts and circumstances 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:

- increasing competition from existing and new competitors;
- rapidly evolving and groundbreaking advances that fundamentally alter the dental industry or the way new and existing customers market and provide products and services to consumers;
- the ability to protect our intellectual property rights;
- · continued compliance with regulatory requirements;
- declines in, or the slowing of the growth of, sales of our intraoral scanners domestically and/or internationally and the impact either would have on the adoption of Invisalign products;
- the willingness and ability of our customers to maintain and/or increase product utilization in sufficient numbers;

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- 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;
- 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, military and other risks relating to our operations; and
- the loss of key personnel, labor shortages or work stoppages for us or our suppliers.

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, 2020, which was filed with the Securities and Exchange Commission (SEC) on February 26, 2021 and our latest Quarterly Report on Form 10-Q for the quarter ended September 30, 2021, which was filed with the SEC on November 2, 2021. Align undertakes no obligation to revise or update publicly any forward-looking statements for any reason.

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