ALIGN TECHNOLOGY INC
Form 10-K
February 28, 2019

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

FORM 10-K

(Mark One)
ý ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2018
OR
¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to
Commission file number: 0-32259

ALIGN TECHNOLOGY, INC.
(Exact name of registrant as specified in its charter)

Delaware	94-3267295
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

2820 Orchard Parkway
San Jose, California 95134
(Address of principal executive offices)
(408) 470-1000
(Registrant's telephone number, including area code)
Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
Common Stock, $0.0001 par value	The NASDAQ Stock Market LLC (NASDAQ Global Market)

Securities registered pursuant to Section 12(g) of the Act:
None
Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ý No ¨
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes ¨ No ý
Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ý No ¨
Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ý No ¨
Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ý

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of “large accelerated filer,” “accelerated filer,” and “smaller reporting company” in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	x	Accelerated filer	o
Non-accelerated filer	o	Smaller reporting company	o
		Emerging growth company	o

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 7(a)(2)(B) of the Securities Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No ý

The aggregate market value of the registrant’s common stock held by non-affiliates of the registrant was $22,262,043,858 as of June 29, 2018 based on the closing sale price of the registrant’s common stock on the NASDAQ Global Market on such date. Shares held by persons who may be deemed affiliates have been excluded. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

On February 22, 2019, 79,989,347 shares of the registrant’s common stock were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant’s definitive Proxy Statement relating to its 2019 Annual Stockholders’ Meeting to be filed pursuant to Regulation 14A within 120 days after the registrant’s fiscal year end of December 31, 2018 are incorporated by reference into Part III of this Annual Report on Form 10-K.

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In addition to historical information, this annual report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These statements include, among other things, our expectations regarding the anticipated impact of our new products and product enhancements will have on doctor utilization and our market share, our expectations regarding product mix and product adoption, our expectations regarding the existence and impact of seasonality, our expectations regarding the sales growth of our intra-oral scanner sales in international markets, our expectations regarding the financial and strategic benefits of establishing regional order acquisition, treatment planning and manufacturing facilities, our intention to hire more sales representatives in 2019 and their expected impact on our sales, our expectations regarding the continued expansion of our international markets, the anticipated impact of the Invisalign Experience program on demand creation, our expectation to incur additional costs related to the planned corporate structure reorganization, the level of our operating expenses and gross margins and other factors beyond our control, as well as other statements regarding our future operations, financial condition and prospects and business strategies. These statements may contain words such as “expects,” “anticipates,” “intends,” “plans,” “believes,” “estimates,” or other words indicating future res These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from those reflected in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in Item 2 “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” and in particular, the risks discussed below in Part I, Item 1A “Risk Factors.” We undertake no obligation to revise or update these forward-looking statements. Given these risks and uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements.

PART I

ITEM 1.BUSINESS

Our Company

Align Technology, Inc (“We”, “Our”, “Align”) is a global medical device company engaged in the design, manufacture and marketing of Invisalign® clear aligners and iTero® intraoral scanners and services for orthodontics, and restorative and aesthetic dentistry. Align’s products are intended primarily for the treatment of malocclusion or the misalignment of teeth and are designed to help dental professionals achieve the clinical outcomes that they expect. Align Technology was founded in March 1997 and incorporated in Delaware in April 1997. Our corporate headquarters is located at 2820 Orchard Parkway, San Jose, California, U.S.A., 95134, and our telephone number is 408-470-1000. Our internet address is www.aligntech.com. Our Americas regional headquarters is located in Raleigh, North Carolina; our European regional headquarters is located in Amsterdam, the Netherlands; and our Asia Pacific regional headquarters is located in Singapore.

We have two operating segments: (1) Clear Aligner and (2) Scanners and Services ("Scanner"). For the year ended December 31, 2018, Clear Aligner net revenues represent approximately 86% of worldwide net revenues, while Scanner net revenues represent the remaining 14% of worldwide net revenues. We sell the vast majority of our products directly to our customers: orthodontists and general practitioner dentists ("GPs"), as well as to restorative and aesthetic dentists, including prosthodontists, periodontists, and oral surgeons. In addition, we sell directly to Dental Support Organizations (DSOs) who contract with dental practices to provide critical business management and support including non-clinical operations, and we sell directly to dental laboratories who manufacture or customize a variety of products to assist in the provision of oral health care by a licensed dentist. Our Clear Aligner operating segment includes revenues from non-Invisalign aligners supplied to SmileDirectClub, LLC ("SDC"). Refer to "Supply Agreement with SmileDirectClub, LLC" section.

We received 510(k) clearance from the United States Food and Drug Administration (“FDA”) to market the Invisalign System in 1998. The Invisalign System is regulated by the FDA as a Class II medical device. In order to provide Invisalign treatment to their patients, orthodontists and GPs must initially complete an Invisalign training course. The

Invisalign System is sold primarily through a direct sales force in North America, Asia Pacific ("APAC"), Europe, Middle East and Africa (EMEA) and Latin America. To date, over 6.1 million people worldwide have been treated with our Invisalign System.

Our iTero scanner is used by dental professionals and/or labs and service providers for restorative and orthodontic digital procedures as well as Invisalign case submission. We received 510(k) clearance from the FDA to market iTero software for expanded indications in 2013. Scanners and computer-aided design/computer-aided manufacturing ("CAD/CAM") services are primarily sold through our direct sales force and a few distributors in North America, Europe and certain Asia Pacific countries, and through distribution partners in smaller non-core international country markets.

Clear Aligner Segment

Malocclusion and Traditional Orthodontic Treatment

Malocclusion, or the misalignment of teeth, is one of the most prevalent clinical dental conditions, affecting billions of people, or approximately 60% to 75% of the population. Annually, approximately 12 million people in major developed countries elect treatment by orthodontists worldwide. Most orthodontic patients are treated with the use of traditional methods such as metal arch wires and brackets, referred to as braces, and may be augmented with elastics, metal expanders, headgear or functional appliances, and other ancillary devices as needed. Upon completion of the treatment, the dental professional may, at his or her discretion, have the patient use a retainer appliance. Of the 12 million annual orthodontic cases started, approximately 75% or 8.4 million are applicable to Invisalign treatment our served market. In addition, approximately 300 million people with malocclusion could benefit from straightening their teeth but are unlikely to seek treatment through a doctor’s office. This represents an incremental opportunity for us as we expand the market for orthodontics by educating more consumers about the benefits of straighter teeth using Invisalign clear aligners and connect them with an Invisalign doctor of their choice.

The Invisalign System

The Invisalign System is a proprietary method for treating malocclusion based on a proprietary computer-simulated virtual treatment plan and a series of doctor-prescribed, custom manufactured, clear plastic, removable aligners. The Invisalign System offers a range of treatment options, specialized services, and proprietary software for treatment visualization and is comprised of the following phases:

Orthodontic diagnosis and transmission of treatment data to us. The Invisalign-trained dental professional prepares and sends us a patient’s treatment data package which consists of a prescription form, a digital scan or a polyvinyl-siloxane (or "PVS") impression of the relevant dental arches, photographs of the patient and, at the dental professional’s election, x-rays of the patient’s dentition. Intraoral digital scans may be submitted through either Align's iTero scanner or a few qualified third-party scanners. See "Third Party Scanners and Digital scans for Invisalign treatment submission." More than 63% of Invisalign case submissions are submitted via digital scan instead of a physical PVS impression.

Preparation of computer-simulated treatment plan. Using propriety software which we do not sell, we generate a proposed custom, three-dimensional treatment plan, called a ClinCheck treatment plan. The ClinCheck treatment plan simulates appropriate tooth movement in stages and details timing and placement of any features or attachments that will be used during treatment. Attachments are tooth-colored “buttons” that are sometimes used to increase the biomechanical force on a specific tooth or teeth in order to effect the desired movement(s).

Review and approval of the treatment plan by an Invisalign-trained doctor. The patient’s ClinCheck treatment plan is then made available to the prescribing dental professional via the Invisalign Doctor Site which enables the dental professional to project tooth movement with a level of accuracy not previously possible with metal arch wires and brackets. By reviewing, modifying as needed and approving the treatment plan, the dental professional retains control over the treatment plan.

Manufacture of custom aligners. Upon the dental professional’s approval of the ClinCheck treatment plan, we use the data underlying the simulation, in conjunction with stereolithography technology (a form of 3D printing technology), to construct a series of molds depicting the future position of the patient’s teeth. Each mold is a replica of the patient’s teeth at each stage of the simulated course of treatment. From these molds, aligners are fabricated by pressure-forming polymeric sheets over each mold. Aligners are thin, clear plastic, removable dental appliances that are custom manufactured in a series to correspond to each stage of the ClinCheck treatment plan.

Shipment to the dental professional and patient aligner wear. All the aligners for a patient are shipped directly to the dental professional, who then dispenses them to the patient at regular check-up intervals throughout the treatment. Aligners are generally worn for a period of time which correspond to the stages of the approved ClinCheck treatment plan. The patient replaces the aligners with the next pair in the series when prescribed, advancing tooth movement with each aligner stage. Throughout treatment, the doctor may place attachments or use other auxiliaries to achieve desired tooth movements, per the doctor's original prescription and resulting ClinCheck treatment plan. In October 2016, we introduced one-week aligner wear. At the treating doctor's discretion, weekly aligner changes are recommended for all Invisalign treatments for Invisalign Comprehensive, Invisalign First Comprehensive, Invisalign Lite, Invisalign Assist and Invisalign Go packages, thereby reducing treatment time by up to 50% compared to two week aligner wear.

Additional aligners. Should the dental professional determine that the treatment is not tracking for various reasons, such as patient compliance, certain teeth movement not tracking to plan, or they need to extend the treatment a few stages further to

achieve their treatment goals, the dental professional can request additional aligners at any point during the treatment, subject to certain requirements in our terms and conditions.

Clear Aligner Products

Comprehensive Products - Invisalign Treatment Options:

Invisalign Comprehensive. Invisalign Comprehensive Package replaces both Invisalign Full and Invisalign Teen treatments and includes the Mandibular Advancement feature launched in March 2017. Used for a wide range of malocclusion, the Invisalign Comprehensive treatment plans each consist of the number of aligners necessary to achieve the doctor's treatment goals. The Invisalign Comprehensive treatment includes all the features of Invisalign treatment, plus additional features that address the orthodontic needs of teenage patients such as compliance indicators, compensation for tooth eruption. Aligners for Invisalign Comprehensive treatments are manufactured and then delivered to the dental professionals in a single shipment. Invisalign Comprehensive Package is sold in the U.S., Canada and select international countries.

Invisalign Assist. Used for anterior alignment and aesthetically-oriented cases, the Invisalign Assist treatment offers added support to our dental practitioners throughout the treatment process, including progress tracking that allows the dental professional to submit new impressions every nine stages. When the progress tracking feature is selected, aligners are shipped to the dental professional after every nine stages thereby helping to achieve successful treatment outcomes. Predominantly marketed to GPs, Invisalign Assist is intended to make it easier to select appropriate cases for their experience level or treatment approach, submit cases more efficiently and manage appointments with suggested tasks. Invisalign Assist is sold in the U.S. and Canada.

Invisalign First Phase 1 and Invisalign First Comprehensive Phase 2 Package. Designed with features specifically for younger patients with early mixed dentition with a 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 7 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. Invisalign First clear aligners became commercially available to Invisalign-trained doctors in the U.S., Canada, Australia, New Zealand, Japan, and certain countries in the EMEA region as of July 1, 2018, and became available in Brazil in January 2019.

Non-Comprehensive Products - Invisalign Treatment Options:

Invisalign Express 10, Invisalign Express 5, Express Package and Lite Package. Lower-cost solutions are used for less complex orthodontic cases, non-comprehensive treatment relapse cases, or straightening prior to restorative or cosmetic treatments such as veneers. Invisalign Express 10, Invisalign Express 5 and Express Package use up to 10 sets, 5 sets and 7 sets of aligners, respectively. Invisalign Lite use up to 14 sets of aligners. Non-comprehensive products are available in select country markets and delivered to the dental professionals in a single shipment.

Invisalign Go. A simplified and streamlined solution designed for GPs to more easily identify and treat patients with mild malocclusion. Invisalign Go combines case assessment support, a simplified ClinCheck treatment plan and a progress assessment feature for case monitoring. Invisalign Go is available in select country markets.

Non-Case Products:

Clear Aligner non-case products include retention products, Invisalign training fees and sales of ancillary products, such as cleaning material and adjusting tools used by dental professionals during the course of treatment.

Retention. We offer up to four sets of custom clear aligners called Vivera Retainers made with proprietary material strong enough to maintain tooth position and correct minor relapse if necessary. Vivera Retainers are available to both Invisalign and non-Invisalign patients. In select markets, we also offer single arch retainers.

Feature Enhancements

We have consistently introduced enhanced features across the Invisalign System over the past several years to improve treatment outcomes or address broader clinical indications.

Invisalign Comprehensive with Mandibular Advancement (launched in March 2017) is the first clear aligner solution for Class II correction in growing tween and teen patients. This new offering combines the benefits of our clear aligner system with

features for moving the lower jaw forward while simultaneously aligning the teeth without the need for elastics typically used to treat teen Class II patients. In 2017, it was available in Canada, core country markets in EMEA and certain country markets in APAC and Latin America. In October 2018, Invisalign Treatment with mandibular advancement was approved by the FDA and became commercially available in the U.S. in November 2018.

In November 2018, we introduced enhancements designed to improve clinical outcomes and user experience including: wing overlap and engagement in deep bite cases with anterior intrusion, new options to set up mandibular advancement cases beyond edge-to-edge, an option to prescribe symmetrical advancement of the left and right side, new default protocol of 2 mm incremental advancement, and improvements to support leveling the curve of Spee in deep bite cases.

SmartTrack™ Aligner Material

SmartTrack is a patented, custom-engineered Invisalign clear aligner material that delivers gentle, more constant force considered ideal for orthodontic tooth movements. Conventional aligner materials relax and lose a substantial percent of energy in the initial days of aligner wear, but SmartTrack maintains more constant force over the period of time the patient wears the aligners. The flexible SmartTrack material also more precisely conforms to tooth morphology, attachments and interproximal spaces to improve control of tooth movement throughout treatment.

Non-Invisalign Aligners Supplied to SmileDirectClub, LLC:

SmileDirectClub Aligners. On July 25, 2016, we entered into a supply agreement with SmileDirectClub, LLC ("SDC") to manufacture non-Invisalign clear aligners for SDC's doctor-led, at-home program for simple teeth straightening. In October 2016, we became SDC's exclusive third-party supplier and began supplying aligners directly to SDC. SDC aligners include up to 20 stages without attachments or interproximal reduction ("IPR"). Align manufactures the aligners per SDC’s specifications for minor tooth movement using EX-30, a non-proprietary aligner material used prior to the introduction of SmartTrack aligner material. Align does not market or sell SDC products and ships supply of aligners directly to SDC when requested. While we are SDC's only third-party supplier, SDC also manufactures their own aligners. The supply agreement terminates by its terms December 31, 2019 and we do not intend on renewing it (Refer to Note 8 "Legal Proceedings" of the Notes to Consolidated Financial Statements for details on SDC dispute).

Scanner Segment

Intraoral scanning is an emerging technology that we believe will have substantial impact on the future of dentistry. By enabling the dental practitioner to create a 3D image of the patient's teeth (digital scan) using a handheld intraoral scanner inside the mouth, digital scanning is more efficient and precise and more comfortable for patients, compared to the discomfort and subjective nature of taking physical impressions. The digitally scanned model is more accurate than a physical impression and substantially reduces the rate of restoration "remakes" so patients are recalled less often and the appointment time for the restoration is shorter because of fewer adjustments which results in greater overall patient satisfaction. The digital model file can be used for various procedures and services including fabrication of physical dental models for use by labs to create restorative units such as veneers, inlays, onlays, crowns, bridges and implant abutments; digital records storage; orthodontic diagnosis; orthodontic retainers and appliances; and Invisalign digital impression submission.

iTero Scanner. The iTero Element scanner (launched in September 2015) is available as a single hardware platform with software options for restorative or orthodontic procedures. The expanded portfolio (launched in May 2018) includes 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. The iTero Element Flex is a wand-only device that transforms compatible laptop computers into a highly portable scanner that works anywhere - it's ideal for practices with multiple locations who need a scanner that is convenient and easy to transport. We market and sell the iTero Element in North America and in select international markets. iTero Element 2 and iTero Element Flex scanners are available in the U.S., Canada, the majority of European countries, including France, Germany, Italy, Spain, and the United Kingdom as well as select Asia Pacific markets. The iTero scanner is interoperable with our Invisalign treatment such that a full arch digital scan can be submitted as part of the Invisalign case submission process. In addition, the Invisalign Outcome Simulator and Invisalign Assessment tool are exclusive to the iTero scanner. Prior to the launch of iTero Element 2 and iTero Element Flex, we sold and continue to sell iTero Element and, prior to that, we sold the iTero 2.9 scanner. On February 18, 2019, we launched the iTero Element 5D Imaging system which provides a new comprehensive approach to clinical applications, workflows and user experience that expands the suite of existing high-precision, full-color imagining and fast scan times of the iTero Element portfolio. In addition to offering all of the features and functionality that doctors have come to expect and rely on with the iTero Element 2 scanner, the iTero

Element 5D scanner is the first integrated dental imaging system that simultaneously records 3D, intra-oral color and near-infrared ("NIRI") imaging and enables comparison over time using iTero TimeLapse. NIRI technology of the iTero Element 5D Imaging System aids in detection and monitoring of interproximal caries lesions above the gingiva without using harmful radiation. The iTero Element 5D Imaging System is commercially available now in Canada, European Union countries accepting CE-Marking (excluding Greece), Switzerland, Norway, Australia, New Zealand, Hong Kong and Thailand. It is not available in the U.S. or Latin America.

Restorative software for iTero. Software designed for GPs, prosthodontists, periodontists, and oral surgeons which includes restorative workflows providing them with the ability to send digital impressions to the lab of choice and communicate seamlessly with external treatment planning, custom implant abutment, chairside milling, and laboratory CAD/CAM systems.

Orthodontic software for iTero. Software designed for orthodontists for digital records storage, orthodontic diagnosis, and for the fabrication of printed models and retainers.

CAD/CAM Services and Ancillary Products

iTero Models and Dies. An accurate physical model and dies are manufactured based on the digital scan and sent to the laboratory of the dentist’s choice for completion of the needed restoration. The laboratory also has the option to export the digital file for immediate production of coping and full-contour restorations on their laboratory CAD/CAM systems. The laboratory conducts then completes the ceramic buildup or staining and glazing and delivers the end result - a precisely fitting restoration. iTero prosthetics have a near-zero remake rate.

OrthoCAD iCast. iCast provides a digital alternative to traditional stone cast models which allows for simplified storage and digital record retrieval. The iCast digital model contains a full American Board of Orthodontics ("ABO") base and is available from an iTero scan or from a traditional alginate impression.

OrthoCAD iRecord. iRecord scans provide a digital alternative to traditional stone cast models which allows for simplified storage and digital record retrieval. iRecord scan data may also be exported to orthodontic laboratories for the fabrication of retainers, orthodontic appliances, and hard model fabrication.

Ancillary Products. We also sell other ancillary products for the iTero scanner, such as disposable sleeves for the wand.

Third Party Scanners and Digital scans for Invisalign treatment submission. We support an open systems approach to digital scans and other intraoral scanning companies interested in qualifying their scanners to submit a digital impression in place of a traditional PVS impression as part of the Invisalign case submission process. We have qualified third party scanners for digital scan submission including 3M™ True Definition scanner and the Sirona CEREC Omnicam scanner. Information regarding legal proceedings associated with the scanner may be found in Item 3 of this Annual Report on Form 10-K under the heading “Legal Proceedings.”

iTero Applications and Tools

Invisalign Outcome Simulator. The Invisalign Outcome Simulator is an exclusive chair-side and cloud-based application for the iTero scanner that allows doctors to help patients visualize how their teeth may look at the end of Invisalign treatment through a dual view layout that shows a prospective patient an image of his/her own current dentition next to his/her simulated final position after Invisalign treatment.

Invisalign 3D Assessment tool. The Invisalign Progress Assessment tool provides the ability to compare a patient's new scan with a specific stage of their ClinCheck treatment plan to visually assess and communicate Invisalign treatment progress with an easy to read, color-coded tooth movement report that allows the doctor to know how each tooth is tracking.

TimeLapse. TimeLapse technology allows doctors or practitioners to compare a patient's historic 3D scans to the present-day scan, enabling clinicians to identify and measure orthodontic movement, tooth wear, and gingival recession. This highlights areas of diagnostic interest to dental professionals and helps foster a proactive conversation with the patient regarding potential restorative or orthodontic solutions.

Our iTero Element, iTero Element 2 and iTero Element Flex scanners include the Invisalign Outcome Simulator, Invisalign 3D Assessment tool and Timelapse as well as the orthodontic software and/or restorative software. The orthodontic or restorative software may also be purchased subsequently for an upgrade fee. Additional applications such as the Invisalign Outcome Simulator are not available for sale separately.

Other proprietary software mentioned in this Annual Report on Form 10-K such as ClinCheck and ClinCheck Pro software, the Invisalign Doctor Site, and feature enhancements are included as part of the Invisalign System and are not sold separately nor do they contribute as individual items to revenue.

Business Strategy

Our goal is to establish the Invisalign System as the standard method for treating malocclusion and our intraoral scanning platform as the preferred scanning protocol for digital scans. Our technology and innovations are designed to meet the demands of today's patients with treatment options that are convenient, comfortable, affordable, while helping to improve overall oral health. We strive to help our doctors move their practices forward by connecting them with new patients, providing digital solutions to help increase practice efficiency and helping them deliver the best possible treatment outcomes and experiences to millions of people around the world.

We achieve this by continued focus and execution of our strategic growth drivers:

1. International Expansion. In order to provide the millions of consumers access to a better smile, we continue increasing our presence globally by making our products available in more countries. We expect to continue to grow and expand our business by investing in resources, infrastructure, and initiatives that will drive Invisalign treatment growth in our current and new international markets. As our core countries within the EMEA and APAC regions continue to grow in both number of new Invisalign trained doctors and customer utilization, we strive to make sure we can support that growth through investments such as headcount, clinical support, education and advertising. We have transitioned most of our smaller country markets from an indirect to a direct sales model, and, while we do not expect a material impact from these countries for some time, in the near term we will leverage our existing infrastructure in adjacent country markets as we build local sales organizations to drive long-term market penetration. In addition, we are scaling and expanding our operations and facilities to better support our customers across the globe. In 2018, we opened new treatment planning facilities in Madrid, Spain to support our customers within this region and we expanded our facilities in Costa Rica to support our growth.

2. Orthodontist Utilization. We continue to innovate and increase the product applicability and predictability to address a wide range of cases, from simple to complex, thereby enabling doctors to confidently treat teenagers and adults with the Invisalign System. Over the last several years, we launched clinical innovations such as Invisalign G6 and Invisalign G7. In March 2017, we launched Invisalign Comprehensive with Mandibular Advancement, the first clear aligner solution for Class II correction in growing tween and teen patients in Canada and certain country markets in EMEA and APAC. This offering combines the benefits of our clear aligner system with features for moving the lower jaw forward while simultaneously aligning the teeth. Approximately 30% to 45% of teen cases need Class II correction. In October 2018 we received 510(k) approval for Invisalign with Mandibular Advancement in the U.S. and began its commercial launch in November 2018. We also continue to make improvements to our Invisalign treatment software, ClinCheck Pro, designed to deliver an exceptional user experience and increase treatment control to help our doctors achieve their treatment goals.

3. GP Dentist Treat & Refer. We want to enable GPs, who have access to a large patient base, to more easily identify Invisalign cases they can treat, monitor patient progress or, if needed, help refer cases to an orthodontist while providing high-quality restorative, orthodontic, and dental hygiene care. In 2018, we continued to commercialize Invisalign Go, a simplified and streamlined solution designed for GPs and trained over 3,000 new iGo doctors primarily in EMEA. In the EMEA region, we segmented sales and marketing for certain country markets into two separate organizations to serve each customer segment, orthodontists and GP dentists separately, thereby increasing our focus and effectiveness on GP dentists. In the first quarter of 2019, we plan to add 50 new sales representatives in EMEA to cover the GP dentist channel. The iTero scanner is an important component to that customer experience

and is central to a digital approach as well as overall customer utilization of Invisalign treatment. The iTero scanner is optimized for Invisalign treatment with the Invisalign Outcome Simulator and Progress Assessment tool. In June 2017, we launched TimeLapse technology that allows doctors or practitioners to compare a patient's 3D historic scans to the present-day scan, enabling clinicians to identify and measure orthodontic movement, tooth wear, and gingival recession. This highlights areas of diagnostic interest to dental professionals and helps foster a proactive conversation with the patient regarding potential restorative or orthodontic solutions. In 2018, we announced multi-year agreements with Heartland Dental and Aspen Dental, two large dental support organizations, to extend iTero Element intraoral scanners to their supported dentists and teams nationwide.

4. Patient Demand & Conversion. Our goal is to make Invisalign a highly recognized name brand worldwide by creating awareness for Invisalign treatment among consumers and motivating potential patients to seek Invisalign treatment. We accomplish this objective through an integrated consumer marketing strategy that includes television, media, social networking and event marketing as well as educating patients on treatment options and directing them to high volume Invisalign doctors. In January 2017, we launched a new Smile Concierge program with the objective to help more U.S. consumers start Invisalign treatment and improve their overall experience by shortening their research cycles and utilizing consumer insights to help our doctors better engage with consumers. Our Smile Concierge program educates consumers on the benefits of Invisalign treatment, answers their questions, and helps them schedule an appointment with an Invisalign doctor. In addition, the Invisalign Experience program reflects the Company's overarching approach to engaging consumers through brand experiences in consumer-based settings and environments. Through the Invisalign Experience program we're learning more than ever about reducing barriers to treatment for potential patients so that they are excited about getting a better smile with an Invisalign doctor. In 2018, we expanded the interactive brand experience that was piloted in 2017 and finished the year with twelve Invisalign Experience locations in major U.S. cities. The program expansion is designed to address the rapidly evolving consumer market for clear aligners and connects consumers interested in Invisalign treatment with Invisalign doctors in their communities. We also partnered with a few Invisalign doctors in select U.S. cities piloting doctor-owned Invisalign Experience centers to test new ways to reach consumers and connect them directly with doctors to start Invisalign treatment. This pilot is intended to help doctors integrate consumer-friendly design and consultation workflow into their practices and test the new Invisalign Experience branding and a consumer-focused approach to consultations and Invisalign treatment starts. It includes an initial digital scan and smile visualization with a scanner and immediate appointments for walk-ins. In addition to providing potential leads to participating Invisalign practices, we are seeing a positive halo effect and increased growth rates for all of the Invisalign practices in the surrounding area whether they participate in the location network or not. While we are still early in the development of our Invisalign Experience locations and the overarching Invisalign Experience program, we believe it will have a positive impact on demand creation for Invisalign practices by engaging directly with consumers (Refer to Note 8 "Legal Proceedings" of the Notes to Consolidated Financial Statements for a communication received from SDC on the Invisalign Experience program).

Manufacturing and Suppliers

Our manufacturing facilities are located in Juarez, Mexico, and Ziyang, China, where we conduct our aligner fabrication, distribute and repair our scanners and perform our CAD/CAM services, and in Or Yehuda, Israel where we produce our handheld intraoral scanner wand and perform the final assembly of our iTero scanner. Our Invisalign digital treatment planning and interpretation for iTero restorative cases are conducted at our facilities located in San Jose, Costa Rica, Chengdu, China, Cologne, Germany and Madrid, Spain. Information regarding risks associated with our manufacturing process and foreign operations may be found in Item 1A of this Annual Report on Form 10-K under the heading "Risk Factors."

Our quality system is required to be in compliance with the Quality System regulations enforced by the FDA, and similar regulations enforced by other worldwide regulatory authorities. We are certified to EN ISO 13485:2003, an internationally recognized standard for medical device manufacturing. We have a formal, documented quality system by which quality objectives are defined, understood and achieved. Systems, processes and procedures are implemented to ensure high levels of product and service quality. We monitor the effectiveness of the quality system based on internal data and direct customer feedback and strive to continually improve our systems and processes, taking corrective action, as needed.

Since the manufacturing process of our products requires substantial and varied technical expertise, we believe that our manufacturing capabilities are important to our success. In order to produce our highly customized, highly precise,

medical quality products in volume, we have developed a number of proprietary processes and technologies. These technologies include complex software algorithms and solutions, CT scanning, stereolithography and automated aligner fabrication. To increase the efficiency of our manufacturing processes, we continue to focus our efforts on software development and the improvement of rate-limiting processes or bottlenecks. We continuously upgrade our proprietary, three-dimensional treatment planning software to enhance computer analysis of treatment data and to reduce time spent on manual and judgmental tasks for each case, thereby increasing the efficiency of our technicians. In addition, to improve efficiency and increase the scale of our operations, we continue to invest in the development of automated systems for the fabrication and packaging of aligners.

We are highly dependent on manufacturers of specialized scanning equipment, rapid prototyping machines, resin and other advanced materials for our aligners, as well as the optics, electronic and other mechanical components of our intraoral scanners. We maintain single supply relationships for many of these machines and materials technologies. In particular, our CT scanning and stereolithography equipment used in our aligner manufacturing and many of the critical components for the optics of our intraoral scanners are provided by single suppliers. We are also committed to purchasing all of our resin and polymer, the primary raw

materials used in our manufacturing process for clear aligners, from a single source. The need to replace one of our single source suppliers could cause a disruption in our ability to timely deliver certain of our products or increase costs. See Item 1A Risk Factors — “We maintain single supply relationships for certain of our key machines and materials technologies, and our business and operating results could be harmed if supply is restricted or ends or the price of raw materials used in our manufacturing process increases.”

Sales and Marketing

Our sales efforts are focused primarily on the Invisalign System and continuing to increase adoption and utilization by orthodontists and GPs worldwide. In North America, Europe, certain Asia Pacific country markets, and, more recently in Brazil and certain countries in the Middle East and Africa, we have direct sales and support organizations, which includes quota carrying sales representatives, sales management and sales administration. We also have distribution partners that sell the Invisalign System in smaller non-core international country markets. We continued to expand in our existing markets through targeted investments in sales resources, professional marketing and education programs, along with consumer marketing in select country markets.

For the iTero scanner, we have a small team of direct sales representatives and a few distributors in North America who leverage leads generated by our Invisalign sales and marketing resources, including customer events and industry trade-shows. We sell the iTero scanner in select country markets internationally and will expand to additional markets over time to grow the scanner business.

We provide training, marketing and clinical support to orthodontists and GPs. As of December 31, 2018, we had approximately 69,940 active Invisalign trained doctors, which is defined as having submitted at least one case in the prior 12 month period.

Research and Development

We are committed to investing in world-class technology development, which we believe is critical to achieving our goal of establishing the Invisalign System as the standard method for treating malocclusion and our intraoral scanning platform as the preferred scanning protocol for digital scans.

Our research and development activities are directed toward developing the technology innovations that we believe will deliver our next generation of products and platforms. These activities range from accelerating product and clinical innovation to developing manufacturing process improvements to researching future technologies and products.

In an effort to demonstrate Invisalign’s broad treatment capabilities, various clinical case studies and articles have been published that highlight the clinical applicability of Invisalign to malocclusion cases, including those of severe complexity. We undertake pre-commercialization trials and testing of our technological improvements to the product and manufacturing process.

Intellectual Property

We believe our intellectual property position represents a substantial business advantage. As of December 31, 2018, we had 449 active U.S. patents, 423 active foreign patents, and 486 pending global patent applications.

Our active U.S. patents expire between 2019 and 2037. When patents expire, we lose the protection and competitive advantages they provided to us, which could negatively impact our operating results; however, we continue to pursue further intellectual property protection through U.S. and foreign patent applications and non-disclosure

agreements. We also seek to protect our software, documentation and other written materials under trade secret and copyright laws. We cannot be certain that patents will be issued as a result of any patent application or that patents that have been issued to us or that may be issued in the future will be found to be valid and enforceable and sufficient to protect our technology or products. Our intellectual property rights may not be successfully asserted in the future or may be invalidated, circumvented or challenged. In addition, the laws of various foreign countries do not protect our intellectual property rights to the same extent as U.S. laws. Our inability to protect our proprietary information could harm our business. Information regarding risks associated with failing to protect our proprietary technology and our intellectual property rights may be found in Item 1A of this Annual Report on Form 10-K under the heading “Risk Factors.”

Seasonal Fluctuations

General economic conditions impact our business and financial results, and we experience seasonal trends within our two operating segments, customer channels and the geographic locations that we serve. Sales of Invisalign treatments are often weaker in Europe during the summer months due to our customers and their patients being on holiday. Similarly, other international holidays like Chinese New Year can also negatively impact our sales. In North America, summer is typically the busiest season for orthodontists with practices that have a high percentage of adolescent and teenage patients as many parents want to get their teenagers started in treatment before the start of the school year; however, many GPs are on vacation during this time and therefore tend to start fewer cases. For our Scanner segment, capital equipment sales are often stronger in the fourth calendar quarter. Consequently, these seasonal trends have caused and may continue to cause fluctuations in our quarterly results, including fluctuations in sequential revenue growth rates.

Backlog

All Invisalign treatments are individually unique and prescribed by a doctor so, no two cases are alike. The period from which a treatment data package (or a "case") is received until the acceptance of the digital ClinCheck treatment plan is dependent on the dental professional's discretion to modify, accept or cancel the treatment plan. Therefore, we consider the case a firm order to manufacture aligners once the dental professional has approved the ClinCheck treatment plan. Our Invisalign backlog consists of ClinCheck treatment plans that have been accepted but not yet shipped. Because aligners are shipped shortly after the ClinCheck treatment plan has been accepted, we believe that backlog is not a good indicator of future Invisalign revenues. Our quarterly Invisalign revenues can be impacted by the timing of the ClinCheck treatment plan acceptances and our ability to ship those cases in the same quarter. We define our intraoral scanner backlog as orders where credit and financing is approved and payment is reasonably assured but the scanner has not yet shipped. Our intraoral scanner backlog as of December 31, 2018 was not material to the business as a whole.

Competition

Currently, our products compete directly against products manufactured and distributed by various companies, both within and outside the U.S. Although the number of competitors varies by segment, geography and customer, we encounter a wide variety of competitors, including well-established regional competitors in certain foreign markets, as well as larger companies or divisions of larger companies with substantial sales, marketing, research and financial capabilities. Due in part to the expiration of certain key patents owned by us beginning in 2017, we are facing increased competition in the clear aligner market markets as a result of the entry of new, large companies into certain markets who have the ability to leverage their existing channels in the dental market to compete directly with us. In addition, corresponding foreign patents started to expire in 2018 and will likely result in increased competition in some of the markets outside the U.S. Furthermore, we also face competition from companies that now offer clear aligners directly to the consumer and do not require the consumer to see a doctor before or during orthodontic treatment. Unlike these direct to consumer competitors, we are committed to a doctor in the core of everything we do, and Invisalign Treatment requires a doctor's prescription and an in person physical examination of the patients dentition before treatment can begin. Information regarding risks associated with increased competition may be found in Item 1A of this Annual Report on Form 10-K under the heading "Risk Factors."