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): March 18, 2020

VENUS CONCEPT INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-38238**	**06-1681204**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification Number)**

235 Yorkland Blvd, Suite 900
Toronto, Ontario M2J 4Y8
(Address of principal executive offices, including Zip Code)

Registrant's telephone number, including area code (877) 848-8430

(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 per share	**VERO**	**The 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 ☒

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 8.01. Other Events.

The Company is providing an updated risk factors which are filed as Exhibit 99.1 hereto.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The following exhibits are filed herewith.

Exhibit No.	Description
99.1	Risk Factors

SIGNATURES

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

VENUS CONCEPT INC.

Date: March 18, 2020

By: /s/ Domenic Della Penna
Domenic Della Penna
Chief Financial Officer

RISK FACTORS

Our operations and financial results are subject to various risk and uncertainties, including those described below, any of which could adversely affect our business, results of operations, financial condition and prospects. In such an event, the market price of our Common Stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also adversely affect our business operations. You should carefully consider the risks described below. On November 7, 2019, we completed the Merger. For additional information related to the Merger, see the Current Report on Form 8-K that we filed with the SEC on November 7, 2019 and the Current Report on Form 8-K/A that we filed with the SEC on December 3, 2019.

Risks Related to Our Business

Following the Merger, we may be unable to integrate successfully the businesses of Restoration Robotics and Venus Concept Ltd. and realize the anticipated benefits of the Merger.

The Merger, which closed on November 7, 2019, involved the combination of two companies which operated as independent companies. Following the Merger, we have been required to devote significant management attention and resources to integrating our business practices and operations. We may fail to realize some or all of the anticipated benefits of the Merger if the integration process takes longer than expected or is more costly than expected. Potential difficulties we may encounter in the integration process include the following:

- the inability to successfully combine the businesses in a manner that permits us to achieve the anticipated benefits of the Merger, including cost savings from our cost reduction initiatives, in the time frame currently anticipated or at all;
- complexities associated with managing the combined businesses;
- integrating personnel from the two companies;
- creating uniform standards, controls, procedures, policies and accounting and other information systems;
- difficulty or failure to transfer or obtain the licenses or permits required for post-Merger operation;
- potential unknown liabilities and unforeseen increased expenses, delays or regulatory conditions associated with the Merger; and
- performance shortfalls at one or both of the two companies as a result of the diversion of management's attention caused by completing the Merger and integrating the companies' operations.

Restoration Robotics and Venus Concept Ltd. have operated independently prior to the Merger. The integration process may also result in the diversion of management's attention, the disruption or interruption of, or the loss of momentum in, each company's ongoing businesses or inconsistencies in standards, controls, procedures and policies, any of which could adversely affect our ability to maintain relationships with customers, suppliers and employees or the ability to achieve the anticipated benefits of the Merger, or could reduce the earnings or otherwise adversely affect the business and financial results of the combined company.

The unaudited pro forma condensed combined financial data for Restoration Robotics and Venus Concept Ltd. is preliminary, and our actual financial position and operations after the Merger may differ materially from the unaudited pro forma combined financial data.

The unaudited pro forma combined financial data for Restoration Robotics and Venus Concept Ltd. is presented for illustrative purposes only and is not necessarily indicative of the

combined company's actual financial condition or results of operations of future periods, or the financial condition or results of operations that would have been realized had the entities been combined during the periods presented. The combined company's actual results and financial position after the Merger may differ materially and adversely from the unaudited pro forma financial data. The purchase price allocation reflected herein is preliminary, and final allocation of the purchase price will be based upon the actual purchase price and the fair value of the assets and liabilities of Restoration Robotics as of the date of the completion of the Merger. Further, the combined company expects to recognize a significant amount of additional goodwill in the Merger. The goodwill will be subject to annual impairment assessments and a material change may be necessary if the results of operations and cash flows are unable to support the goodwill subsequent to the Merger.

Our product sale strategy is focused primarily on a subscription-based business model, and the success of this sales strategy depends on the continued adoption and use of our subscription-based products and services.

To address the financial barriers faced by physicians and aesthetic service providers globally, in our direct operations, we focus our product sale strategy on a subscription-based business model. Our subscription-based model includes an up-front fee and a monthly payment schedule, typically over a period of 36 months, with approximately 40% of total contract payments collected in the first year. If economic circumstances are appropriate, we provide customers in good standing with the opportunity to "upgrade" to new agreements for the newest available or alternative technology we provide throughout the subscription period. Our success depends on growing market adoption by traditional and non-traditional providers and use of our subscription-based business model. Our subscription-based model may not be adopted by customers and potential customers at the rate we anticipate. Our ability to increase the number of customers who purchase our products and services or participate in our subscription-based programs and make our products a significant part of their practices, depends in part on the success of our direct sales and marketing programs. Before potential customers make a subscription-based purchase, they may need to recoup the cost of products that they have already purchased from competitors, and therefore they may decide to delay participating in our subscription-based programs, or decide not to participate at all. If we are unable to increase market adoption and use of our products and services through our subscription-based model, the number of systems we sell may be lower than anticipated.

Our subscription-based model exposes us to the credit risk of our customers over the life of the subscription agreement. In the event that our customers fail to make the monthly payments under their subscription agreements, our financial results may be adversely affected.

For the years ended December 31, 2018 and 2017, approximately 75% and 77%, respectively, of our system revenues were derived from our subscription-based model. For the nine months ended September 30, 2019 and 2018, approximately 70% and 77%, respectively, of system revenues were derived from our subscription-based model. Although the ARTAS® System will not be available under our subscription-based model, we expect that our subscription-based business model to continue to represent the majority of our revenue for the foreseeable future. We collect an up-front fee, combined with a monthly payment schedule typically over a period of 36 months, with approximately 40% of total contract payments collected in the first year. For accounting purposes, these arrangements are considered to be sales-type finance leases, where the present value of all cash flows to be received under the subscription agreement is recognized as revenue upon shipment of the system to the customer. As part of our sales and marketing effort, we do not require our customers to undergo a credit check or register a lien or security interest under the Uniform Commercial Code or similar legislation, as is typically required with a third-party equipment leasing financing. Instead, to ensure that each monthly product payment is made on time and that the customer's systems are serviced in accordance with the terms of the warranty, every product requires a monthly activation code, which we provide to the customer upon receiving each monthly payment. If a customer does not timely pay a monthly installment, the customer will not receive an activation code and will be unable to use the system for any procedures. This process does not protect us from the economic impact of a customer's failure to make its monthly payments and as an unsecured creditor, we are subject to a greater risk in the event of a customer default. We cannot provide any assurance that the financial position of customers

purchasing its products and services under a subscription agreement will not change adversely before we receive all of the monthly installment payments due under the contract. In the event that there is a default by any of the customers to whom we have sold systems under the subscription-based model, we may recognize bad debt expenses in our general and administrative expenses. If this bad debt expense is material, it could negatively affect our results of operations and cash flows.

One of our large customers filed for bankruptcy protection in February 2019 and we recorded a provision for bad debts of $8.3 million against the receivable for this customer for the year ended December 31, 2018, and if we experience other customer defaults under our subscription agreements, our financial results may be adversely affected.

In February 2019, one of our large customers filed for bankruptcy protection. Prior to the bankruptcy filing, we had entered into numerous subscription agreements between 2015 and 2017 with this customer. We recorded a provision for bad debts of $8.3 million against the receivable for this customer for the year ended December 31, 2018. In connection with the bankruptcy, the debtors filed an adversary action against Venus Concept Ltd. (and several others) seeking to avoid any security interest of Venus Concept Ltd., to recover 89 units that had been transferred back to Venus Concept Ltd., the return of approximately $150,000 paid to Venus Concept Ltd. within the 90 days before the bankruptcy filing and to disallow Venus Concept Ltd.'s asserted claim of approximately $5.9 million. Venus Concept Ltd. and the debtors entered into a settlement agreement, which was approved by the bankruptcy court on May 24, 2019, pursuant to which, among other things, a third-party purchaser would buy and assume certain units from the debtors and pay a total of approximately $2.7 million to Venus Concept Ltd. over 25 months, debtors would release and waive any and all claims against us, including the preference claim, we would retain and have all rights to previously terminated units, and any units in possession of the debtors or that were subsequently discovered to be property of the debtor would be returned to us without further cost to us. Pursuant to the settlement agreement, Venus Concept Ltd. agreed to waive and release the debtors from all claims (other than those specifically carved out). We do not anticipate receiving any further distribution from this customer's bankruptcy due to the releases provided for in the settlement agreement. Although we are currently receiving monthly payments under the new agreement with the purchaser of this customer's assets, we cannot assure you that we will receive the full amount. Furthermore, we cannot assure you that we will not experience further customer defaults under our subscription agreements that could have a material adverse effect on our financial position.

We offer credit terms to some qualified customers. In the event that any of these customers default on the amounts payable to us, our financial results may be adversely affected.

In addition to our subscription-based model, we generally offer credit terms of 30 to 60 days to qualified customers and distributors. In the event that there is a default by any of the customers to whom we have provided credit terms, we may recognize bad debt expenses in our general and administrative expenses. If this bad debt expense is material, it could negatively affect our future results of operations and cash flows. Additionally, in the event of deterioration of general business conditions, we may be subject to increased risk of non-payment of our accounts receivables. We may also be adversely affected by bankruptcies or other business failures of our customers, distributors, and potential customers. A significant delay in the collection of accounts receivables or a reduction of accounts receivables collected may impact our liquidity or result in bad debt expenses.

Our competitors may emulate our subscription-based model and erode our competitive advantage.

Our subscription-based model allows us to penetrate new markets and access a broader customer base because it offers an alternative to traditional equipment lease financing. For the nine months ended September 30, 2019 and the year ended December 31, 2018, approximately 70% and 75%, respectively, of systems revenues were derived from the subscription-based model. However, to the extent we continue to be successful in growing the market adoption of our products through our subscription-based model, competitors may seek to emulate this model. Although, we believe that our products compete effectively with the products offered by our competitors, our

customers may be more willing to purchase the products of our competitors if they were offered through a subscription-based model. If customers decide to use the products of its competitors instead of our systems, our financial performance will be adversely affected.

Our recurring losses from operations and negative cash flows raise substantial doubt about our ability to continue as a going concern.

We have had recurring net operating losses and negative cash flows from operations, and until we generate revenue at a level to support our cost structure, we expect to continue to incur substantial operating losses and net cash outflows. As of September 30, 2019 and December 31, 2018, we had an accumulated deficit of $54.9 million and $35.1 million, respectively. Our recurring losses from operations and negative cash flows raise substantial doubt about our ability to continue as a going concern, meaning that we may be unable to continue operations for the foreseeable future or realize assets and discharge liabilities in the ordinary course of operations. In order to continue our operations, we must achieve profitable operations and/or obtain additional equity or debt financing. There can be no assurance that we will be successful in raising additional capital or that such capital, if available, will be on terms that are acceptable to us. If we are unable to raise sufficient additional capital, we may be compelled to reduce the scope of our operations and planned capital or research and development expenditures or sell certain assets, including intellectual property assets. The report of Venus Concept Ltd.'s independent registered public accounting firm on its consolidated financial statements as of and for the years ended December 31, 2018 and 2017, which are incorporated herein by reference, includes an explanatory paragraph indicating that there is substantial doubt about our ability to continue as a going concern. The perception of our ability to continue as a going concern may make it more difficult for us to obtain financing for the continuation of our operations and could result in the loss of confidence by investors, suppliers and employees. Our consolidated financial statements do not include any adjustments that may result from the outcome of this uncertainty.

Venus Concept's loan and security agreements contain restrictions that limit its flexibility in operating its business.

On October 11, 2016, Venus Concept Ltd. entered into a credit agreement as a guarantor with Madryn Health Partners, LP, as administrative agent, and certain of its affiliates as lenders, or collectively, Madryn, as amended, or the Madryn Credit Agreement, pursuant to which Madryn agreed to make certain loans to certain of Venus Concept's subsidiaries, or the Subsidiary Obligors. On November 7, 2019, in connection with the Merger, we joined the Madryn Credit Agreement as a guarantor pursuant to that certain Tenth Amendment to Credit Agreement, Consent and Joinder Agreement. The Madryn Credit Agreement is comprised of four tranches of debt aggregating $70.0 million. As at September 30, 2019, the Subsidiary Obligors had borrowed $60.0 million under the term A-1 and A-2 and B tranches of the Madryn Credit Agreement. Term C borrowings of $10.0 million were undrawn and are no longer available. Borrowings under the Madryn Credit Agreement are secured by substantially all of our assets and the assets of the Subsidiary Obligors. The outstanding principal amount of the loans and all accrued and unpaid interest are due and payable in full on September 30, 2022.

The Madryn Credit Agreement also contains various covenants that limit our ability and the ability of our subsidiaries to engage in specified types of transactions. Subject to limited exceptions, these covenants limit our ability, without Madryn's consent, to, among other things:

- sell, lease, transfer, exclusively license or dispose of our assets;
- create, incur, assume or permit to exist additional indebtedness or liens, which may limit our ability to raise additional capital;
- make restricted payments, including paying dividends on, repurchasing or making distributions with respect to our capital stock;
- pay any cash dividend or make any other cash distribution or payment in respect of our capital stock;

- make specified investments (including loans and advances);
- make changes to certain key personnel including our President and Chief Executive Officer;
- merge, consolidate or liquidate; and
- enter into certain transactions with affiliates.

In addition, the Madryn Credit Agreement contains certain covenants that require us together with our subsidiaries to achieve certain minimum revenue and liquidity thresholds. The minimum revenue and liquidity covenants require that we and our subsidiaries, on a consolidated basis, achieve (i) minimum reported revenue targets for any four consecutive fiscal quarter period of an amount equal to the greater of (A) $100,000,000 and (B) one hundred and fifty percent (150%) of the aggregate outstanding amount of the loans as of the last day of such four consecutive fiscal quarter period, (ii) minimum levels of cash held in deposit accounts controlled by Madryn to be no less than $2,000,000 and (iii) minimum levels of cash held in all deposit accounts, plus availability under the CNB Loan Agreement (as defined below), to be no less than $5,000,000.

Prior to the Merger, Venus Concept Ltd. had failed to satisfy minimum liquidity covenant and failed to timely pay an interest payment, which non-compliance and default was waived. If we together with our subsidiaries fail to comply with these covenants in the future, such failure will result in a default and enable Madryn to require us and the Subsidiary Obligors to repay all outstanding principal amounts and accrued interest. In the event of a default, if we and the Subsidiary Obligors are unable to repay all outstanding amounts, Madryn may foreclose on the collateral granted to it to collateralize the indebtedness, which will significantly affect our ability to operate our business.

If all or any portion of the loans under the Madryn Credit Agreement are prepaid then a prepayment premium must be paid equal to: (i) 6.50% if prepaid after August 31, 2019 but on or prior to August 31, 2020; (ii) 5.00% if prepaid after August 31, 2020 but on or prior to February 28, 2021; (iii) 4.00% if prepaid after February 28, 2021 but on or prior to August 31, 2021; (iv) 3.00% percent if prepaid after August 31, 2021 but on or prior to February 28, 2022; and (v) 2.00% if prepaid after February 28, 2022.

On August 29, 2018, Venus Concept Ltd. entered into an Amended and Restated Loan Agreement as a guarantor with City National Bank of Florida, or CNB, as amended, or the CNB Loan Agreement, pursuant to which CNB agreed to make certain loans and other financial accommodations to the Subsidiary Obligors. In connection with the CNB Loan Agreement, Venus Concept Ltd. also entered into a Guaranty Agreement with CNB dated as of August 29, 2018, or the CNB Guaranty, pursuant to which Venus Concept Ltd. agreed to guaranty the obligations of its subsidiaries under the CNB Loan Agreement. As of September 30, 2019, the CNB Loan Agreement provided for a revolving loan commitment of $10.0 million and $7.6 million was drawn thereunder. Borrowings under the CNB Loan Agreement are secured by substantially all of the assets of the Subsidiary Obligors and the CNB Guaranty.

The CNB Loan Agreement contains various covenants that limit Venus Concept Ltd.'s and its subsidiaries' ability to engage in specified types of transactions. Subject to limited exceptions, these covenants limit Venus Concept Ltd.'s ability, without CNB's consent, to, among other things, sell, lease, transfer, exclusively license or dispose of Venus Concept Ltd.'s assets, incur, create or permit to exist additional indebtedness, or liens, to make dividends and certain other restricted payments, and to make certain changes to its management and/or ownership structure.

In addition, the CNB Loan Agreement contains certain covenants that require the Subsidiary Obligors to achieve certain minimum account balances, or a minimum debt service coverage ratio and a maximum total liability to tangible net worth ratio. If the Subsidiary Obligors fail to comply with these covenants, it will result in a default and require Venus Concept Ltd. and the Subsidiary Obligors to repay all outstanding principal amounts and accrued interest. Prior to the Merger, Venus Concept Ltd. was not in compliance with the minimum debt service

coverage ratio of its credit facility with CNB, which non-compliance was waived. On October 30, 2019, Venus Concept Ltd. and CNB executed a Third Amendment and Waiver to Amended and Restated Loan Agreement which, among other things, revised certain of the financial covenants and waived compliance with the debt service coverage ratio covenant for the fiscal quarter ending September 30, 2019.

In the event of a default, and if Venus Concept Ltd. and the Subsidiary Obligors are unable to repay all outstanding amounts, CNB may foreclose on the collateral granted to it to collateralize the indebtedness, which includes the enforcement of the CNB Guaranty, which will significantly affect Venus Concept Ltd.'s ability to operate its business. The occurrence of any event of default under the CNB Loan Agreement would trigger an event of default under the Madryn Credit Agreement. Additionally, the occurrence of any event of default under the Madryn Credit Agreement would trigger an event of default under the CNB Loan Agreement.

We will require additional financing to achieve our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development, commercialization and other operations or efforts.

Since our inception, we have invested a significant portion of our efforts and financial resources in research and development and sales and marketing activities. Research and development, clinical trials, product engineering, ongoing product upgrades and other enhancements and seeking regulatory clearances and approvals to market future products will require substantial funds to complete. As of December 31, 2019, on a pro forma basis after giving effect to the Merger and the Concurrent Financing, we expect to have capital resources consisting of cash and cash equivalents of approximately $15.9 million. We believe that we will continue to expend substantial resources for the foreseeable future in connection with the ongoing commercializing of our systems, increasing our sales and marketing efforts, and continuing research and development and product enhancements activities.

We believe our existing cash and cash equivalents and cash expected to be generated from the sale of our systems and other products and services will not be enough for us to fund our planned operations for the next twelve months. Therefore, we will need additional capital to fund our future operations. In addition, our operating plans may change as a result of many factors some of which may be unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings or other sources, such as strategic collaborations. Such financing may result in dilution to stockholders, the issuance of securities may have rights, preferences, or privileges senior to those of holders of our Common Stock, the imposition of more burdensome debt covenants and repayment obligations, the licensing of rights to our technology or other restrictions that may affect our business. In addition, we may seek additional capital if favorable market conditions or given other strategic considerations even if we believe we have sufficient capital to fund our current or future operating plans.

Additional funds may not be available when we need them, on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we may be required to:

- delay or curtail our efforts to develop system product enhancements or new products, including any clinical trials that may be required to market such enhancements;
- delay or curtail our plans to increase and expand our sales and marketing efforts; or
- delay or curtail our plans to enhance our customer support and marketing activities.

We are restricted by covenants in the Madryn Credit Agreement and the CNB Loan Agreement. These covenants restrict, among other things, our ability to incur additional indebtedness, which may limit our ability to obtain additional debt financing. In addition, the Madryn Credit Agreement contains certain minimum liquidity and minimum revenue covenants, which, if we fail to maintain or achieve, will result in a default under the agreement and the requirement for us to repay all outstanding principal amounts and accrued interest repay all amounts outstanding.

We will need to continue to incur significant expenses to grow our business, which could negatively affect our future profitability.

In order to grow our business and increase revenues, we will need to introduce and commercialize new products, grow our sales and marketing force, implement new software systems, as well as identify and penetrate new markets. Such endeavors have in the past increased, and may continue in the future, to increase our expenses, including sales and marketing, and research and development. We will have to continue to increase our revenues while effectively managing our expenses in order to achieve profitability and to sustain it. Our failure to control expenses could make it difficult to achieve profitability or to sustain profitability in the future. Moreover, we cannot assure you that our expenditures will result in the successful development and introduction of new products in a cost-effective and timely manner or that any such new products will achieve market acceptance and generate revenues for our business.

We may not be able to correctly estimate or control our future operating expenses, which could lead to cash shortfalls.

Our operating expenses may fluctuate significantly in the future because of a variety of factors, many of which are outside of our control. These factors include:

- the cost of growing our ongoing commercialization and sales and marketing activities;
- the costs of manufacturing and maintaining enough inventories of our systems to meet anticipated demand and inventory write-offs related to obsolete products or components;
- the costs of enhancing the existing functionality and development of new functionalities for our systems;
- the costs of preparing, filing, prosecuting, defending, and enforcing patent claims and other patent related costs, including litigation costs and the results of such litigation;
- the variability of ARTAS® procedures being performed between periods if particular high-volume practitioners perform a smaller number of procedures in each period as a result of the concentration of procedures performed by certain practitioners;
- any product liability or other lawsuits and the costs associated with defending them or the results of such lawsuits;
- the costs associated with conducting business and maintaining subsidiaries and other entities in foreign jurisdictions;
- customers in jurisdictions where our systems are not approved delaying their purchase, and not purchasing our systems, until they are approved or cleared for use in their market;
- the costs to attract and retain personnel with the skills required for effective operations;
- costs associated with integration of the Merger; and
- the costs associated with being a public company.

Our budgeted expense levels are based in part on our expectations concerning future revenue from systems sales, products sales and servicing and procedure-based fees. We may be unable to reduce our expenditures in a timely manner to compensate for any unexpected shortfalls in revenue. Accordingly, a significant shortfall in market acceptance or demand for our systems and procedures could have a material adverse impact on our business and financial condition.

Because we incur a substantial portion of our expenses in currencies other than the U.S. dollar, our financial condition and results of operations may be adversely affected by currency fluctuations and inflation.

In the nine months ended September 30, 2019 and the year ended December 31, 2018, 53% and 49%, respectively, of our global revenues were denominated in U.S. dollars and our reporting currency was the U.S.

dollar. We pay a meaningful portion of our expenses in NIS, CAD, and other foreign currencies. Expenses in NIS and CAD accounted for 23.5% and 14%, respectively, for the nine months ended September 30, 2019, and 32% and 14%, respectively, of our expenses for the year ended December 31, 2018. Salaries paid to our employees, general and administrative expenses and general sales and related expenses are paid in many different currencies. As a result, we are exposed to the currency fluctuation risks relating to the denomination of its future revenues in U.S. dollars. More specifically, if the U.S. dollar devaluates against the CAD or the NIS, our CAD and NIS denominated expenses will be greater than anticipated when reported in U.S. dollars. Inflation in Israel compounds the adverse impact of such devaluation by further increasing the amount of our Israeli expenses. Israeli inflation may also in the future outweigh the positive effect of any appreciation of the U.S. dollar relative to the CAD and the NIS, if, and to the extent that, it outpaces such appreciation or precedes such appreciation. We generally do not engage in currency hedging to protect the Company from fluctuations in the exchange rates of the CAD, NIS and other foreign currencies in relation to the U.S. dollar (and/or from inflation of such foreign currencies), we may be exposed to material adverse effects from such movements. We cannot predict any future trends in the rate of inflation in Israel or the rate of devaluation (if any) of the U.S. dollar or any other currency against the NIS or CAD.

Downturns in the economy or economic uncertainty may reduce patient and customer demand for our systems and services, which could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. Furthermore, the aesthetic industry in which we operate is particularly vulnerable to unfavorable economic trends. Treatments using our systems involves elective procedures, the cost of which must be borne by patients, and is not reimbursable through government or private health insurance. Economic uncertainty may reduce patient demand for the procedures performed using our systems; if there is not sufficient patient demand for the procedures for which our systems are used, practitioner demand for these systems could drop, negatively impacting operating results. The decision to undergo a procedure using our systems is driven by consumer demand. In times of economic uncertainty or recession, individuals generally reduce the amount of money that they spend on discretionary items, including aesthetic procedures. If our customers' patients face economic hardships, our business would be negatively impacted and our financial performance would be materially harmed in the event that any of the above factors discourage patients from seeking the procedures for which our systems are used. A weak or declining economy could also strain our manufacturers or suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our systems or services. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the economic climate and financial market conditions could adversely impact our business. The impact of economic uncertainty on our industry may vary from region to region.

It is difficult to forecast our future performance and our financial results may fluctuate unpredictably.

The rapid evolution of the markets for medical technologies and aesthetic products make it difficult for us to predict our future performance. Several factors, many of which are outside of our control, may contribute to fluctuations in our financial results, such as:

- variations in market demand for our systems and services from quarter to quarter;
- delays in purchasing decisions in jurisdictions where our systems are not approved, and decisions not to purchase our systems until they are approved or cleared for use in a particular market;
- the inability of physicians to obtain the necessary financing to purchase the ARTAS® iX System or our other systems, which may not be available under our subscription-based model;
- customers operating under our subscription-based program may slow down or stop paying their monthly contractual obligations;
- performance of new functionalities and system updates, such as the robotic implantation functionality in the ARTAS® iX System;

- performance of our international distributors or local partners;
- positive or negative media coverage of our systems, positive or negative patient experiences, the procedures or products of our competitors, or our industry generally;
- our ability to maintain our current, or obtain further, regulatory clearances, approvals or CE Certificates of Conformity;
- delays in, or failure of, product and component deliveries by our third-party manufacturers or suppliers;
- seasonal or other variations in patient demand for aesthetic procedures;
- introduction of new medical aesthetic procedures or products and services that compete with our products and services;
- changes in accounting rules that may cause restatement of our consolidated financial statements or have other adverse effects; and
- adverse changes in the economy that reduce patient demand for elective aesthetic procedures.

The historic seasonality of our industry and other factors may contribute to fluctuations in our operating results and stock price and make it difficult to compare our results of operations to prior periods and predict future financial results.

We believe that our business is affected by seasonal and other trends. Specifically, we believe our business is affected by seasonal trends during the summer months in the U.S. and Europe due to vacations taken by physician customers and their patients, as well as fluctuations in operating results due to uneven timing of distributor and corporate account orders and marketing into new geographic regions. Historically, we have sold a relatively small number of ARTAS® and ARTAS® iX Systems at a relatively high price, with each sale of an ARTAS® System or ARTAS® iX System typically involving a significant amount of time, which may also contribute to fluctuations in operating results in the future. In addition, there is typically a substantial increase in sales in the last two months of the year. It is difficult for us to evaluate the degree to which these factors may make our revenue unpredictable in the future, and these seasonal and other trends may continue to lead to fluctuations in quarterly operating results. As a result of these factors, future fluctuations in quarterly results could cause our revenue and cash flows to be below analyst and investor expectations, which could cause decline in our stock price. Due to future fluctuations in revenue and costs, as well as other potential fluctuations, you should not rely upon our operating results in any period as an indication of future performance.

Our success depends on growing physician adoption and use of our systems and adoption by physicians in non-traditional specialty areas.

Aesthetic and hair restoration procedures are performed primarily by physicians who practice dermatology or plastic surgery. Our success depends on the growth of aesthetic and hair restoration procedures performed by physicians other than dermatologists and plastic surgeons, and aesthetic procedures performed by general and family practitioners and aesthetic medical spas. Our ability to increase the number of physicians willing to make a significant capital expenditure to purchase our systems or participate in our subscription program and make them a significant part of their practices, depends on the success of our sales and marketing programs. We must be able to demonstrate that the cost of our systems and the revenue that a physician can derive from performing procedures are compelling when compared to the costs and revenue associated with alternative aesthetic treatments the physician can offer and persuade physicians to purchase our systems instead of those of our competitors, many of whom already have existing relationships with our target physicians. In addition, we believe our marketing programs, including clinical and practice development support, will be critical to increasing utilization and awareness of our systems, particularly the ARTAS® and ARTAS® iX Systems, but these programs require physician commitment and involvement to succeed. We must also be successful in persuading physicians in non-traditional specialties to introduce procedures performed with our systems into their practices. If we are unable to increase adoption and use of its systems by physicians in other non-traditional specialties, our growth and prospects may be adversely affected.

Our success depends in part upon patient satisfaction with the effectiveness of our hair restoration systems.

In order to generate repeat and referral business, patients must be satisfied with the effectiveness of a hair restoration procedure using one of our hair restoration systems. If the ARTAS® System, ARTAS® iX System or NeoGraft® system procedure is not done correctly, and or the patient suffers from complications and other adverse effects, the patient may not be satisfied with the benefits of our hair restoration systems. Furthermore, if the transplanted hair follicles do not grow or survive the transplant, the patient will likely not view the procedure as having a satisfactory outcome. If patients are not satisfied with the aesthetic benefits of a hair restoration procedure using one of our systems or feel that it is too expensive for the results obtained, our reputation and future sales will suffer.

If there is not sufficient patient demand for our procedures, our financial results and future prospects will be negatively impacted.

Our procedures are elective aesthetic procedures, the cost of which must be borne by the patient and is not covered by or reimbursable through government or private health insurance. The decision to undergo one of our procedures is thus driven by patient demand, which may be influenced by a number of factors, such as:

- the success of our sales and marketing programs;
- the extent to which our physician customers recommend our procedures to their patients;
- the extent to which our procedures satisfy patient expectations;
- our ability to properly train our physician customers in the use of our systems so that their patients do not experience excessive discomfort during treatment or adverse side effects;
- the cost, safety, and effectiveness of our systems versus other aesthetic treatments;
- consumer sentiment about the benefits and risks of aesthetic procedures generally and our systems in particular;
- the success of any direct-to-consumer marketing efforts we may initiate; and
- general consumer confidence, which may be impacted by economic and political conditions outside of our control.

Our financial performance will be negatively impacted in the event we cannot generate significant patient demand for procedures performed with our systems.

We compete against companies that offer alternative solutions to our systems, or have greater resources, a larger installed base of customers and broader product offerings than we have. If we are not able to effectively compete with these companies and alternative solutions, our business may not continue to grow.

The medical technology and aesthetic product markets are highly competitive and dynamic and are characterized by rapid and substantial technological development and product innovation. Demand for our systems is impacted by the products and procedures offered by our competitors. Certain of our systems also compete against conventional non-energy-based treatments, such as Botox and collagen injections, chemical peels, and microdermabrasion. In the U.S., we compete against companies that have developed minimally invasive and non-invasive medical aesthetic procedures. Outside of the U.S., likely due to less stringent regulatory requirements, there are more aesthetic products and procedures available in international markets than are cleared for use in the U.S. Sometimes, there are also fewer limitations on the claims our competitors in international markets can make about the effectiveness of their products and the manner in which they can market them. As a result, we may face a greater number of competitors in markets outside of the U.S.

We also compete generally with medical technology and aesthetic companies, including those offering products and products unrelated to skin treatment. Recently, there has been consolidation in the aesthetic industry leading

to companies combining their resources, which increases competition and could result in increased downward pressure on our system prices. For example, Allergan acquired Zeltiq in April 2017, Hologic acquired Cynosure in March 2017, and XIO Group acquired Lumenis in September 2015. These consolidations have created combined entities with greater financial resources, deeper sales channels and greater pricing flexibility than ours. Rumored or actual consolidation of our competitors could cause uncertainty and disruption to our business. In the surgical hair restoration market, we consider our direct competition to be strip surgeries and FUE procedures using hand-held devices. Many of our surgical device and equipment competitors have greater capital resources, sales and marketing operations and service infrastructures than we do, as well as longer commercial histories and more extensive relationships with physicians. Strip surgery and some manual FUE procedures have a greater penetration into the hair restoration market. We face resistance from some established hair restoration practices in converting to ARTAS® procedures due to workflow and staffing changes required, even though we believe that staffing requirements are reduced with the adoption of ARTAS® procedures. Our indirect competition in the hair restoration market also includes non-surgical treatments for hair loss, such as prescription therapeutics, including Propecia, and non-prescription remedies, such as wigs, hair pieces and spray-on applications. Many of our competitors are larger, more experienced companies that have substantially greater resources and brand recognition than we do. Some of these companies have a broad range of product offerings, large direct sales forces and long-term customer relationships with the physicians we target, which could make our market penetration efforts more difficult. Competition in the medical technology and aesthetic hair restoration markets could result in price-cutting, reduced profit margins, and limited market share, any of which would harm our business, financial condition and results of operations.

The success of our subscription-based model depends on customer loyalty.

The success of our subscription-based model depends on customer loyalty. In order to generate recurring revenues and for customers to continue upgrading their technologies to our newest technologies, customers must believe that our systems and service offerings are superior to those of its competitors and enhance the physician's practices and business from a professional, financial and reputational vantage point. To the extent we fail to maintain ongoing relationships with our customers or our systems and service offerings do not satisfy its customers' needs, including their financial goals, our business will be adversely affected.

We may not be able to establish or strengthen our brand.

We believe that establishing and strengthening our brands is critical to achieving widespread acceptance of our systems, particularly because of the highly competitive nature of the market for aesthetic treatments and procedures. Promoting and positioning our brand will depend largely on the success of our marketing efforts and our ability to provide physicians with a reliable systems and services. Given the established nature of our competitors, it is likely that our future marketing efforts will require us to incur significant additional expenses. These brand promotion activities may not yield increased sales and, even if they do, any sales increases may not offset the expenses we incur to promote our brand. If we fail to successfully promote and maintain our brand, or if we incur substantial expenses in an unsuccessful attempt to promote and maintain our brand, systems may not achieve adequate acceptance by physicians, which would adversely affect our business, results of operations and financial condition.

The aesthetic equipment market is characterized by rapid innovation. To compete effectively, we must develop and/or acquire new products and services, seek regulatory clearance and maintain regulatory compliance, market new products successfully, and identify new markets for our technology.

The aesthetic energy-based treatment equipment and hair restoration markets are subject to continuous technological development and product innovation. If we do not continue to innovate and develop new products, services and applications, our competitive position will likely deteriorate as other companies successfully design and commercialize new products, applications and services or enhancements to current products. To continue to

grow in the future, we must continue to develop and/or acquire new and innovative aesthetic and medical products, services and applications, identify new markets, and successfully launch any newly developed or acquired product offerings.

To successfully expand our product and service offerings, we must, among other things:

- develop or otherwise acquire new products that either add to, or significantly improve, our current product offerings;
- obtain regulatory clearance for and adhere to regulatory requirements relating to new products;
- convince existing and prospective customers that our product offerings are an attractive revenue-generating addition to their practice;
- sell our product offerings to a broad customer base;
- identify new markets and alternative applications for our technology;
- protect existing and future products with defensible intellectual property; and
- satisfy and maintain all regulatory requirements for commercialization.

Historically, product introductions have been a significant component of our financial performance. To be successful in the medical aesthetics industry, we believe we need to continue to innovate. Our business strategy is based, in part, on our expectation that we will continue to increase or enhance our product offerings. We need to continue to devote substantial research and development resources to introduce new products, which can be costly and time-consuming to our organization.

We also believe that, to increase revenue from sales of new products, we need to continue to develop our clinical support, further expand and nurture relationships with industry thought leaders, and increase market awareness of the benefits of our new products. However, even with a significant investment in research and development, we may be unable to continue to develop, acquire or effectively launch and market new products and technologies regularly, or at all. If we fail to successfully commercialize new products or enhancements, our business may be harmed.

While we attempt to protect our products through patents and other intellectual property, there are few barriers to entry that would prevent new entrants or existing competitors from developing products that compete directly with our systems. We expect that any competitive advantage we may enjoy from current and future innovations may diminish over time as certain of our intellectual property expires and as companies use or create intellectual property and related products that compete with our innovations. Consequently, we believe that we will have to continuously innovate and improve our products and technology to compete successfully. If we are unable to innovate successfully, our products could become obsolete and our revenue could decline as our customers and prospects purchase competing products.

We may be unsuccessful in penetrating certain international markets through majority-owned subsidiary arrangements with local partners.

We have established several majority-owned subsidiaries in international markets as part of our international growth strategy. Although we select our local partners based on demonstrated experience and expertise in the local aesthetic market, the nature of our arrangements with local partners requires us to share control with unaffiliated third parties. We may not be able to identify local partners with the requisite experience and expertise in their local markets or successfully negotiate an agreement with such local partners. Moreover, the ability of these subsidiaries to execute their business plans depends on the local partners to fulfill their obligations. If local partners fail to fulfill their obligations to our satisfaction, our financial results could be adversely affected or we may be required to increase our level of commitment to the subsidiary and dedicate

additional resources. Although our agreements with our local partners generally allow us control over business operations, differences in views could also result in delayed execution of the subsidiary's business plan. If these differences cause a subsidiary to deviate from our business plans, our results of operations could be adversely affected.

We may be unsuccessful in expanding and managing our direct sales and marketing forces effectively.

We rely on our own direct sales force and in-house marketing organization to sell our systems and services in North America and in international markets, either through wholly-owned or majority-owned subsidiaries. In order to meet our anticipated sales objectives, we expect to continue to grow our global sales and marketing organization over the next several years. There are significant risks involved in building and managing a sales and marketing organization, including risks related to our ability to:

- hire qualified individuals as needed;
- generate sufficient leads within our target customer group for our sales force;
- provide adequate training for the effective sale and marketing of our systems and services;
- retain and motivate our direct sales and marketing professionals;
- effectively oversee geographically dispersed sales and marketing teams; and
- work successfully with local partners of our majority-owned subsidiaries.

Our failure to adequately address these risks could have a material adverse effect on our ability to increase sales and use of our systems and services, which would cause our revenues to be lower than expected and harm our results of operations. In addition, as we transition to direct sales in certain international markets, the transition may result in a slow-down of growth or even a reduction in sales in those markets during the transition process as our distributors anticipate losing the ability to sell our systems.

We depend on third-party distributors to market and sell our systems in certain markets.

In addition to a direct sales and marketing forces, we currently depend on third-party distributors to sell, market, and service our systems in certain markets outside of North America and to train our customers in these markets. For the nine months ended September 30, 2019, and the year ended December 31, 2018, on a pro forma basis after giving effect to the Merger, we generated 7% and 8%, respectively, of our systems revenues from sales made through third-party distributors. Our agreements with third-party distributors generally set forth minimum quarterly purchase commitments required for each distributor and provide the distributor the exclusive right to distribute its systems within a designated territory. As we continue to expand into new markets outside of North America, we may need to engage additional third-party distributors which is subject to a number of risks, including:

- the lack of day-to-day control over the activities of third-party distributors;
- third-party distributors may not commit the necessary resources to market, sell, train, support and service our systems to the level of our expectations;
- third-party distributors may emphasize the sale of third-party products over our products;
- third-party distributors may not be as selective as we would be in choosing customers to purchase our systems or as effective in training physicians in marketing and patient selection;
- third-party distributors may violate applicable laws and regulations, which may expose us to potential liability or limit our ability to sell products in certain markets
- third-party distributors may terminate their arrangements with us on limited, or no, notice or may change the terms of these arrangements in a manner unfavorable to us; and

- disagreements with our distributors that could require or result in costly and time-consuming litigation or arbitration, which we could be required to conduct in jurisdictions in which we are not familiar with the governing law.

In addition, one of our strategic initiatives is to directly provide marketing personnel and resources for third-party distributors. If we fail to establish and maintain satisfactory relationships with our third-party distributors, our revenue and market share may not grow as anticipated, and we could be subject to unexpected costs which would harm our results of operations and financial condition.

Our expanded use of social media platforms presents new risks and challenges, which, if not managed properly, could have a material adverse effect on our business, financial condition and results of operations.

We have implemented a robust public relations outreach strategy that incorporates both digital media and top national media in the fashion and beauty industries. In addition, as part of our practice enhancing services, we provide customers with digital marketing services, including a social media strategy, to support the growth of their practices. Negative posts or comments about us or any of our brands on any social networking website could seriously damage our reputation. In addition, the inappropriate use of certain media vehicles could cause brand damage or information leakage or could lead to legal implications from the improper collection and/or dissemination of personally identifiable information.

Economic and other risks associated with international sales and operations could adversely affect Venus Concept's business.

On a pro forma basis, after giving effect to the Merger, sales in markets outside of the U.S. accounted for approximately 58% of our revenue for the nine months ended September 30, 2019 and 52% of our revenue for the year ended December 31, 2018. As part of our growth strategy, we intend to expand the percentage of our business that comes from sales in markets outside of North America through increased penetration in countries where we currently market and sell our systems through our third-party distributor network and local partners, combined with expansion into new international markets. The majority of our research and development activities and the manufacture of our systems is located outside of the U.S. As a result of our international business, we are subject to a number of risks, including:

- difficulties in staffing and managing our international operations, including the sales offices of our subsidiaries;
- increased competition as a result of more products and procedures receiving regulatory approval or otherwise free to market in international markets;
- longer accounts receivable payment cycles and difficulties in collecting accounts receivable;
- reduced or varied protection for intellectual property rights in some countries;
- import and export restrictions, trade regulations, and non-U.S. tax laws;
- fluctuations in currency exchange rates;
- foreign certification and regulatory clearance or approval requirements;
- difficulties in developing effective marketing campaigns in unfamiliar foreign countries;
- customs clearance and shipping delays;
- political, social, and economic instability abroad, terrorist attacks, and security concerns in general and uncertainties related to the coronavirus;
- preference for locally manufactured products;
- potentially adverse tax consequences, including the complexities of foreign value-added tax systems, tax inefficiencies related to our corporate structure, and restrictions on the repatriation of earnings;

- the burdens of complying with a wide variety of foreign laws and different legal standards; and
- increased financial accounting and reporting burdens and complexities.

If one or more of these risks were realized, it could require us to dedicate significant financial and management resources, and our results of operations and financial condition could be adversely affected.

Business or economic disruptions or global health concerns could have an adverse effect our business, operating results or financial condition.

Global business or economic disruptions could adversely affect our business. For example, in December 2019, an outbreak of a novel strain of coronavirus originated in Wuhan, China, and has since spread to a number of other countries, including the United States. To date, this outbreak has already resulted in extended shutdowns of certain businesses in China, Europe and the United States. Global health concerns, such as the coronavirus, could also result in social, economic, and labor instability in the countries in which we or the third parties with whom we engage operate. We cannot presently predict the scope and severity of any potential business shutdowns or disruptions, but if we or any of the third parties with whom we engage, including our suppliers, manufacturers, customers, regulators and other third parties with whom we conduct business, were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner presently planned could be materially and negatively affect. Disruptions to our business could include restrictions on the ability of our sales and marketing personnel and distributors to travel and sell our systems, disruptions of our global supply chain, reduced demand and/or suspension of operations by our customers which could impact their ability to make monthly payments, or deferral of aesthetic or hair restoration procedures in impacted areas. In addition, the outbreak of contagious diseases or the fear of such an outbreak could adversely affect the economies and financial markets of many countries, resulting in an economic downturn that could affect the demand for our systems. Any of these events could negatively impact our business, operating results or financial condition.

The success of our hair restoration business depends upon the success of the ARTAS® System and ARTAS® iX System, which has a limited commercial history. If we are unsuccessful in developing the market for robotic hair restoration or the market acceptance for the ARTAS® System and ARTAS® iX System fails to grow significantly, our business and future prospects will be negatively impacted.

We commenced commercial sales of the ARTAS® System for hair follicle dissection in the U.S. in 2011. Our success in the hair restoration market depends on the acceptance among physicians and patients of the ARTAS® and ARTAS® iX Systems as the preferred system for performing hair restoration surgery. Acceptance of the ARTAS® and ARTAS® iX Systems by physicians is significantly dependent on our ability to convince physicians of the benefits of the ARTAS® and ARTAS® iX Systems to their practices and, accordingly, develop the market for robotic-assisted hair restoration surgery. Acceptance of the ARTAS® procedure by patients is equally important as patient demand will influence physicians to offer the ARTAS® procedure, and the degree of market acceptance of the ARTAS® and ARTAS® iX Systems by physicians and patients is unproven. We believe that market acceptance of the ARTAS® and ARTAS® iX Systems will depend on many factors, including:

- the perceived advantages or disadvantages of the ARTAS® and ARTAS® iX Systems compared to other hair restoration products and treatments;
- the safety and efficacy of the ARTAS® and ARTAS® iX Systems relative to other hair restoration products and treatments;
- the price of the ARTAS® and ARTAS® iX Systems relative to other hair restoration products and treatments;
- our success in expanding and integrating our hair restoration sales and marketing organization;
- the effectiveness of our marketing, advertising, and commercialization initiatives;
- our success in adding new functionalities to the ARTAS® and ARTAS® iX Systems and enhancing existing functions; and
- our ability to obtain regulatory clearance to market the ARTAS® and ARTAS® iX Systems for additional treatment indications in the U.S.

Further, the ARTAS® iX System, which was launched in July 2018, includes our recently cleared robotic implantation functionality. As this functionality is relatively new, it is possible that it could include defaults, “bugs” or present other technical issues which could prompt potential physician customers to delay their purchase of the ARTAS® iX System or could prompt physicians that have purchased the ARTAS® iX System to either return or not utilize the system.

We cannot assure you that the ARTAS® System or ARTAS® iX System will achieve broad market acceptance among physicians and patients. Because we expect to derive a significant portion of our revenue in the hair restoration market from ARTAS® and ARTAS® iX Systems sales, servicing and procedure-based fees, any failure of this product to satisfy physician or patient demand or to achieve meaningful market acceptance will harm our business and future prospects.

Our inability to effectively compete with competitive hair restoration treatments or procedures may prevent us from achieving significant market penetration in the hair restoration market or improving our operating results.

We designed the ARTAS® System to assist physicians in performing follicular unit extraction surgery. Demand for the ARTAS® Systems and ARTAS® procedures could be limited by other products and technologies. Competition to address hair loss comes from various sources, including:

- therapeutic options including Rogaine, which is applied topically, and Propecia, which is ingested, both of which have been approved by FDA;
- non-surgical options, such as wigs, hair-loss concealer sprays and similar products; and
- other surgical alternatives, including hair transplantation surgery using the strip surgery method or using hand-held devices.

Surgical alternatives to the ARTAS® and ARTAS® iX Systems may be able to compete more effectively than the ARTAS® procedure in established practices with trained staff and workflows built around performing these surgical alternatives. Practices experienced in offering strip surgery or follicular unit extractions using hand-held devices may be reluctant to incorporate or convert their practices to offer ARTAS® procedures due to the effort involved to make such changes.

Many options may be able to provide satisfactory results for male hair loss, generally at a lower cost to the patient than the ARTAS® and ARTAS® iX Systems. As a result, if patients choose these competitive alternatives, our results of operation could be adversely affected.

While traditional hair transplantation surgery has been available for many years, the ARTAS® System has only been commercially available since 2011. As a result, we have a limited track record compared to traditional hair transplantation surgery and the safety and efficacy of the ARTAS® System is not yet supported by long-term clinical data, which could limit sales, and the ARTAS® System could prove to be less safe or effective than initially thought.

The ARTAS® System that we market in the U.S. is regulated as a medical device by the FDA and has received premarket clearance under Section 510(k) of the Federal Food, Drug and Cosmetic Act, or FDCA. In the 510(k) clearance process, before a device may be marketed, FDA must determine that a proposed device is “substantially equivalent” to a legally-marketed “predicate” device, which includes a device that has been previously cleared through the 510(k) process, a device that was legally marketed prior to May 28, 1976 (pre-amendments device), a device that was originally on the U.S. market pursuant to an approved premarket approval, or PMA, application and later down-classified, or a 510(k)-exempt device. This process is typically shorter and generally requires the submission of less supporting documentation than FDA’s PMA process and does not always require long-term clinical studies.

Hair transplantation surgery has been a treatment option for hair restoration for many years, while we only began commercializing the ARTAS® System in 2011. Consequently, we lack the breadth of published long-term clinical data supporting the safety and efficacy of the ARTAS® System and the benefits it offers that might have been generated in connection with other hair restoration techniques. As a result, physicians may be slow to adopt the ARTAS® System, we may not have comparative data that our competitors have or are generating, and we may be subject to greater regulatory and product liability risks. Furthermore, future patient studies or clinical experience may indicate that treatment with the ARTAS® System does not improve patient outcomes compared to other hair restoration techniques. Such results would slow the adoption of the ARTAS® System by physicians, would significantly reduce our ability to achieve expected sales from this system.

We have limited complication or patient success rate data with respect to treatment using the ARTAS® System. If future patient studies or clinical testing do not support our belief that our system offers a more advantageous

treatment for hair restoration, market acceptance of the ARTAS® System could fail to increase or could decrease and our business could be harmed. Moreover, if future results and experience indicate that our implant products cause unexpected or serious complications or other unforeseen negative effects, we could be subject to mandatory product recalls, suspension or withdrawal of FDA or other governmental clearance or approval or, CE Certificates of Conformity, significant legal liability or harm to our business reputation. Furthermore, if patients that receive traditional hair transplantation surgery, such as strip surgery, were to experience unexpected or serious complications or other unforeseen effects, the market for the ARTAS® System may be adversely affected, even if such effects are not applicable to the ARTAS® System.

If we choose to, or are required to, conduct additional studies, such studies or experience could slow the market adoption of the ARTAS® System by physicians, significantly reduce our ability to achieve expected revenue from this system.

One of our subsidiaries is the subject of an investigation by the People's Republic of China, or the PRC, State Administration for Market Regulation, or SAMR, regarding the potential misclassification of one product as a non-medical device. If this subsidiary is determined to have sold the Versa platform under an improper classification, the subsidiary could face material administrative penalties, including loss of future sales, corrective actions, disgorgement of profits and fines.

Our Chinese subsidiary, or Venus Concept China, imports and sells registered medical devices and unregistered non-medical devices in the PRC. One of its unregistered products has been the subject of inquiries from two district level branches of the SAMR, Xuhui MSA and Huangpu MSA, as to whether the product was properly sold as a non-medical device. In January 2019, Venus Concept China had applied to register a version of this non-medical device as a medical device with the National Medical Products Administration of PRC, or NMPA. On June 12, 2019, Venus Concept China was informed that Xuhui MSA had opened an administrative investigation case related to whether the device is an unregistered medical device, as a result of a complaint that Xuhui MSA received from a former distributor of Venus Concept China. Huangpu MSA notified Venus Concept China that it would be suspending its separate investigation against Venus Concept China, pending the results of the Xuhui MSA investigation. We and Venus Concept China have voluntarily stopped sales in China of this product. On December 11, 2019, Xuhui MSA informed Venus Concept China that a determination had been made by the Shanghai Medical Products Administration that Versa's IPL function should be administered as a Class II medical device. Xuhui MSA also suggested that Venus Concept China consider a voluntary recall of all Versa units sold in China. Venus Concept China is currently contemplating a recall plan. In late January 2020, Venus Concept China received a copy of the Shanghai Medical Products Administration's determination that because of the intended uses for Versa's IPL function comprise medical treatment functions such as "treatment of benign pigmented epidermis and skin lesions," Versa's IPL function should be administered as a Class II medical device. Venus Concept China has not yet received a notice of proposed penalty decision from Xuhui MSA. Venus Concept China has not yet received a determination from NMPA on its application for registering Versa's IPL function as a medical device. In addition to the product that is the subject of an administrative investigation, Venus Concept China also sells two other products in the PRC, which are not registered as medical devices with the NMPA. Venus Concept China may not be able to convince the relevant SAMR authorities that the product that is the subject of an administrative investigation was properly classified, or that any of its other products that might be the subject of future government investigations, is properly classified. If any of the products sold by us as unregistered products is ultimately determined to be a medical device, the registration process with the NMPA could be extensive and time-consuming, potentially resulting in Venus Concept China's inability to sell such products in the PRC for several years. Venus Concept China's prior sales of those products could also subject it to material administrative penalties if it is determined that the products were sold in the absence of necessary registrations with NMPA. These administrative penalties could include limitations on future sales, corrective actions, including product recalls, disgorgement of profits and fines, the future imposition of which could materially adversely affect our business, operations, financial condition and reputation in the market. Although the revenue generated from the product that is the subject of the investigation did not represent a material amount

of our total revenues for the year ended December 31, 2018, or for the nine months ended September 30, 2019, monetary penalties nonetheless could be material.

We are the subject of purported class action lawsuits, and additional litigation may be brought against us in the future.

In May and June 2018, a number of purported stockholder class action complaints were filed, in the California Superior Court for the County of San Mateo and the United States District Court for the Northern District of California, respectively, against us, the members of our former board of directors (and affiliated venture funds), as well as certain of our current and former officers and the underwriters in our initial public offering, or IPO. In June 2019, a substantially similar purported stockholder class action complaint was filed in the California Superior Court for the County of San Mateo against us, the members of our former board of directors (and affiliated venture funds), as well as certain of our former officers and the underwriters in our IPO. The complaints all allege, among other things, that our Registration Statement filed with the SEC on September 1, 2017 and the Prospectus filed with the SEC on October 13, 2017 in connection with our IPO were inaccurate and misleading, contained untrue statements of material facts, omitted to state other facts necessary to make the statements made not misleading and omitted to state material facts required to be stated therein. In addition, in July 2019, a shareholder derivative complaint was filed in the United States District Court for the Northern District of California which alleges that certain of our current and former executive officers and directors breached their fiduciary duties, have been unjustly enriched and violated Section 14(a) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, in connection with our IPO and our 2018 proxy statement. The complaints seek unspecified money damages, other equitable relief and attorneys' fees and costs.

On December 6, 2019, a putative shareholder class action was filed in the United States District Court for the District of Delaware alleging that we, along with certain members of our board of directors and former officers, violated Sections 14(a) and 20(a) of the Exchange Act by including false or misleading statements in the proxy statement filed with the SEC by Restoration Robotics on September 10, 2019 in connection with the Merger between Restoration Robotics and Venus Concept Ltd. The complaint seeks, among other things, compensatory and/or rescissory damages, and attorneys' fees and costs.

While we believe these claims to be without merit, we cannot assure you that additional claims alleging the same or similar facts will not be filed. Any litigation could result in substantial costs and a diversion of management's attention and resources.

We rely on a limited number of third-party contract manufacturers for the production of our systems and only have contracts with certain suppliers for the components used in our systems. The failure of these third parties to perform could adversely affect our ability to meet demand for our systems in a timely and cost effective manner.

We rely on third-party contract manufacturers in Karmiel, Israel, Nazareth, Israel, Mazet, France, Weston, Florida and San Jose, California for the manufacture of the majority of our systems. Other than with respect to the ARTAS® iX System, the majority of the components used in our systems are available off the shelf and we do not rely on any single supplier, and as a result we do not have any long-term supply agreements for these components. Our reliance on third-party contract manufacturers and suppliers involves a number of risks, including, among other things:

- contract manufacturers or suppliers may fail to comply with regulatory requirements or make errors in manufacturing that could negatively affect the efficacy or safety of our systems or cause delays in shipments of our systems;
- we or our contract manufacturers or suppliers may not be able to respond to unanticipated changes in customer orders, and if orders do not match forecasts, we or our contract manufactures may have excess or inadequate inventory of materials and components;

- we or our contract manufacturers and suppliers may be subject to price fluctuations due to a lack of long-term supply arrangements for key components;
- we or our contract manufacturers and suppliers may lose access to critical services and components, resulting in an interruption in the manufacture, assembly and shipment of its systems;
- we may experience delays in delivery by our contract manufacturers and suppliers due to changes in demand from us or their other customers;
- fluctuations in demand for systems that our contract manufacturers and suppliers manufacture for others may affect their ability or willingness to deliver components to us in a timely manner;
- our suppliers or those of our contract manufacturers may wish to discontinue supplying components or services to us for risk management reasons;
- we may not be able to find new or alternative components or reconfigure our system and manufacturing processes in a timely manner if the necessary components become unavailable; and
- our contract manufacturers and suppliers may encounter financial hardships unrelated to our demand, which could inhibit their ability to fulfill its orders and meet our requirements.

If any of these risks materialize, they could significantly increase our costs and effect our ability to meet demand for our systems. If we are unable to satisfy commercial demand for our systems in a timely manner, our ability to generate revenue would be impaired, market acceptance of our systems and our reputation could be adversely affected, and customers may instead purchase or use our competitors' products. In addition, we could be forced to secure new or alternative contract manufacturers or suppliers. Securing a replacement contract manufacturer or supplier could be difficult. The introduction of new or alternative manufacturers or suppliers also may require design changes to our medical device products that are subject to FDA and other regulatory clearances or approvals, or a new or revised CE Certificate of Conformity. We may also be required to assess the new manufacturer's compliance with all applicable regulations and guidelines, which could further impede our ability to manufacture our systems in a timely manner. As a result, we could incur increased production costs, experience delays in deliveries of our systems, suffer damage to our reputation, and experience an adverse effect on our business and financial results.

We rely on a single third-party manufacturer for the manufacturing of the reusable procedure kits, disposable procedure kits and spare procedures kits used with the ARTAS® System and the ARTAS® iX System.

NPI Solutions, Inc., or NPI, produces reusable procedure kits, disposable procedure kits and spare kits used with the ARTAS® System and ARTAS® iX System. If the operations of NPI are interrupted or if it is unable or unwilling to meet our delivery requirements due to capacity limitations or other constraints, we may be limited in our ability to fulfill new customer kit orders required for use with the existing ARTAS® System and ARTAS® iX System. Any change to another contract manufacturer would likely entail significant delay, require us to devote substantial time and resources, and could involve a period in which our products could not be produced in a timely or consistently high-quality manner, any of which could harm our reputation and results of operations.

We have a manufacturing agreement for consumables with NPI for the supply of consumable products, including reusable procedure kits, disposable procedure kits and spare procedure kits used with the ARTAS® System and ARTAS® iX System, pursuant to both of which we make purchases on a purchase order basis. The agreement is effective for an initial term of two years and will continue to automatically renew for additional twelve-month periods, subject to either party's right to terminate the agreement upon 180 days advance notice during the initial term if our quarterly forecasted demand falls below 75% of our historical forecasted demand for the same period in the previous year or upon 120 days' advance notice after the initial term.

In addition, our reliance on NPI involves a number of other risks, including, among other things, that:

- our various procedure kits may not be manufactured in accordance with agreed upon specifications or in compliance with regulatory requirements, or its manufacturing facilities may not be able to maintain

compliance with regulatory requirements, which could negatively affect the safety or efficacy of our procedure kits, cause delays in shipments of our procedure kits, or require us to recall procedure kits previously delivered to customers or subject us to enforcement actions by regulatory agencies;

- we may not be able to timely respond to unanticipated changes in customer orders, and if orders do not match forecasts, we may have excess or inadequate inventory of materials and components;
- we may be subject to price fluctuations when a supply contract is renegotiated or if our existing contract is not renewed;
- NPI may wish to discontinue manufacturing and supplying products to us for risk management reasons; and
- NPI may encounter financial or other hardships unrelated to our demand for products, which could inhibit its ability to fulfill our orders and meet our requirements.

If any of these risks materialize, it could significantly increase our costs, our ability to generate net sales would be impaired, market acceptance of our products could be adversely affected, and customers may instead purchase or use our competitors' products, which could have a materially adverse effect on our business, financial condition and results of operations.

Furthermore, if we are required to change the manufacturing of our various procedure kits, we will be required to verify that the new manufacturer maintains facilities, procedures and operations that comply with our quality and applicable regulatory requirements, which could further impede our ability to manufacture the procedure kits in a timely manner. Transitioning to a new supplier could be time-consuming and expensive, may result in interruptions in our operations and product delivery. The occurrence of these events could harm our ability to meet the demand for our products in a timely or cost-effective manner.

We cannot assure you that we will be able to secure alternative equipment and materials and utilize such equipment and materials without experiencing interruptions in our workflow. If we should encounter delays or difficulties in securing, reconfiguring or revalidating the equipment and components we require for the ARTAS® System and ARTAS® iX System, including the related consumables, our reputation, business, financial condition and results of operations could be negatively affected.

If NPI is unable to manufacture the reusable procedure kits, disposable procedure kits and spare procedures kits used with the ARTAS® System and the ARTAS® iX System in high-quality commercial quantities successfully and consistently to meet demand, our growth in the hair restoration market may be limited.

To manufacture our reusable procedure kits, disposable procedure kits and spare procedure kits in the quantities that we believe will be required to meet anticipated market demand, NPI will need to increase manufacturing capacity, which will involve significant challenges. In addition, the development of commercial-scale manufacturing capabilities will require us and NPI to invest substantial additional funds and hire and retain the technical personnel who have the necessary manufacturing experience. Neither we nor NPI may successfully complete any required increase to existing manufacturing processes in a timely manner, or at all.

If NPI is unable to produce the reusable procedure kits, disposable procedure kits and spare kits in sufficient quantities to meet anticipated customer demand, our revenue, business, and financial prospects would be harmed. The limited experience NPI has in producing larger quantities of the procedure kits may also result in quality issues, and possibly result in product recalls. Manufacturing delays related to quality control could harm our reputation and decrease our revenue. Any recall could be expensive and generate negative publicity, which could impair our ability to market the ARTAS® System and the ARTAS® iX System and procedures and negatively affect our results of operations.

If we are unable to manufacture our next generation ARTAS® System, called the ARTAS® iX System in high-quality commercial quantities successfully and consistently to meet demand, our penetration of the hair restoration market will be limited, and our reputation could be harmed.

To manufacture our ARTAS® iX System in the quantities that we believe will be required to meet anticipated market demand, we will need to develop and maintain sufficient manufacturing capacity, which will involve significant challenges. Historically, we have not manufactured any of our other ARTAS® System products in-house or without the contract manufacturer involvement. We have been manufacturing the ARTAS® iX System without a third-party contract manufacturer's involvement for over 18 months. The continuous development of commercial-scale manufacturing capabilities will require us (or our contract manufacturer for ARTAS® iX System, if we decide to utilize one on a long-term basis) to invest substantial additional funds and hire and retain the technical personnel who have the necessary manufacturing experience. We also may become subject to additional, onerous regulatory requirements from the U.S. regulatory agencies as well as foreign regulatory agencies. Neither we nor a third-party manufacturer, if one is utilized, may successfully complete any required increase to existing manufacturing processes in a timely manner, or at all.

If we or a contract manufacturer, if one is utilized, are unable to produce the ARTAS® iX System in sufficient quantities to meet anticipated customer demand, our revenue, business, financial prospects, and reputation would be harmed. The limited experience we have or a third-party manufacturer may have, if one is utilized, in producing the ARTAS® iX System may also result in quality issues, and possibly result in product recalls. Manufacturing delays related to quality control could harm our reputation and decrease our revenue. Any recall could be expensive and generate negative publicity, which could impair our ability to market the ARTAS® iX System and procedures and further affect our results of operations.

Both our manufacturing of certain of our systems and NPI's manufacturing of the ARTAS procedure kits are dependent upon third-party suppliers and, in some cases, sole suppliers, for the majority of our components, subassemblies and materials, making us vulnerable to supply shortages and price fluctuations, which could harm our business.

We and NPI, as the case may be, rely on several sole source suppliers, including Kuka Robotics, Inc., FLIR Integrated Imaging Solutions Inc. and 3D-CAM International Corporation, for certain components of the ARTAS® iX System, reusable procedure kits, disposable procedure kits and spare procedure kits. We also rely on other suppliers for some of the components used to manufacture our other devices. These suppliers, may be unwilling or unable to supply components of these systems to us or NPI reliably and at the levels we anticipate or require to meet demand for our products. For us to be successful, our suppliers must be able to provide products and components in substantial quantities, in compliance with regulatory requirements, in accordance with agreed upon specifications, at acceptable costs and on a timely basis. An interruption in our commercial operations could occur if we encounter delays or difficulties in securing these components, and if we cannot then obtain an acceptable substitute. We source a number of components used in the manufacture of our systems from China; the severity of the coronavirus outbreak could make access to our existing supply chain difficult or impossible and could materially impact our business, and any disruption in the chain of supply may result in manufacturing delays and inventory shortages. If we are required to transition to new third-party suppliers for certain components of our systems or our ARTAS procedure kits, we believe that there are only a few such suppliers that can supply the necessary components. A supply interruption, price fluctuation or an increase in demand beyond our current suppliers' capabilities could harm our ability to manufacture our systems and NPI's ability to manufacture our ARTAS procedure kits until new sources of supply are identified and qualified. In addition, the use of components or materials furnished by these alternative suppliers could require us to alter our operations.

Our reliance on these suppliers subjects us to a number of risks that could harm our reputation, business, and financial condition, including, among other things:

- interruption of supply resulting from modifications to or discontinuation of a supplier's operations;
- delays in product shipments resulting from uncorrected defects, reliability issues, or a supplier's variation in a component;
- a lack of long-term supply arrangements for key components with our suppliers;

- inability to obtain adequate supply in a timely manner, or to obtain adequate supply on commercially reasonable terms;
- difficulty and cost associated with locating and qualifying alternative suppliers for our components in a timely manner;
- production delays related to the evaluation and testing of products from alternative suppliers, and corresponding regulatory qualifications;
- delay in delivery due to our suppliers prioritizing other customer orders over ours;
- damage to our reputation caused by defective components produced by our suppliers;
- increased cost of our warranty program due to product repair or replacement based upon defects in components produced by our suppliers; and
- fluctuations in delivery by our suppliers due to changes in demand from us or their other customers.

Where practicable, we are seeking, or intending to seek, second-source manufacturers for certain of our components. However, we cannot provide assurance that we will be successful in establishing second-source manufacturers or that the second-source manufacturers will be able to satisfy commercial demand for our systems.

If any of these risks materialize, costs could significantly increase and our ability to meet demand for our products could be impacted. If we are unable to satisfy commercial demand for our systems in a timely manner, our ability to generate revenue from these systems would be impaired.

We forecast sales to determine requirements for components and materials used in our systems and if our forecasts are incorrect, we may experience delays in shipments or increased inventory costs.

We keep limited materials, components and finished products on hand. To manage our operations, with third-party contract manufacturers and suppliers, we forecast anticipated system orders and material requirements to predict our inventory needs and enter into purchase orders on the basis of these requirements. Several components of our systems require significant order lead time. As our business continues to expand and if our needs for components and materials increases beyond our estimates, our manufacturers and suppliers may be unable to meet our demand. In addition, if we underestimate our component and material requirements, we may have inadequate inventory, which could interrupt, delay, or prevent delivery of our systems. In contrast, if we overestimate our requirements, we may have excess inventory, which would increase use of our working capital. Any of these occurrences would negatively affect our financial condition and the level of satisfaction our customers have with our business.

Although we actively train our customers on the use of our systems and post-treatment care, misuse by the operator of our systems may result in adverse results and may subject us to liability or otherwise harm our reputation and our business.

We and our independent distributors market and sell our systems to physicians. In the U.S. and certain international markets, subject to local regulations, physician customers can generally allow nurse practitioners, technicians and other non-physicians to perform aesthetic procedures using our systems under their direct supervision. Although we and our distributors provide training on the use of our systems as well as the proper post-treatment care, we do not supervise the procedures performed with our systems, nor can we be certain that physicians are directly supervising procedures according to our recommendations. The potential misuse of our systems or failing to adhere to operating guidelines can cause skin damage and underlying tissue damage, which could harm the reputation of our systems and expose us to costly product liability litigation. In addition, patients may not comply with post-treatment guidelines, which could also lead to adverse results and subject us to liability.

We and our distributors offer system training sessions, but neither we nor our distributors require purchasers or operators of our systems to attend training sessions. The lack of required training for operators of our systems and the use of our systems by non-physicians may result in product misuse and adverse treatment outcomes, which could harm our reputation and expose us to costly product liability litigation.

Product liability suits could be brought against us for defective design, labeling, material, workmanship, or software or misuse of our systems, and could result in expensive and time-consuming litigation, payment of substantial damages, an increase in our insurance rates and substantial harm to our reputation.

If our systems are defectively designed, manufactured, or labeled, contain defective components or software, or are misused, we may become subject to substantial and costly litigation by our customers or their patients. For example, if a patient is injured or suffers unanticipated adverse events after undergoing a procedure using one of our systems, or if system operating guidelines are found to be inadequate, we may be subject to product liability claims. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, product liability claims may result in:

- decreased demand for our systems, or any future systems or services;
- damage to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to customers, patients or clinical trial participants;
- regulatory investigations, product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue; and
- the inability to commercialize future products.

We currently have product liability insurance, but any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions and deductibles, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient funds to pay such amounts. Moreover, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses.

Third parties may attempt to reverse engineer or produce counterfeit versions of our systems which may negatively affect our reputation, or harm patients and subject us to product liability claims.

Third parties have sought in the past, and in the future may seek, to reverse engineer or develop counterfeit products that are substantially similar or compatible with our systems and available to practitioners at lower prices than our own. Practitioners may be able to make unauthorized use of our systems' technology. In addition, if copies of products that have been reverse engineered or counterfeit products are used with or in place of our own, we could be subject to product liability claims resulting from the use of damaged or defective goods and suffer damage to our reputation.

Security breaches and other disruptions could compromise our information and expose us to liability.

In the ordinary course of our business and to the extent necessary, we rely on software to control the ongoing use of our systems, collect and aggregate diagnostic data, and collect and store sensitive data, including intellectual property and proprietary business information, and certain personally identifiable information of customers, distributors, consultants and employees in our data centers and on our networks. The secure processing, maintenance, and transmission of this information is important to our operations and business strategy. We have established physical, electronic, and policy measures to secure our systems in an attempt to prevent a system breach and the theft of data we collect, and we rely on commercially available systems, software, tools, and monitoring in our effort to provide security for our information technology systems and the digital information we collect, process, transmit and store. The third-party providers of such information technology systems and related infrastructure may have or may obtain access to our systems and data within them. Despite our security measures, our information technology systems and related infrastructure, and those of our current and any future collaborators, contractors and consultants and other third parties on which we rely, may be vulnerable to attacks by computer viruses, malware, hackers or breaches due to malfeasance, employee or contractor error, telecommunication or electrical failures, terrorism or other created or natural disasters. The risk of a cyber-attack or cyber intrusion by computer hackers from around the world, including those from foreign governments and terrorists, has greatly increased in number, intensity and sophistication. In addition, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information or other intellectual property. The costs to us to mitigate network security problems, bugs, viruses, worms, malicious software programs and security vulnerabilities could be significant, and while we have implemented security measures to protect our data security and information technology systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service and other harm to our business and our competitive position. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs. Moreover, if a computer security breach affects our systems or results in the unauthorized release of personally identifiable information, our reputation could be materially damaged. In addition, such a breach may require notification to governmental agencies, the media or individuals pursuant to various federal and state privacy and security laws, if applicable, including the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Clinical Health Act of 2009, or HITECH, and its implementing rules and regulations, as well as regulations promulgated by the Federal Trade Commission and state breach notification laws, or the laws or one or more foreign jurisdictions including the European Union's, or the EU, the General Data Protection Regulation 2016/679, or GDPR. We could also be exposed to a risk of loss or litigation and potential liability, which could materially adversely affect our business, results of operations and financial condition.

The clinical trial process required to obtain regulatory clearances or approvals is lengthy and expensive with uncertain outcomes and could result in delays in new product introductions.

In order to obtain 510(k) clearance for certain of our systems, including the ARTAS® System, we were required to conduct clinical trials, and we expect to conduct clinical trials in support of marketing authorization for future products and product enhancements. Conducting clinical trials is a complex and expensive process, can take many years, and outcomes are inherently uncertain. We may suffer significant setbacks in clinical trials, even after earlier clinical trials showed promising results, and failure can occur at any time during the clinical trial process. Any of our products may malfunction or may produce undesirable adverse effects that could cause us or regulatory authorities to interrupt, delay or halt clinical trials. We, FDA, or another regulatory authority may suspend or terminate clinical trials at any time to avoid exposing trial participants to unacceptable health risks.

Successful results of pre-clinical studies are not necessarily indicative of future clinical trial results, and predecessor clinical trial results may not be replicated in subsequent clinical trials. Additionally, FDA may disagree with our interpretation of the data from our pre-clinical studies and clinical trials, or may find the clinical trial design, conduct or results inadequate to prove safety or efficacy, and may require us to pursue

additional pre-clinical studies or clinical trials, which could further delay the clearance or approval of our products. The data we collect from our pre-clinical studies and clinical trials may not be sufficient to support FDA clearance or approval, and if we are unable to demonstrate the safety and efficacy of our future products in our clinical trials, we will be unable to obtain regulatory clearance or approval to market our products.

In addition, we may estimate and publicly announce the anticipated timing of the accomplishment of various clinical, regulatory and other product development goals, which are often referred to as milestones. These milestones could include the obtainment of the right to affix the CE Mark in the European Union; the submission to FDA of an investigational device exemption, or IDE, application to commence a pivotal clinical trial for a new product; the enrollment of patients in clinical trials; the release of data from clinical trials; and other clinical and regulatory events. The actual timing of these milestones could vary dramatically compared to our estimates, in some cases for reasons beyond our control. We cannot assure you that we will meet our projected milestones and if we do not meet these milestones as publicly announced, the commercialization of our products may be delayed and, as a result, our stock price may decline.

Delays in the commencement or completion of clinical testing could significantly affect our product development costs. We do not know whether planned clinical trials will begin on time, need to be redesigned, enroll an adequate number of patients in a timely manner or be completed on schedule, if at all. The commencement and completion of clinical trials can be delayed or terminated for a number of reasons, including delays or failures related to:

- FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical studies;
- obtaining regulatory approval to commence a clinical trial;
- reaching agreement on acceptable terms with prospective clinical research organizations, or CROs, and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- manufacturing sufficient quantities of a product for use in clinical trials;
- obtaining institutional review board, or IRB, or ethics committees' approval to conduct a clinical trial at each prospective site;
- recruiting and enrolling patients and maintaining their participation in clinical trials;
- having clinical sites observe trial protocol or continue to participate in a trial;
- addressing any patient safety concerns that arise during the course of a clinical trial;
- addressing any conflicts with new or existing laws or regulations; and
- adding a sufficient number of clinical trial sites.

Patient enrollment in clinical trials and completion of patient follow-up depend on many factors, including the size of the patient population, the nature of the trial protocol, the proximity of patients to clinical sites, the eligibility criteria for the clinical trial, patient compliance, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the product being studied in relation to other available therapies, including any new treatments that may be cleared or approved for the indications we are investigating. For example, patients may be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post-treatment procedures or follow-up to assess the safety and efficacy of a product, or they may be persuaded to participate in contemporaneous clinical trials of a competitor's product. In addition, patients participating in our clinical trials may drop out before completion of the trial or suffer adverse medical events unrelated to our products. Delays in patient enrollment or failure of patients to continue to participate in a clinical trial may delay commencement or completion of the clinical trial, cause an increase in the costs of the clinical trial and delays, or result in the failure of the clinical trial.

We could also encounter delays if FDA concluded that our financial relationships with our principal investigators resulted in a perceived or actual conflict of interest that may have affected the interpretation of a study, the integrity of the data generated at the applicable clinical trial site or the utility of the clinical trial itself. Principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive cash compensation and/or stock options in connection with such services. If these relationships and any related compensation to or ownership interest by the clinical investigator carrying out the study result in perceived or actual conflicts of interest, or FDA concludes that the financial relationship may have affected interpretation of the study, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection of our marketing application by FDA. Any such delay or rejection could prevent us from commercializing any of our products in development.

Furthermore, clinical trials may also be delayed because of ambiguous or negative interim results. In addition, a clinical trial may be suspended or terminated by us, FDA, the IRB overseeing the clinical trial at issue, the Data Safety Monitoring Board for such trial, any of our clinical trial sites with respect to that site, or other regulatory authorities due to several factors, including:

- failure to conduct the clinical trial in accordance with applicable regulatory requirements or our clinical protocols;
- inspection of the clinical trial operations or trial sites by FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- inability of a clinical investigator or clinical trial site to continue to participate in the clinical trial;
- unforeseen safety issues or adverse side effects;
- failure to demonstrate a benefit from using the product; and
- lack of adequate funding to continue the clinical trial.

Additionally, changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial. If we experience delays in completion of, or if we terminate, any of our clinical trials, the commercial prospects for our products may be harmed and our ability to generate product revenue from these products will be delayed or not realized at all. In addition, any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenue. Any of these occurrences may significantly harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of a clinical trial may also ultimately lead to the denial of regulatory approval of the subject product.

We have increased the size of our company significantly over a short period, and difficulties managing our continued growth could adversely affect our business, operating results, and financial condition.

We have increased our head count from a few employees in 2009 to 524 employees as of December 1, 2019, which includes employees of Restoration Robotics. This growth has placed, and may continue to place, a strain on our management and administrative, operational and financial infrastructure. Our ability to manage our operations and growth requires the continued improvement of our operational, financial and management controls and reporting systems and procedures. If we are unable to manage our growth effectively or if we are unable to attract, incentivize and integrate additional highly qualified personnel, our business, operating results, and financial condition may be harmed.

We depend on skilled and experienced personnel to operate our business effectively. If we are unable to recruit, hire, and retain these employees, our ability to manage and expand our business will be hampered, which could negatively affect our future revenue and profitability.

We are highly dependent on the skills, experience, and efforts of our executive officers and other key employees. Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, sales and marketing, product development and other personnel. The loss of services of any of these individuals could delay or prevent enhancement of the execution of our business and the development of future products and services. Although we have entered into employment agreements with certain members of our senior management team, these agreements do not provide for a fixed term of service.

Competition for qualified personnel in the medical device field is intense due to the limited number of individuals who possess the skills and experience required by the industry. Our ability to retain skilled employees and our success in attracting and hiring new skilled employees will be a critical factor in determining whether we will be successful in the future. We will face significant challenges and risks in hiring, training, managing, and retaining sales and marketing, product development, financial reporting, and regulatory compliance employees, many of whom may be geographically dispersed. In addition, to the extent we hire personnel from competitors, we may be subject to allegations that they have been improperly solicited or that they have divulged proprietary or other confidential information, or that their former employers own their research output. The failure to attract and retain personnel, particularly sales and marketing and product development personnel, could materially harm our ability to compete effectively and grow our business.

We incur significant costs because of operating as a public company, and our management devotes substantial time to new compliance initiatives.

We incur significant legal, accounting and other expenses as a public company, including costs resulting from public company reporting obligations under the Exchange Act and regulations regarding corporate governance practices. The listing requirements of the Nasdaq Global Market and the rules of the Securities and Exchange Commission, or the SEC, require that we satisfy certain corporate governance requirements relating to director independence, filing annual and interim reports, stockholder meetings, approvals and voting, soliciting proxies, conflicts of interest and a code of conduct. Our management and other personnel devote a substantial amount of time to ensure that we comply with all of these requirements. Moreover, the reporting requirements, rules and regulations will continue to increase our legal and financial compliance costs and will make some activities more time-consuming and costlier. Any changes we make to comply with these obligations may not be sufficient to allow us to satisfy our obligations as a public company on a timely basis, or at all. These reporting requirements, rules and regulations, coupled with the increase in potential litigation exposure associated with being a public company, could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors or board committees or to serve as executive officers, or to obtain certain types of insurance, including directors' and officers' insurance, on acceptable terms.

If we fail to maintain adequate and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.

We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, and the rules and regulations of Nasdaq. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in our Annual Report on Form 10-K filing for that year, as required by Section 404 of the Sarbanes-Oxley Act. As a private company, Venus Concept Ltd. was never required to test its internal controls within a specified period. We will now be required to incur substantial professional fees and internal costs to expand our accounting, finance, and compliance functions and that it expends significant management resources. We may experience difficulty in meeting these reporting requirements in a timely manner.

We may discover weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If the combined company is not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act, or if it is unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If that were to happen, the market price of our Common Stock could decline and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities and could face potential stockholder litigation.

We have identified material weaknesses in our internal control over financial reporting and if we fail to remediate these weaknesses and maintain proper and effective internal controls, our ability to produce accurate and timely financial statements could be impaired, which could harm our operating results, our ability to operate our business and investors' views of the Company.

Prior to the Merger, Venus Concept Ltd. was a private company. The Merger will be accounted for as a reverse acquisition with Venus Concept Ltd. as the acquiring company for accounting purposes, and the Company as the legal acquirer. As a result, upon consummation of the Merger, the historical financial statements of Venus Concept Ltd. became the historical financial statements of the combined organization. As a private company, Venus Concept Ltd. has not historically prepared public company level financial statements. In connection with the audit of its consolidated financial statements, Venus Concept Ltd. has identified material weaknesses in its internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim consolidated financial statements will not be prevented or detected on a timely basis.

Venus Concept Ltd. has experienced significant global expansion of operations and revenue growth. As this has occurred, the Company has increased the number of personnel in the organization and specifically in its financial reporting team. Despite this progress, Venus Concept Ltd. identified control deficiencies in aggregate that constitute material weaknesses in the five components of internal control as defined by COSO 2013 (control environment, risk assessment, control activities, information and communication, and monitoring). In particular, compared to public company level processes and standards, Venus Concept Ltd. did not have in place an effective control environment with formal processes and procedures and an adequate number of accounting personnel with the appropriate technical training in, and experience with, U.S. GAAP to allow for a detailed review of accounting transactions that would identify errors in a timely manner. Furthermore, given the growth of the Company, Venus Concept Ltd. had not adopted and implemented technology solutions that would automate lease accounting processes and enable the accurate and timely preparation of financial statements. Finally, Venus Concept Ltd. did not design or maintain effective controls over the financial statement close and reporting process in order to ensure the accurate and timely preparation of financial statements in accordance with US GAAP.

We have undertaken a number of steps to address these material weaknesses and continue to develop and implement our remediation plan, which we believe will address their underlying causes.

These remediation measures may be time consuming, costly, and might place significant demands on our financial and operational resources. Although we have made enhancements to our control procedures in these areas, the material weaknesses will not be remediated until the necessary controls have been implemented and are operating effectively. We do not know the specific time frame needed to fully remediate the material weaknesses identified.

Implementing any appropriate changes to our internal controls and continuing to update and maintain internal controls may distract our officers and employees, entail substantial costs to implement new processes and modify our existing processes and take significant time to complete. If we fail to enhance our internal control over financial reporting to meet the demands that are placed upon us as a public company, including the requirements of the Sarbanes-Oxley Act, we may be unable to report our financial results accurately, which could increase operating costs and harm our business, including investors' perception of our business. The actions we plan to take are subject to continued management review supported by confirmation and testing, as well as audit committee oversight. While we expect to fully remediate these material weaknesses, we cannot assure you that we will be able to do so in a timely manner, which could impair our ability to report our financial position.

We or the third parties upon whom we depend may be adversely affected by earthquakes or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Some of our facilities are located in San Jose, California, which in the past has experienced both severe earthquakes and floods. We do not carry earthquake or flood insurance. Earthquakes or other natural disasters could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects.

If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of these facilities, that damaged critical infrastructure, such as our manufacturing resource planning for the ARTAS® System and enterprise quality systems, or that otherwise disrupted operations, it may be difficult for us to achieve our growth strategy for our hair restoration business. The disaster recovery and business continuity plan we have in place are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. We may incur substantial expenses because of the limited nature of our disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake or flood insurance, could have a material adverse effect on our business.

Furthermore, integral parties in our supply chain are similarly vulnerable to natural disasters or other sudden, unforeseen and severe adverse events. If such an event were to affect our supply chain, it could have a material adverse effect on our business.

We may not be able to enforce in all of the jurisdictions in which we have employees covenants not to compete and therefore may be unable to prevent our competitors from benefiting from expertise of some of our former employees.

We currently have non-competition agreements with a majority of our employees. These agreements prohibit these employees, if they cease working for us, from directly competing with us or working for our competitors. We may not be able to enforce in all of the jurisdictions in which we have employee covenants not to compete and therefore may be unable to prevent our competitors from benefiting from expertise of some of our former employees.

Our employees and independent contractors, including consultants, manufacturers, distributors, commercial collaborators, service providers and other vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have an adverse effect on our results of operations.

We are exposed to the risk that our employees and independent contractors, including consultants, manufacturers, distributors, commercial collaborators, service providers and other vendors may engage in misconduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or other unauthorized activities that violate the laws and regulations of FDA and other similar regulatory bodies, including those laws that require the reporting of true, complete and accurate information to

such regulatory bodies; manufacturing standards; U.S. federal and state healthcare fraud and abuse, data privacy laws and other similar non-U.S. laws; or laws that require the true, complete and accurate reporting of financial information or data. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, the creation of fraudulent data in our nonclinical studies or clinical trials, or illegal misappropriation of product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third-parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. In addition, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and financial results, including, without limitation, the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, individual imprisonment, other sanctions, contractual damages, reputational harm, diminished profits and future earnings and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

We may seek to acquire companies or technologies, which could disrupt our ongoing business, divert the attention of our management and employees and adversely affect our results of operations.

We may, from time to time, evaluate potential strategic acquisitions of other complementary businesses, products or technologies, as well as consider joint ventures and other collaborative projects. We may not be able to identify suitable future acquisition candidates, consummate acquisitions on favorable terms or complete otherwise favorable acquisitions because of antitrust or other regulatory concerns. We cannot be certain that the acquisition of the NeoGraft® business we completed in 2018 or our business combination with Restoration Robotics, which closed on November 7, 2019, or any future acquisitions that we may make, will enhance our business or strengthen our competitive position. In particular, we may encounter difficulties assimilating or integrating the acquired businesses, technologies, products, personnel or operations of the acquired companies, and in retaining and motivating key personnel from these businesses. The integration of these businesses may not result in the realization of the full benefits of synergies, cost savings, innovation and operational efficiencies that may be possible from this integration and these benefits may not be achieved within a reasonable period of time.

Risks Related to Intellectual Property

If we are unable to obtain, maintain, retain and enforce adequate intellectual property rights covering our products and any future products we develop, others may be able to make, use, or sell products that are substantially the same as our, which could adversely affect our ability to compete in the market.

Our commercial success is dependent in part on obtaining, maintaining, retaining and enforcing our intellectual property rights, including our patents and the patents we exclusively licenses. If we are unable to obtain, maintain, retain and enforce sufficiently broad intellectual property protection covering our products and any other products we develop, others may be able to make, use, or sell products that are substantially the same as our products without incurring the sizeable development and licensing costs that we have incurred, which would adversely affect our ability to compete effectively in the market.

We have obtained and maintained our existing patents, seek to diligently prosecute our existing patent applications, and seek to file patent applications and obtain additional patents and other intellectual property rights to restrict the ability of others to market products that compete with our current and future products. As of September 30, 2019, Venus Concept Ltd.'s patent portfolio was comprised of 7 issued U.S. patents (all of which cover our (MP)^2® technology that are associated with two different patent families), 10 pending U.S. patent applications, 1 pending U.S. provisional patent application, 12 issued foreign counterpart patents, and 11 pending foreign counterpart patent applications. As of September 30, 2019, Restoration Robotics patent portfolio was

comprised of 93 issued U.S. patents, 14 pending U.S. patent applications, 119 issued foreign counterpart patents, and 33 pending foreign counterpart patent applications. However, patents may not be issued on any pending or future patent applications we file, the claims that issue may provide limited or no coverage of its products and technologies, and, moreover, issued patents owned or licensed to us now or in the future may be found by a court to be invalid or otherwise unenforceable at any time. We may choose to not apply for patent protection or may fail to apply for patent protection on important technologies or product candidates in a timely fashion. In addition, we may be unable to obtain patents necessary to protect our technology or products due to prior uses of or claims to similar processes or systems by third parties, or to blocking intellectual property owned by third parties. Even though we have issued patents, and even if additional patents are issued to us in the future, they may be challenged, narrowed, invalidated, held to be unenforceable or circumvented, which could limit our ability to prevent competitors from using similar technology or marketing similar products, or limit the length of time our technologies and products have patent protection. Also, even if our existing and future patents are determined to be valid and enforceable, they may not be drafted or interpreted sufficiently broadly enough to prevent others from marketing products and services similar to ours, by easily designing products around our patents or otherwise developing competing products or technologies. In addition, the ownership or inventorship of one or more of our patents and patent applications may be challenged by one or more parties in one or more jurisdictions, including in a patent interference or a derivation proceeding in the United States Patent and Trademark Office, or the USPTO, or a similar foreign governmental agency or during the course of a litigation. If a competitor were able to successfully design around our patents, we may not be able to block such competition, and furthermore the competitor's products may be more effective or commercially successful than its products. In addition, our current patents will eventually expire or they may otherwise cease to provide meaningful competitive advantage, and we may be unable to adequately develop new technologies and obtain future patent protection to preserve our competitive advantage or avoid other adverse effects on our business.

We have a number of foreign patent applications, and while we generally try to pursue patent protection in the jurisdictions in which we do or intend to do significant business, the filing, prosecuting, maintaining and defending patents relating to our current or future products in all countries throughout the world would be prohibitively expensive. Furthermore, the laws of some foreign jurisdictions do not protect intellectual property rights to the same extent as laws in the U.S., and many companies have encountered significant difficulties in obtaining, protecting, and defending such rights in foreign jurisdictions. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to its products in various jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products, and we may be unable to prevent such competitors from importing those infringing products into territories where we do not have patent protection or into territories where we do have patent protection but there is no prohibition against such importation, or even if such prohibitions exist, the law or related enforcement is not as strong as in the U.S. These products may compete with our systems and our patents and our other intellectual property rights may not be effective or sufficient to prevent competitors from competing in those jurisdictions. If we encounter such difficulties or are otherwise precluded from effectively protecting and enforcing our intellectual property rights in foreign jurisdictions, our business prospects could be substantially harmed.

Our patents may not afford us protection against competitors with similar technology. Because the systems of obtaining patent rights in the U.S. and many foreign jurisdictions mandate that the first filer of a patent application is the only one that may be awarded patent rights related to the invention disclosed therein, and there may be a delay up to eighteen months after filing for the patent applications of others to become public (or, in some cases, are not published until they issue as patents), we cannot be certain that we were the first to file for protection of the inventions set forth in such patent applications. Another party may own patents, may have filed or may in the future file patent applications which may result in issued patents, covering our systems or technology. Third-party patent applications and patents could significantly reduce the scope of protection of patents owned by or licensed to us and limit our ability to obtain a meaningful scope of patent protection or market and sell our products or develop, market and sell future products. In the U.S., other parties may attack the validity of our patents after they issue, in a court proceeding, or in an ex-parte reexamination proceeding or one

or more post-grant procedures that were authorized under the America Invents Act of 2011, that were available commencing on March 16, 2013 such as post-grant review, covered business method review or inter partes review, in front of the Patent Trial and Appeal Board of the USPTO. The costs of these proceedings could be substantial. Additionally, patents and patent applications owned by third parties may prevent us from pursuing certain opportunities such as entering into specific markets or developing certain products. Finally, we may choose to enter into markets in which certain competitors own patents or control patent rights to technology that may impede our ability to compete effectively.

We may in the future become involved in lawsuits to defend ourselves against intellectual property disputes, which could be expensive and time consuming, and ultimately unsuccessful, and could result in the diversion of significant resources, and hinder our ability to commercialize our existing or future products.

Our success depends in part on not infringing the patents or not violating other intellectual property rights of others. Intellectual property disputes can be costly to defend and may cause our business, operating results and financial condition to suffer. Significant litigation regarding patent rights occurs in the medical technology and aesthetic product industries. Whether merited or not, it is possible that U.S. and foreign patents and pending patent applications controlled by third parties may be alleged to cover our products. We may also face allegations that our employees have misappropriated the intellectual property rights of their former employers or other third parties. Our competitors in both the U.S. and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit, or otherwise interfere with our ability to make, use, sell, and/or export our products. Our competitors may have one or more patents for which they can threaten and/or initiate patent infringement actions against us and/or any of our third-party suppliers. Our ability to defend ourselves and/or our third-party suppliers may be limited by our financial and human resources, the availability of reasonable defenses, and the ultimate acceptance of our defenses by the courts or juries. Furthermore, if such patents are successfully asserted against us, this may result in an adverse impact on our business, including injunctions, damages, and/or attorneys' fees. From time to time and in the ordinary course of business, we may develop noninfringement and/or invalidity positions with respect to third-party patents, which may or not be ultimately adjudicated as successful by a judge or jury if such patents were asserted against us.

We may receive in the future, particularly as a public company, communications from patent holders, including non-practicing entities, alleging infringement of patents or other intellectual property rights or misappropriation of trade secrets, or offering licenses to such intellectual property. Any claims that we assert against perceived infringers could also provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property rights. At any given time, we may be involved as either a plaintiff or a defendant in a number of patent infringement actions, the outcomes of which may not be known for prolonged periods of time.

The large number of patents, the rapid rate of new patent applications and issuances, the complexities of the technologies involved, and the uncertainty of litigation significantly increase the risks related to any patent litigation. Any potential intellectual property litigation also could force us to do one or more of the following:

- stop selling, making, using, or exporting products that use the disputed intellectual property;
- obtain a license from the intellectual property owner to continue selling, making, exporting, or using products, which license may require substantial royalty payments and may not be available on reasonable terms, or at all;
- incur significant legal expenses;
- pay substantial damages or royalties to the party whose intellectual property rights we may be found to be infringing, potentially including treble damages if the court finds that the infringement was willful;
- if a license is available from a third-party, we may have to pay substantial royalties, upfront fees or grant cross-licenses to intellectual property rights for our products and services;

- pay the attorney fees and costs of litigation to the party whose intellectual property rights we may be found to be infringing;
- find non-infringing substitute products, which could be costly and create significant delay due to the need for FDA regulatory and other regulatory clearance;
- find alternative supplies for infringing products or processes, which could be costly and create significant delay due to the need for FDA regulatory clearance; and/or
- redesign those products or processes that infringe any third-party intellectual property, which could be costly, disruptive, and/or infeasible.

From time to time, we may be subject to legal proceedings and claims in the ordinary course of business with respect to intellectual property. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our Common Stock. Finally, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

If any of the foregoing occurs, we may have to withdraw existing products from the market or may be unable to commercialize one or more of our products, all of which could have a material adverse effect on our business, results of operations and financial condition. Any litigation or claim against us, even those without merit, may cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business and harm our reputation. Furthermore, as the number of participants in the medical aesthetic and robotic hair restoration surgery market grows, the possibility of intellectual property infringement claims against us increases.

In addition, we may indemnify our customers, suppliers and international distributors against claims relating to the infringement of the intellectual property rights of third parties relating to our products, methods, and/or manufacturing processes. Third parties may assert infringement claims against our customers, suppliers, or distributors. These claims may require us to initiate or defend protracted and costly litigation on behalf of our customers, suppliers or distributors, regardless of the merits of these claims. If any of these claims succeed, we may be forced to pay damages on behalf of our customers, suppliers, or distributors or may be required to obtain licenses for the products they use. If we cannot obtain all necessary licenses on commercially reasonable terms, our customers may be forced to stop using our products, or our suppliers may be forced to stop providing us with products.

Similarly, interference or derivation proceedings provoked by third parties or brought by the USPTO or any foreign patent authority may challenge the priority of inventions or other matters of inventorship with respect to our patents or patent applications. We may also become involved in other proceedings, such as re-examination or opposition proceedings, before the USPTO or its foreign counterparts relating to our intellectual property or the intellectual property rights of others. An unfavorable outcome in any such proceedings could require us to cease using the related technology or to attempt to license rights to it from the prevailing party or could cause us to lose valuable intellectual property rights. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, if any license is offered at all. Litigation or other proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may also become involved in disputes with others regarding the ownership of intellectual property rights. For example, we may in the future jointly develop intellectual property with certain parties, and disagreements may therefore arise as to the ownership of the intellectual property developed pursuant to these future relationships. If we are unable to resolve these disputes, we could lose valuable intellectual property rights.

The legal determinations relating to patent rights afforded to companies in the medical technology and aesthetic product fields can be uncertain and involve complex legal, factual and scientific questions, sometimes involving important legal principles which remain uncertain or unresolved, and such uncertainty could affect the outcome or intellectual property related legal determinations in which we are involved.

Both the U.S. Supreme Court and the U.S. Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the U.S. are interpreted. Similarly, foreign courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. In addition, the U.S. Congress is currently considering legislation that would change certain provisions of U.S. federal patent law. We cannot predict future changes U.S. and foreign courts may make in the interpretation of patent laws or changes to patent laws which might be enacted into law by U.S. and foreign legislative bodies. Those changes may materially affect our patent rights, and our ability to obtain patents in the future.

The Leahy-Smith America Invents Act, or the Leahy-Smith Act, includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted and also affect patent litigation. The USPTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, which became effective on March 16, 2013. The first to file provisions limit the rights of an inventor to patent an invention if not the first to file an application for patenting that invention, even if such invention was the first invention. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business.

However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the enforcement and defense of our issued patents. For example, the Leahy-Smith Act provides that an administrative tribunal known as the Patent Trial and Appeals Board, or PTAB, provides a venue for challenging the validity of patents at a cost that may be lower than district court litigation and on timelines that are much faster. Although it is not clear what, if any, long-term impact the PTAB proceedings will have on the operation of our business, the initial results of patent challenge proceedings before the PTAB since its inception in 2013 have resulted in the invalidation of many U.S. patent claims. The availability of the PTAB as a lower-cost, faster and potentially more potent tribunal for challenging patents could increase the likelihood that our own patents will be challenged, thereby increasing the uncertainties and costs of maintaining and enforcing them.

The protection for our proprietary developments is uncertain because legal means may afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage arising from our proprietary developments, which could adversely affect our financial condition and results of operations. For example, any of the following could occur:

- others may be able to make systems or devices that are similar to ours but that are not covered by the claims of our patents;
- others may assert that we were not the first to make the inventions covered by our issued patents or pending patent applications;
- our pending patent applications may not result in issued patents or obtain the coverage originally sought;
- any of our present or future patents or patent claims or other intellectual property rights may lapse or be invalidated, rendered unenforceable, circumvented, challenged or abandoned;
- we may not have, or may fail to obtain, patents in all jurisdictions in which our products are sold or in which systems or devices that are similar to ours are made or sold by third parties;
- our issued patents may not provide us with any competitive advantages;
- the claims of our issued patents or patent applications when issued may not cover our products or the future products we develop;

- there may be dominating or blocking patents of which we are not aware that are relevant to our technologies, including our controlled-cooling technology;
- our ability to assert our intellectual property rights against potential competitors or to settle current or future disputes may be limited by our agreements with third parties, financial constraints, market realities, competitive concerns or other factors;
- there may be prior public disclosures of which we are not aware that could invalidate our inventions or place some of our intellectual property in the public domain;
- the laws of foreign countries may not protect our proprietary rights to the same extent as the laws of the U.S.;
- our intellectual property rights may not be enforceable in jurisdictions where competition may be intense or where legal protection may be weak and the outcomes are uncertain; and
- we may not develop additional proprietary products that are patentable.

From time to time, we analyze our competitors' products and services, and may in the future seek to enforce our patents or other rights to counter perceived infringement. In order to preserve and enforce our patent and other intellectual property rights, we may need to make claims or file lawsuits against third parties. Such lawsuits can be expensive and time-consuming and could divert our efforts and attention from other aspects of our business. In addition, in an infringement proceeding, a court may decide that the patent we seek to enforce is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that the patent in question does not cover products accused of infringement. An adverse result in any litigation also could put one or more of our patents at risk of being interpreted more narrowly than previously thought. Similarly, some of our competitors are very large companies that may be able to devote significantly more resources to intellectual property litigation, and may have significantly broader patent portfolios to assert against us if we assert our rights against them. Finally, because of the substantial discovery required in connection with intellectual property litigation in the U.S., substantial burden could be placed on us relating to discovery activities and related costs associated with intellectual property litigation.

Prosecution of patent applications, post-grant opposition proceedings, and litigation to establish the validity, enforceability, and scope of patents, assert patent infringement claims against others or defend against patent infringement claims by others are expensive and time-consuming. There can be no assurance that, in the event that claims of any of our patents are challenged by one or more third parties, any court or patent authority ruling on such challenge will determine that such patent claims are valid and enforceable. An adverse outcome in such litigation or post grant proceeding could cause us to lose associated patent rights and may have a material adverse effect on our business.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. In addition, periodic maintenance fees on issued patents often must be paid to the USPTO and foreign patent agencies over the lifetime of the patent. While an unintentional lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our products or procedures, we may not be able to stop a competitor from marketing products that are the same as or similar to our own, which would have a material adverse effect on our business.

We may not be able to adequately protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on our products in all countries throughout the world would be prohibitively expensive. The requirements for patentability may differ in certain countries, particularly developing countries, and the breadth of patent claims allowed can be inconsistent. In addition, the laws of some foreign countries may not protect our intellectual property rights to the same extent as laws in the U.S. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, furthermore, may export otherwise infringing products to territories in which we have patent protection that may not be sufficient to terminate infringing activities.

We do not have patent rights in certain foreign countries in which a market may exist. Moreover, in foreign jurisdictions where we do have patent rights, proceedings to enforce such rights could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, and our patent applications at risk of not issuing. Additionally, such proceedings could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Thus, we may not be able to stop a competitor from marketing and selling in foreign countries products that are the same as or similar to our products, and our competitive position in the international market would be harmed.

Unauthorized use of our intellectual property may have occurred or may occur in the future. Any failure to detect or identify unauthorized use of, and otherwise adequately protect, our intellectual property could adversely affect our business, including by reducing the demand for our products.

Unauthorized use of our intellectual property may have occurred or may occur in the future. Any reverse engineered or counterfeit products that purport to be our systems that are currently in the market or that may be introduced in the future may harm our reputation and our sale of products. Moreover, if we commence litigation to stop or prevent any unauthorized use of our technology that occurs from reverse engineering or counterfeiting of our products, or if we have to defend allegations of such unauthorized use of a third party's technology, such litigation would be time-consuming, force us to incur significant costs and divert our attention and the efforts of its management and other employees.

We depend on certain technologies that are licensed to us. We do not control these technologies and any loss of our rights to them could prevent us from selling our products.

We are dependent on intellectual property license agreements for certain key technology for which we pay royalty fees. We do not own the patents that underlie our licenses. Our rights to use the technology we license are subject to the negotiation of, continuation of and compliance with the terms of those licenses. In some cases, we do not control the prosecution, maintenance, or filing of the patents to which we hold licenses, or the enforcement of these patents against third parties. These patents and patent applications are not written by us or our advisors, and we did not have control over the drafting and prosecution. Our licensors might not have given the same attention to the drafting and prosecution of these patents and applications as we would have if we had been the owners of the patents and applications and had control over the drafting and prosecution. We cannot be certain that drafting and/or prosecution of the licensed patents and patent applications by the licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights.

Our intellectual property agreements with third parties may be subject to disagreements over contract interpretation, which could narrow the scope of our rights to the relevant intellectual property or technology or increase our financial or other obligations to our licensors.

Certain provisions in our intellectual property agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could affect the scope of our rights to the

relevant intellectual property or technology or affect financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact conceives or develops intellectual property that we regard as our own. Our assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.

We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of our competitors or are in breach of non-competition or non-solicitation agreements with our competitors.

We could in the future be subject to claims that we or our employees have inadvertently or otherwise used or disclosed alleged trade secrets or other proprietary information of former employers or competitors. Although we have procedures in place that seek to prevent our employees and consultants from using the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may in the future be subjected to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other proprietary information of a former employer or competitor. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. If our defense to those claims fails, in addition to paying monetary damages, a court could prohibit us from using technologies or functionalities that are essential to our products, if such technologies or functionalities are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. An inability to incorporate technologies or functionalities that are important or essential to our products would have a material adverse effect on our business and may prevent us from selling our products or from practicing our processes. In addition, we may lose valuable intellectual property rights or personnel. Moreover, any such litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our products, which could have an adverse effect on our business, results of operations and financial condition.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

We have trademark registrations and applications in the U.S. and also in certain foreign countries for Venus Concept, Venus Viva®, Venus Versa®, Venus Freeze®, Venus Legacy®, Venus Bliss™, NeoGraft®, (MP)^2®, Restoration Robotics, ARTAS®, and ARTAS® iX. Actions taken by us to establish and protect our trademarks might not prevent imitation of our products or services, infringement of our trademark rights by unauthorized parties or other challenges to our ownership or validity of our trademarks. If any of these events occur, we may not be able to protect and enforce our rights in these trademarks, which we need in order to build name recognition with potential partners or customers in our markets of interest. In addition, unauthorized third parties may have registered trademarks similar and identical to our trademarks in foreign jurisdictions or may in the future file for registration of such trademarks. If they succeed in registering or developing common law rights in such trademarks, and if we were not successful in challenging such third-party rights, we may not be able to use such trademarks to market our products and services in those countries. If we are unable to register our trademarks, enforce our trademarks, or bar a third-party from registering or using a trademark, our ability to establish name recognition based on our trademarks and compete effectively in our markets of interest may be adversely affected. In addition, our enforcement against third-party infringers or violators may be expensive and time-consuming, and the outcome is unpredictable and may not provide an adequate remedy.

If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.

We rely on trade secret protection to protect our interests in proprietary know-how and processes for which, for example, patents are difficult or impossible to obtain or enforce, or which we believe would be best protected by means that do not result in public disclosure. We may not be able to protect our trade secrets adequately. We have limited control over the protection of trade secrets used by our third-party manufacturers and suppliers and could lose future trade secret protection if any unauthorized disclosure of such information occurs. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors and outside scientific advisors may unintentionally or willfully disclose our proprietary information to competitors. Litigating a claim that a third-party illegally obtained and is using any of our trade secrets is expensive and time-consuming, and the outcome is unpredictable. In addition, courts outside the U.S. are sometimes less willing to protect trade secrets. We rely, in part, on non-disclosure and confidentiality agreements with our employees, consultants and other parties to protect our trade secrets and other proprietary technology. These agreements generally require that all confidential information developed by the individual or made known to the individual by us during the course of the individual's relationship with us be kept confidential and not be disclosed to third parties. However, we may fail to enter into the necessary agreements, and even if entered into, these agreements may be of limited duration or may be breached and we may not have adequate remedies for any unauthorized use or disclosure of our confidential information. Moreover, others may independently and legitimately develop equivalent trade secrets or other proprietary information. In addition, if third parties are able to establish that we are using their proprietary information without their permission, we may be required to obtain a license to that information, or if such a license is not available, re-design our products to avoid any such unauthorized use or permanently stop manufacturing and selling the related products.

We could in the future be subject to claims that we or our employees have intentionally or inadvertently used or disclosed alleged trade secrets or other proprietary information of former employers or competitors. Although we have procedures in place that seek to prevent our employees and consultants from using the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may in the future be subject to claims that we caused an employee to breach the terms of his or her non-disclosure obligations under one or more agreements, or that we or these individuals have, inadvertently or intentionally used or disclosed the alleged trade secrets or other proprietary information of a former employer or competitor. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, any such litigation could result in substantial costs and could be a distraction to management. If our defense to those claims fails, in addition to paying monetary damages, a court could prohibit it from using technologies or functionalities that are essential to our systems. An inability to incorporate technologies or functionalities that are important or essential to our systems could have a material adverse effect on our business and may prevent us from selling our products or from practicing our processes. In addition, we may lose valuable intellectual property rights or personnel. Moreover, any such litigation or corresponding threat may adversely affect our ability to retain or hire employees or contract with independent sales representatives. A loss of key personnel could hamper or prevent our ability to commercialize our products, which could have an adverse effect on our business, results of operations and financial condition.

We also rely on physical and electronic security measures to protect our proprietary information, but these security measures may be breached or may not provide adequate protection for our property. There is a risk that third parties may obtain and improperly utilize our proprietary trade secrets or other proprietary information to our competitive disadvantage. We may not be able to detect or prevent the unauthorized access or use of such information or take appropriate and timely steps to enforce our intellectual property rights.

We may become subject to claims for remuneration for service invention rights by our employees, which could result in litigation and adversely affect our business.

A significant portion of our intellectual property has been developed by our employees based in Israel in the course of their employment for Venus Concept Ltd. Under the Israeli Patent Law, 5727-1967, or the Patent Law,

inventions conceived by employees during and within the scope of employment with an employer are regarded as "service inventions," which belong to the employer, absent a specific agreement between the employee and employer giving the employee service invention rights. The Patent Law also provides that if there is no agreement between an employer and an employee with respect to the employee's right to receive compensation for such "service inventions," the Israeli Compensation and Royalties Committee, a body constituted under the Patent Law, shall determine whether the employee is entitled to remuneration for his or her service inventions and the scope and conditions for remuneration. While Venus Concept Ltd.'s employees have generally explicitly waived their right to any additional compensation for their contribution to service invention rights, certain current or former employees may not have signed such waivers, and we may face claims from current or former employees demanding remuneration in consideration for Venus Concept Ltd.'s employees' contribution to service invention rights, which may lead to future litigation, which could be costly and could divert management's attention and we could be required to pay such remuneration.

Indemnification obligations for third party intellectual property claims may increase our costs or require it to cease selling certain products, which could adversely affect our financial condition and results of operations.

We may be subject to indemnification claim obligations with respect to our intellectual property rights pursuant to its agreements with our customers. Such indemnification provisions are customary in the industry. Successful claims of infringement or misappropriation by a third-party against us or a customer or other third-party that we indemnify could not only prevent us from distributing certain products or performing certain services, but could also require us to pay substantial damages, royalties, legal fees or other fees.

Risks Related to Government Regulation

Our devices and our operations are subject to extensive government regulation and oversight both in the U.S. and abroad, and our failure to comply with applicable requirements could harm our business.

Certain of our systems are regulated as medical devices subject to extensive regulation in the U.S. and elsewhere, including by FDA and its foreign counterparts. FDA and foreign regulatory agencies regulate, among other things, with respect to medical devices:

- design, development and manufacturing;
- testing, labeling, content and language of instructions for use and storage;
- clinical trials;
- product safety;
- marketing, sales and distribution;
- premarket clearance and approval;
- record keeping procedures;
- advertising and promotion;
- recalls and field safety corrective actions;
- post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury;
- post-market approval studies; and
- product import and export.

The regulations to which we are subject are complex and have tended to become more stringent over time. Regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated sales.

In the U.S., before we can market a new medical device, or a new use of, new claim for or significant modification to an existing product, we must first receive either clearance under Section 510(k) of the FDCA or approval of a PMA application from FDA, unless an exemption applies. We consider our Venus Glow™ and NeoGraft® systems exempt from FDA's 510(k) clearance requirement. We have obtained 510(k) clearance from FDA for Venus Concept's Freeze® and Venus Freeze Plus, Venus Viva® SR, Venus Legacy® BX and Legacy CX, Venus Versa®, Venus Velocity™, Venus Heal™, Venus Bliss™ systems, ARTAS® and ARTAS® iX Systems.

In the 510(k) clearance process, before a device may be marketed, FDA must determine that a proposed device is "substantially equivalent" to a legally-marketed "predicate" device, which includes a device that has been previously cleared through the 510(k) process, a device that was legally marketed prior to May 28, 1976 (pre-amendments device), a device that was originally on the U.S. market pursuant to a PMA application and later down-classified, or a 510(k)-exempt device. To be "substantially equivalent," the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data are sometimes required to support substantial equivalence. If a product is not eligible for 510(k) clearance it may require approval of a *de novo* reclassification petition or a PMA. If there is no known predicate for a device, a company can request a *de novo* reclassification of the product. FDA's *de novo* process allows a company to request for certain new devices marketing authorization as class I or class II devices, rather than being subject to PMA requirements as class III devices. In the PMA process, FDA must determine that a proposed device is safe and effective for its intended use based, in part, on extensive data, including, but not limited to, technical, preclinical, human clinical studies conducted under an IDE, and manufacturing and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life- sustaining, life-supporting or implantable devices. Modifications to products that are approved through a PMA application generally require FDA approval. Similarly, certain modifications made to products cleared through a 510(k) may require a new 510(k) clearance. Both the PMA approval and the 510(k) clearance process can be expensive, lengthy and uncertain. FDA's 510(k) clearance process usually takes from three to 12 months, but can take longer. For products subject to PMA, the regulatory process generally takes from one to three years or even longer, from the time the application is filed with FDA and involves substantially greater risks and commitment of resources than either the 510(k) clearance or *de novo* processes. We may not be able to obtain necessary regulatory approvals or clearances on a timely basis, if at all, for any of our products under development, and delays in receipt of, or failure to receive such approvals or clearances could have a material adverse effect on our business. In addition, FDA may disagree with certain of our device classifications. Such a misclassification could render the devices as misbranded and/or adulterated.

FDA can delay, limit or deny clearance or approval of a device for many reasons, including:

- we may not be able to demonstrate to FDA's satisfaction that the product or modification is substantially equivalent to the proposed predicate device or safe and effective for its intended use;
- the data from our pre-clinical studies and clinical trials may be insufficient to support clearance or approval, where required; and
- the manufacturing process or facilities we use may not meet applicable requirements.

FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our products. For example, in December 2016, the 21st Century Cures Act, or Cures Act, was signed into law. The Cures Act, among other things, is intended to modernize the regulation of medical devices and spur innovation, but its ultimate implementation remains unclear. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may fail to obtain any marketing clearances or approvals, lose any marketing clearance or approval that we may have obtained, and we may not achieve or sustain profitability.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the U.S. or abroad. For example, certain policies of the Trump administration may impact our business and industry. Namely, the Trump administration has taken several executive actions, including the issuance of several Executive Orders, that could impose significant burdens on, or otherwise materially delay, FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. Notably, on January 30, 2017, President Trump issued an Executive Order, applicable to all executive agencies including FDA, requiring that for each notice of proposed rulemaking or final regulation issued in fiscal year 2017, the agency had to identify at least two existing regulations to be repealed, unless prohibited by law. These requirements are referred to as the "two-for-one" provisions. This Executive Order includes a budget neutrality provision that required the total incremental cost of all new regulations in the 2017 fiscal year, including repealed regulations, to be no greater than zero, except in limited circumstances. For fiscal years 2018 and beyond, the Executive Order requires agencies to identify regulations to offset any incremental cost of a new regulation and approximate the total costs or savings associated with each new regulation or repealed regulation. In interim guidance issued by the Office of Information and Regulatory Affairs within OMB on February 2, 2017, the administration indicates that the "two-for-one" provisions may apply not only to agency regulations, but also to significant agency guidance documents. In addition, on February 24, 2017, President Trump issued an executive order directing each affected agency to designate an agency official as a "Regulatory Reform Officer" and establish a "Regulatory Reform Task Force" to implement the two-for-one provisions and other previously issued executive orders relating to the review of federal regulations, however it is difficult to predict how these requirements will be implemented, and the extent to which they will impact FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

Even after we have obtained the proper regulatory clearance or approval to market a product, we have ongoing responsibilities under FDA regulations. The failure to comply with applicable regulations could jeopardize our ability to sell our systems and result in enforcement actions such as:

- warning letters;
- fines;
- injunctions;
- civil penalties;
- debarment;
- termination of distribution;
- recalls or seizures of products;
- delays in the introduction of products into the market;
- total or partial suspension of production;
- refusal to grant future clearances or approvals;
- withdrawals or suspensions of current clearances or approvals, resulting in prohibitions on sales of our product or products; and
- in the most serious cases, criminal penalties.

Any of these sanctions could result in higher than anticipated costs or lower than anticipated sales and harm our reputation, business, financial condition and results of operations.

We are subject to extensive governmental regulation in foreign jurisdictions, such as Europe, and our failure to comply with applicable requirements could cause our business to suffer.

We must maintain regulatory approval in foreign jurisdictions in which we plan to market and sell our systems. In the European Economic Area or the EEA, manufacturers of medical devices need to comply with the Essential Requirements laid down in Annex II to the EU Medical Devices Directive (Council Directive 93/42/EEC). Compliance with these requirements is a prerequisite to be able to affix the CE mark to medical devices, without which they cannot be marketed or sold in the EEA. To demonstrate compliance with the Essential Requirements and obtain the right to affix the CE Mark, manufacturers of medical devices must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. Except for low risk medical devices (Class I with no measuring function and which are not sterile), where the manufacturer can issue an EC Declaration of Conformity based on a self-assessment of the conformity of its products with the Essential Requirements, a conformity assessment procedure requires the intervention of a Notified Body, which is an organization designated by a competent authority of an EEA country to conduct conformity assessments.

Depending on the relevant conformity assessment procedure, the Notified Body would audit and examine the Technical File and the quality system for the manufacture, design and final inspection of our devices. The Notified Body issues a CE Certificate of Conformity following successful completion of a conformity assessment procedure conducted in relation to the medical device and its manufacturer and their conformity with the Essential Requirements. This Certificate entitles the manufacturer to affix the CE mark to its medical devices after having prepared and signed a related EC Declaration of Conformity.

As a rule, demonstration of conformity of medical devices and their manufacturers with the Essential Requirements must be based, among other things, on the evaluation of clinical data supporting the safety and performance of the products during normal conditions of use. Specifically, a manufacturer must demonstrate that the device achieves its intended performance during normal conditions of use and that the known and foreseeable risks, and any adverse events, are minimized and acceptable when weighed against the benefits of its intended performance, and that any claims made about the performance and safety of the device (e.g., product labeling and instructions for use) are supported by suitable evidence. This assessment must be based on clinical data, which can be obtained from (1) clinical studies conducted on the devices being assessed, (2) scientific literature from similar devices whose equivalence with the assessed device can be demonstrated or (3) both clinical studies and scientific literature. With respect to active implantable medical devices or Class III devices, the manufacturer must conduct clinical studies to obtain the required clinical data, unless reliance on existing clinical data from equivalent devices can be justified. The conduct of clinical studies in the EEA is governed by detailed regulatory obligations. These may include the requirement of prior authorization by the competent authorities of the country in which the study takes place and the requirement to obtain a positive opinion from a competent Ethics Committee. This process can be expensive and time-consuming.

On April 5, 2017, the European Parliament passed the Medical Devices Regulation, which repeals and replaces the EU Medical Devices Directive. Unlike directives, which must be implemented into the national laws of the EEA member States, the regulations would be directly applicable, i.e., without the need for adoption of EEA member State laws implementing them, in all EEA member States and are intended to eliminate current differences in the regulation of medical devices among EEA member States. The Medical Devices Regulation, among other things, is intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the EEA for medical devices and in vitro diagnostic devices and ensure a high level of safety and health while supporting innovation.

The Medical Devices Regulation will however only become applicable three years after publication. Once applicable, the new regulations will among other things:

- strengthen the rules on placing devices on the market and reinforce surveillance once they are available;

- establish explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market;
- improve the traceability of medical devices throughout the supply chain to the end-user or patient through a unique identification number;
- set up a central database to provide patients, healthcare professionals and the public with comprehensive information on products available in the EU; and
- strengthen rules for the assessment of certain high-risk devices, such as implants, which may have to undergo an additional check by experts before they are placed on the market.

These modifications may have an impact on the way we conduct our business in the EEA.

We are subject to governmental regulation and other legal obligations, particularly related to privacy, data protection and information security, which are complex and rapidly changing. Our actual or perceived failure to comply with such obligations could harm our business.

We are subject to diverse laws and regulations relating to data privacy and security, including, in the U.S., the HIPAA, and, in the EU and shortly in the EEA, GDPR. New global privacy rules are being enacted and existing ones are being updated and strengthened. Complying with these numerous, complex and often changing regulations is expensive and difficult, and failure to comply with any privacy laws or data security laws or any security incident or breach involving the misappropriation, loss or other unauthorized use or disclosure of sensitive or confidential patient or consumer information, whether by us, one of our business associates or another third-party, could have a material adverse effect on our business, reputation, financial condition and results of operations, including but not limited to: material fines and penalties; damages; litigation; consent orders; and injunctive relief.

The regulation of data privacy and security, and the protection of the confidentiality of personal information, is increasing and continues to evolve. For example, the GDPR came into effect in May 2018 reforming the European regime. The GDPR implements more stringent operational requirements than its predecessor legislation. For example, the GDPR requires us to make more detailed disclosures to data subjects, requires disclosure of the legal basis on which we can process personal data, makes it harder for us to obtain valid consent for processing, provides more robust rights for data subjects, introduces mandatory data breach notification through the EU, imposes additional obligations on us when contracting with service providers and requires us to adopt appropriate privacy governance including policies, procedures, training and data audit. If we do not comply with our obligations under the GDPR, we could be exposed to fines of up to the higher of 20,000,000 Euros or up to 4% of our total worldwide annual turnover in the event of a significant breach. In addition, we may be the subject of litigation and/or adverse publicity, which could have material adverse effect on our reputation and business.

We are also subject to evolving European laws on data export and electronic marketing. The rules on data export will apply when we transfer personal data to group companies or third parties outside of the EEA. For example, in 2015, the Court of Justice of the EU ruled that the U.S.-EU Safe Harbor framework, one compliance method by which companies could transfer personal data regarding citizens of the EU to the U.S., was invalid and could no longer be relied upon. The U.S.-EU Safe Harbor framework was replaced with the U.S.-EU Privacy Shield framework, which is now under review and there is currently litigation challenging another EU mechanism for adequate data transfers, the standard contractual clauses. It is uncertain whether the Privacy Shield framework and/or the standard contractual clauses will be similarly invalidated by the European courts. These changes may require us to find alternative bases for the compliant transfer of personal data from the EEA to the U.S. and we are monitoring developments in this area. The EU is also in the process of replacing the e-Privacy Directive with a new set of rules taking the form of a regulation, which will be directly implemented in the laws of each European member state, without the need for further enactment. The current draft of the e-Privacy Regulation

retains strict opt-in for electronic marketing and the penalties for contravention have significantly increased with fining powers to the same levels as the GDPR (i.e. the greater of 20,000,000 Euros or 4% of total global annual revenue).

Modifications to our products may require new regulatory clearances or approvals or expansion of the scope of our CE Certificates of Conformity with our notified body.

Modifications to our products may require new regulatory clearances or approvals from FDA or other regulatory authorities or expansion of the scope of our CE Certificates of Conformity with our notified body. Even after achieving the initial market clearance, or approval from FDA or other regulatory authorities or having affixed the CE marked to a product, modifications to our systems during their life cycles may require new regulatory approvals or clearances, including 510(k) clearances, premarket approvals, the conduct of a new conformity assessment with our notified body, or foreign regulatory approvals. If we make changes or modifications to an FDA cleared or approved device, FDA requires device manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplement or clearance. A manufacturer may determine that a modification does not significantly affect safety or efficacy, and that the modification does not represent a major change in its intended use, so that no new 510(k) clearance is necessary, but rather a Letter to File is necessary. However, FDA can review a manufacturer's decision and may disagree. FDA may determine that a traditional 510(k), an abbreviated 510(k), a special 510(k) clearance, or device approval is required for the device as modified. For products sold in the EU, we must notify our notified body if significant changes are made to the products or if there are substantial changes to the quality assurance systems affecting those products. We have similar obligations with Health Canada. Obtaining a new 510(k), other regulatory clearances and approvals, or a revised or new CE Certificate of Conformity can be a time-consuming process, and we may not be able to obtain such clearances or approvals in a timely manner, or at all.

We have made modifications to our products in the past and have determined based on our review of the applicable FDA regulations and guidance that in certain instances new 510(k) clearances or PMA approvals were not required. We may make similar modifications or add additional functionalities in the future that we believe do not require a new 510(k) clearance or approval of a PMA. FDA has issued a guidance document intended to assist manufacturers in determining whether modifications to cleared devices require the submission of a new 510(k), and such guidance has come under scrutiny in recent years, the practical impact of which is unclear. If FDA disagrees with our determination and requires us to submit new 510(k) notifications or PMA applications for modifications to our previously cleared products for which we have concluded that new clearances or approvals are unnecessary, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval, which could require us to redesign our products, conduct clinical trials to support any modifications, and pay significant regulatory fines or penalties. In addition, FDA may not approve or clear our products for the indications that are necessary or desirable for successful commercialization or could require clinical trials to support any modifications. Any delay or failure in obtaining required clearances or approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth. Any of these actions would harm our operating results.

As part of an internal review of our regulatory clearances in the U.S., we determined that Special 510(k) applications were necessary related to an earlier modification to two of our FDA-cleared devices. Specifically, because we added to two of our FDA-cleared devices additional FDA-cleared applicators not initially considered in the device clearance submissions, we believed that Special 510(k) applications should have been filed to allow FDA to review the incorporation into the cleared devices of the separately-cleared applicators. We filed one of the Special 510(k) submissions with FDA. FDA requested that we instead submit a Traditional 510(k) and provide additional information. We have accordingly modified the Special 510(k) submitted to FDA to a Traditional 510(k) application for this device, related to these modifications. Generally the 510(k) initial response process is 90 days, however, the overall process may extend to 180 days or more. We cannot be certain that FDA will respond to our submission in a timely manner or that clearance will be obtained. We also submitted a Traditional 510(k) for the second device and, on September 6, 2019, received 510(k) clearance from FDA. We

believe that the modifications do not affect safety or efficacy, do not affect the intended use of the device, and do not alter the fundamental scientific technology of the device, however, we cannot be certain that FDA will agree with our assessment. FDA may not clear the device or may take other action against us as described above, which could have a material adverse effect on our business.

We are subject to restrictions on the indications for which we are permitted to market our products, and any violation of those restrictions, or marketing of systems for off-label uses, could subject us to enforcement action.

Our promotional materials and training methods must comply with FDA and other applicable laws and regulations, including the prohibition of the promotion of off-label use in both the U.S. and in foreign countries. We train our marketing and direct sales force to not promote our systems for uses outside of FDA-cleared indications for use, known as "off-label uses." We cannot, however, prevent a physician from using one of our systems off-label when, in the physician's independent professional medical judgment, he or she deems it appropriate. There may be increased risk of injury to patients if physicians attempt to use one of our systems off-label. Furthermore, the use of one of our systems for indications other than those cleared by FDA or approved by any foreign regulatory body may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients.

If FDA or any foreign regulatory body determines that our promotional materials or training constitute promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including, among other things, the issuance or imposition of an untitled letter, a warning letter, injunction, seizure, refusal to issue new 510(k)s or PMAs, withdrawal of existing 510(k)s or PMAs, refusal to grant export approvals, and civil fines or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action under other regulatory authority, such as false claims laws, if they consider our business activities to constitute promotion of an off-label use, which could result in significant penalties, including, but not limited to, criminal, civil and administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs and the curtailment of our operations.

FDA regulates the labeling of 510(k)-cleared devices to make sure that the labeling complies with the cleared indications for use and no off-label indication or claim is being promoted by the manufacturer. FDA also engages in market surveys to identify any devices whose intended uses include unapproved uses of the products. Devices are considered adulterated or misbranded when advertising or labeling creates a new intended use, indications for use or even a new claim. Federal laws prohibit the introduction into interstate commerce of adulterated or misbranded devices, and adulteration or misbranding violations can lead to a variety of enforcement activities in the U.S. and in foreign countries, including but not limited to large civil and criminal fines, oversight of sales and marketing practices and modifications of promotional conduct.

We previously received an inquiry from FDA regarding off-label or unapproved uses of the Venus Fiore® on August 1, 2018. Venus Fiore® is not cleared or approved in the U.S. or in jurisdictions outside of the U.S., other than Israel. Venus Fiore® is marketed in Israel for aesthetic and functional treatment of the vagina, labia and mons pubis. However, we have not marketed or promoted Venus Fiore® in the U.S. and explained this to the agency. We added geoblocker functionality to our website, to portray accurately what devices it is marketing in the U.S. Although we have not received subsequent inquiries regarding off-label promotion, FDA may conclude that we are inappropriately promoting off-label or unapproved uses for our products. If the agency brings enforcement actions, we may become subject to significant liability including criminal and civil liabilities. Off-label promotion may also be treated as racketeering in civil litigation or result in expensive and time-consuming lawsuits from physicians or their patients if a patient is injured by the off-label use.

Our systems may cause or contribute to adverse medical events that we are required to report to FDA, and if we fail to do so, we would be subject to sanctions that could harm our reputation, business, financial condition and results of operations.

We are subject to FDA's medical device reporting regulations and similar U.S. state and foreign regulations. FDA's medical device reporting regulations require us to report to FDA when we receive or become aware of information that reasonably suggests that one of our systems may have caused or contributed to a death or serious injury or malfunctioned in a way that, if the malfunction were to recur, it could cause or contribute to a death or serious injury. The timing of our obligation to report is triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events of which we become aware within the prescribed timeframe. We may also fail to recognize that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of one of our systems. If we fail to comply with our reporting obligations, FDA could act, including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our device clearance, seizure of our products or delay in clearance of future products.

FDA, state regulating agencies at times, and foreign regulatory bodies have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture of a product or if a product poses an unacceptable risk to health. FDA's authority to require a recall must be based on a finding that there is reasonable probability that the device could cause serious injury or death. We may also choose to voluntarily recall a product if any material deficiency is found. A government-mandated or voluntary recall by us could occur because of an unacceptable risk to health, component failures, malfunctions, manufacturing defects, labeling or design deficiencies, packaging defects or other deficiencies or failures to comply with applicable regulations. We cannot assure you that product defects or other errors will not occur in the future. Recalls involving any of our systems could be particularly harmful to our business, financial condition and results of operations because it is our only product.

Prior to the Merger, we received a letter from FDA's Center for Devices and Radiological Health (CDRH) requesting our assistance to complete an evaluation of a potential post-market safety concern regarding devices used for hair restoration surgery. The letter stated that the potential safety concern is related to adverse events and possible allergic reaction after hair restoration surgery. We are fully cooperating with FDA in its evaluation and have responded to FDA's questions.

Companies are required to maintain certain records of recalls and corrections, even if they are not reportable to FDA. We may initiate voluntary withdrawals or corrections for any of our systems in the future that we determine do not require notification of FDA. If FDA disagrees with our determinations, it could require us to report those actions as recalls and we may be subject to enforcement action. A future recall announcement could harm our reputation with customers, potentially lead to product liability claims against us and negatively affect our sales.

If we or our distributors do not obtain and maintain international regulatory registrations or approvals for our systems, our ability to market and sell our systems outside of the U.S. will be diminished.

Sale of our systems, outside the U.S. are subject to foreign regulatory requirements that vary widely from country to country. In addition, FDA regulates exports of medical devices from the U.S. While the regulations of some countries may not impose barriers to marketing and selling certain of our systems or only require notification, others require that we or our distributors obtain the approval of a specified regulatory body. Complying with foreign regulatory requirements, including obtaining registrations or approvals, can be expensive and time-consuming, and we cannot be certain that we or our distributors will receive regulatory approvals in each country in which we plan to market a particular system or that we will be able to do so on a timely basis. The time required to obtain registrations or approvals, if required by other countries, may be longer than that required for

FDA clearance, and requirements for such registrations, clearances, or approvals may significantly differ from FDA requirements. If we modify our systems, we or our distributors may need to apply for additional regulatory approvals or other authorizations before we are permitted to sell the modified product. In addition, we may not continue to meet the quality and safety standards required to maintain the authorizations that we or our distributors have received. If we or our distributors are unable to maintain our authorizations in a particular country, we will no longer be able to sell the applicable product in that country, which could harm our business.

Regulatory clearance or approval by FDA does not ensure clearance or approval by regulatory authorities in other countries, and clearance or approval by one or more foreign regulatory authorities does not ensure clearance or approval by regulatory authorities in other foreign countries or by FDA. However, a failure or delay in obtaining regulatory clearance or approval in one country may have a negative effect on the regulatory process in others.

Our ability to continue manufacturing and supplying our products depends on our continued adherence to ongoing FDA and other foreign regulatory authority manufacturing requirements.

Our manufacturing processes and facilities are required to comply with the quality management system regulations of its target markets (i.e., FDA's Quality System Regulations, or QSR, ISO 13485:2016, and the MDSAP). Adherence to quality management system regulations and the effectiveness of our quality management control systems are periodically assessed through internal audits and inspections of manufacturing facilities by regulatory authorities. Failure to comply with applicable quality management system requirements, or later discovery of previously unknown problems with our products or manufacturing processes, including our failure or the failure of our third-party manufacturer to take satisfactory corrective action in response to an adverse quality system inspection, can result in enforcement action, which could have an adverse effect on our business. Our manufacturing process and facilities are audited annually for compliance with the last editions of QSR, ISO13485 and MDSAP requirements. FDA inspected our San Jose facility in January 2020, which audit resulted in two observations. We are in the process of mitigating these issues. On November 20, 2019, the Texas Department of State Health Services, or the DSHS, conducted an inspection of our Lewisville, Texas facility and identified alleged misstatements on the packaging of our Venus Skin® products in violation of the Texas Health and Safety Code (Texas Food, Drug, and Cosmetic Act). The DSHS issued a blanket detention of the Venus Skin® inventory at the Lewisville facility until the matter is resolved. On February 12, 2020, the DSHS accepted our product re-labelling proposal and agreed to release the detained inventory. FDA has not inspected our other facilities, although we expect an FDA inspection in the future. Regulating agencies, including FDA, foreign regulatory authorities, and our notified body can institute a wide variety of enforcement actions, ranging from inspectional observations to more severe sanctions such as:

- untitled letters or warning letters;
- clinical holds;
- administrative or judicially-imposed sanctions;
- injunctions, fines, consent decrees, or the imposition of civil penalties;
- customer notifications for repair, replacement, or refunds;
- recall, detention, or seizure of products;
- operating restrictions, or total or partial suspension of production or distribution;
- refusal by FDA, a foreign regulatory authority or the notified body to grant pending future clearance or pre-market approval, or to issue CE Certificates of Conformity for our devices;
- debarment of us or our employees;
- withdrawal or suspension of marketing clearances, approvals, and CE Certificates of Conformity;

- refusal to permit the import or export of our products; and
- criminal prosecution of us or our employees.

If any of these actions were to occur, it would harm our reputation and cause our system sales and profitability to suffer and may prevent us from generating revenue. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with all applicable regulatory requirements, which could result in the failure to produce our devices on a timely basis and in the required quantities, if at all.

We may be subject to various federal and state laws pertaining to healthcare fraud and abuse, and any violations by us of such laws could result in fines or other penalties.

While procedures utilizing our systems are not currently covered or reimbursed by any third-party payor, our commercial, research and other financial relationships with healthcare providers and others may be subject to various federal and state laws intended to prevent healthcare fraud and abuse. Such laws include the U.S. federal Anti-Kickback Statute and similar laws that apply to state healthcare programs, private payors and self-pay patients; the U.S. federal civil and criminal false claims laws, such as the civil False Claims Act, and civil monetary penalties laws; state and federal data privacy and security laws and regulations; state and federal physician payment transparency laws; and state and federal consumer protection and unfair competition laws.

Further, these laws may impact any sales, marketing and education programs we currently have or may develop in the future and the way we implement any of those programs. Penalties for violations of these laws can include exclusion from federal healthcare programs and substantial civil and criminal penalties.

We may be affected by healthcare policy changes and evolving regulations.

Our global regulatory environment is becoming increasingly stringent and unpredictable, which could increase the time, cost and complexity of obtaining regulatory approvals for our products, as well as the clinical and regulatory costs of supporting those approvals. Several countries that did not have regulatory requirements for medical devices have established such requirements in recent years and other countries have expanded on existing regulations. Certain regulators are exhibiting less flexibility and are requiring local preclinical and clinical data in addition to global data. While harmonization of global regulations has been pursued, requirements continue to differ significantly among countries. We expect this global regulatory environment will continue to evolve, which could impact our ability to obtain future approvals for our products or could increase the cost and time to obtain such approvals in the future.

In the U.S., the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, to which we refer collectively as the Affordable Care Act, or ACA, was enacted into law in 2010. Although most of the provisions of the ACA are now in effect, in December 2018 a federal court judge in the Northern District of Texas ruled in *Texas v. Azar*, or the Texas Case, that the ACA's individual mandate is unconstitutional, and that the remainder of the ACA was inseverable from the individual mandate and therefore invalid. This case was appealed to the Fifth Circuit in January 2019. Because the Texas judge issued a stay of his ruling pending the appeal, the ACA continues to be in effect at this time.

As a result of the passage of the ACA, an excise tax is imposed on the sale of certain medical devices by the U.S. manufacturer, producer, or importer of the device. This excise tax applies to sales of taxable medical devices beginning January 1, 2013. The excise tax equals 2.3% of the "constructive sale price" of the applicable medical device. As a U.S.-based manufacturer and importer of taxable medical devices, are responsible for remitting to the federal government the excise tax on the sales of medical devices it manufactures in, or imports into, the U.S. Although this excise tax was in effect during the years 2013-2015, there was in effect a moratorium on the medical device excise tax through the end of 2019. The excise tax was repealed effective January 1, 2020.

In a referendum on June 23, 2016, voters approved for the United Kingdom, or the UK, to exit the EU. On January 31, 2020, the UK departed the EU, however, there is a transition period until the end of 2020 while the

UK and the EU negotiate additional arrangements. During the transition period, the current rules on trade, travel and business for the UK and the EU will continue to apply. New rules will take effect on January 1, 2021. The UK's exit from the EU will have numerous consequences in all areas of the business, including, economic, regulatory, operational, and the actual impact depends on the ultimate deal reached and is very difficult to assess at this time. Changes in the industry regulations could have an effect on existing CE certificates being renewed and new certificates being issued which would impact the ability to trade; however, it is impossible to assess the full impact at this point.

We are subject to environmental, health and safety laws and regulations, and must maintain licenses or permits, and non-compliance with these laws, regulations, licenses, or permits may expose us to significant costs or liabilities.

We are subject to numerous foreign, federal, state, and local environmental, health and safety laws and regulations relating to, among other matters, safe working conditions and environmental protection, including those governing the generation, storage, handling, use, transportation, and disposal of hazardous or potentially hazardous materials. Some of these laws and regulations require us to obtain licenses or permits to conduct its operations. Environmental laws and regulations are complex, change frequently and have tended to become more stringent over time. If we violate or fail to comply with these laws, regulations, licenses, or permits, we could be fined or otherwise sanctioned by regulators. We cannot predict the impact on its business of new or amended laws or regulations or any changes in the way existing and future laws and regulations are interpreted or enforced, nor can we ensure we will be able to obtain or maintain any required licenses or permits.

Recent U.S. tax legislation and future changes to applicable U.S. or foreign tax laws and regulations may have a material adverse effect on our business, financial condition and results of operations.

We are subject to income and other taxes in the U.S. and foreign jurisdictions. Changes in laws and policy relating to taxes or trade may have an adverse effect on our business, financial condition and results of operations. For example, the U.S. government recently enacted significant tax reform, and certain provisions of the new law may adversely affect us. Changes include, but are not limited to, a federal corporate tax rate decrease from 35% to 21% for tax years beginning after December 31, 2017, the transition of U.S. international taxation from a worldwide tax system to a more generally territorial system, and a one-time transition tax on the mandatory deemed repatriation of foreign earnings. The legislation is unclear in many respects and could be subject to potential amendments and technical corrections and will be subject to interpretations and implementing regulations by the Treasury and Internal Revenue Service, any of which could mitigate or increase certain adverse effects of the legislation. In addition, it is unclear how these U.S. federal income tax changes will affect state and local taxation. Generally, future changes in applicable U.S. or foreign tax laws and regulations, or their interpretation and application could have an adverse effect on our business, financial conditions and results of operations.

Risks Related to Our Operations in Israel

We conduct a significant portion of our operations in Israel and therefore our business, financial condition and results of operations may be adversely affected by political, economic and military conditions in Israel.

Our research and development facilities and key third-party suppliers are located in northern Israel, and some of our key employees are residents of Israel. Accordingly, political, economic and military conditions in Israel may directly affect our business.

Since the establishment of the State of Israel in 1948, a number of armed conflicts have taken place between Israel and its neighboring countries. Any hostilities, armed conflicts, terrorist activities or political instability involving Israel or the interruption or curtailment of trade within Israel or between Israel and its trading partners could adversely affect business conditions and have a material adverse effect on our business, financial condition

and results of operations and could make it more difficult for us to raise capital. In recent years, these have included hostilities between Israel and Hezbollah in Lebanon, and Israel and Hamas in the Gaza Strip, both of which resulted in rockets being fired into Israel causing casualties and disruption of economic activities. In addition, Israel faces threats from more distant neighbors, in particular, Iran.

In addition, hostilities, armed conflicts, terrorist activities or political instability involving Israel could have a material adverse effect on our facilities including our corporate administrative office or on the facilities of our local suppliers, in which event all or a portion of our inventory may be damaged and our ability to deliver products to customers could be significantly delayed. Certain of our executive officers and key employees reside in Israel and some may be required to perform annual military reserve duty and may be called for active duty under emergency circumstances at any time. Our operations could be disrupted by an absence for a significant period of time of one or more of these officers or key employees due to military service, which could adversely affect our business, results of operations and financial condition.

Several countries, principally in the Middle East, restrict doing business with Israel and Israeli companies, and additional countries may impose restrictions on doing business with Israel and Israeli companies whether as a result of hostilities in the region or otherwise. Similarly, Israeli companies are limited in conducting business with entities from several countries. Such restrictions may seriously limit our revenues.

Our commercial insurance does not cover losses that may occur as a result of events associated with the security situation in the Middle East, such as damages to our facilities resulting in disruption of our operations. Although the Israeli government is currently committed to covering the reinstatement value of direct damages that are caused by terrorist attacks or acts of war, there can be no assurance that this government coverage will be maintained, or if maintained, will be sufficient to compensate us fully for damages incurred. Any losses or damages incurred by us could have a material adverse effect on our business, financial condition and results of operations. Any armed conflicts or political instability in the region would likely negatively affect business conditions and could harm our business, financial condition and results of operations.

Our operations may be affected by negative labor conditions in Israel.

Strikes and work-stoppages occur relatively frequently in Israel. If Israeli trade unions threaten additional strikes or work-stoppages and such strikes or work-stoppages occur, those may, if prolonged, have a material adverse effect on the Israeli economy and on our business, including our ability to deliver products to our customers and to receive raw materials from our suppliers in a timely manner.

Risks Related to Our Common Stock

Following completion of the Merger, the market price of our stock price may be volatile, and you may not be able to resell shares of our Common Stock at or above the price you paid.

The market price of our Common Stock following the Merger could be subject to significant fluctuations. Some of the factors that may cause the market price of the combined company's Common Stock to fluctuate include:

- introduction of new products, services or technologies, significant contracts, commercial relationships or capital commitments by competitors;
- failure to meet or exceed financial and development projections the combined company may provide to the public;
- failure to meet or exceed the financial and development projections of the investment community;
- announcements of significant acquisitions, strategic collaborations, joint ventures or capital commitments by the combined company or its competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;

- additions or departures of key personnel;
- significant lawsuits or government investigations, including patent or stockholder litigation;
- if securities or industry analysts do not publish research or reports about the company's business, or if they issue adverse or misleading opinions regarding our business and stock;
- changes in the market valuations of similar companies;
- general market or macroeconomic conditions;
- sales of Common Stock by us or our stockholders in the future;
- trading volume of our Common Stock;
- adverse publicity relating to hair restoration or other minimally invasive or non-invasive medical aesthetic procedures generally, including with respect to other products in such markets;
- the introduction of technological innovations that compete with the products and services of the combined company; and
- period-to-period fluctuations in the combined company's financial results.

In addition, the stock markets in general, and the markets for medical device and aesthetic stocks in particular, have experienced extreme volatility that may have been unrelated to the operating performance of the issuer. These broad market fluctuations may adversely affect the market price or liquidity of our Common Stock. In the past, when the market price of a stock has been volatile, holders of that stock have sometimes instituted securities class action litigation against the issuer. Recently, several securities class action complaints have been filed against us, certain of our current and former executive officers and directors, certain of our investors and certain underwriters in our IPO. These complaints allege violations of Sections 11, 12(a)(2) and 15 of the Securities Act of 1933, as amended, or the Securities Act, due to allegedly false and misleading statements made in connection with our IPO. While we believe that these lawsuits are without merit and we intend to vigorously defend against these claims, we could incur substantial costs in defending these lawsuits and the attention of our management could be diverted from the operation of our business. Further, if more of our stockholders were to bring additional lawsuits on similar or unrelated grounds, we could incur substantial costs defending these additional lawsuits and the attention of our management would be further diverted from the operation of our business.

An active market for our Common Stock may not be maintained.

Our stock began trading on the Nasdaq Global Market in July 2017, but we can provide no assurance that we will be able to maintain an active trading market on the Nasdaq Global Market or any other exchange in the future. If an active market for our Common Stock does not develop or is not maintained, it may be difficult for our stockholders to sell shares without depressing the market price for the shares or at all. An inactive trading market may also impair our ability to raise capital by selling shares and may impair our ability to acquire other businesses, applications, or technologies using our shares as consideration.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about the Company, our business or our market, the Company's stock price and trading volume could decline.

The trading market for the Company's Common Stock will be influenced by the research and reports that equity research analysts publish about us and our business. Equity research analysts may elect not to provide research coverage of our Common Stock, and such lack of research coverage may adversely affect the market price of our Common Stock. In the event that equity research analysts initiate coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our Common Stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of us or fails to publish reports on us regularly, demand for our Common Stock could decrease, which in turn could cause our stock price or trading volume to decline.

We are an emerging growth company and a smaller reporting company within the meaning of the Securities Act and we have taken advantage of certain exemptions from disclosure requirements available to emerging growth companies and smaller reporting companies; this could make our securities less attractive to investors and may make it more difficult to compare our performance with other public companies.

Following the Merger, we will continue to qualify as, an "emerging growth company" within the meaning of the Securities Act, as modified by the JOBS Act. We have taken advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies or smaller reporting companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on certain executive compensation matters and reduced reporting periods. As a result, stockholders may not have access to certain information they may deem important. We cannot predict whether investors will find our securities less attractive because we rely on these exemptions. If some investors find the securities less attractive as a result of reliance on these exemptions, the trading prices of our securities may be lower than they otherwise would be, there may be a less active trading market for our securities and the trading prices of our securities may be more volatile.

Further, Section 102(b)(1) of the JOBS Act exempts emerging growth companies from complying with new or revised financial accounting standards until private companies (that is, those that have not had a Securities Act registration statement declared effective or do not have a class of securities registered under the Exchange Act) are required to comply with the new or revised financial accounting standards. The JOBS Act provides that an emerging growth company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies but any such an election to opt out is irrevocable. We have elected not to opt out of such extended transition period. Accordingly, when a standard is issued or revised and it has different application dates for public or private companies, we, as an emerging growth company, could adopt the new or revised standard at the time private companies adopt the new or revised standard, unless early adoption is permitted by the standard. We intend to continue to use private company adoption dates for ASC 842, Leases. This may make comparison of us with another public company which is neither an emerging growth company nor an emerging growth company which has opted out of using the extended transition period difficult or impossible because of the potential differences in accounting standards used.

If we sell shares of our Common Stock in future financings, stockholders may experience immediate dilution and, as a result, our stock price may decline.

We may from time to time issue additional shares of Common Stock at a discount from the current market price of our Common Stock. As a result, our stockholders would experience immediate dilution upon the purchase of any shares of our Common Stock sold at such discount. In addition, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt securities, preferred stock or Common Stock. If we issue Common Stock or securities convertible into Common Stock, our common stockholders would experience additional dilution and, as a result, our stock price may decline.

Because the Merger resulted in an ownership change under Section 382 of the Code for Restoration Robotics, Restoration Robotics' pre-merger net operating loss carryforwards and certain other tax attributes will be subject to limitation or elimination. The net operating loss carryforwards and certain other tax attributes of Venus Concept Ltd. and of the combined company may also be subject to limitations as a result of ownership changes.

Restoration Robotics incurred substantial losses during its history and carried forward significant net operating losses, or NOLs, to offset future taxable income, if any, until such unused losses expire. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire. If a corporation undergoes an "ownership change" within the meaning of Section 382

of the Code, the corporation's net operating loss carryforwards and certain other tax attributes arising before the ownership change are subject to limitations on use after the ownership change. In general, an ownership change occurs if there is a cumulative change in the corporation's equity ownership by certain stockholders that exceeds 50 percentage points by value over a rolling three-year period. Similar rules may apply under applicable state income tax laws. The Merger resulted in an ownership change for Restoration Robotics and, accordingly, Restoration Robotics' net operating loss carryforwards and certain other tax attributes will be subject to limitation and possibly elimination after the Merger. The Merger may limit our net operating loss carryforwards and certain other tax attributes. Additional ownership changes in the future could result in additional limitations on our net operating loss carryforwards and certain other tax attributes. Consequently, even if the combined company achieves profitability, it may not be able to utilize a material portion of the predecessor companies' or the combined company's net operating loss carryforwards and certain other tax attributes, which could have a material adverse effect on cash flow and results of operations.

We do not intend to pay dividends on our Common Stock, and, consequently, our stockholders' ability to achieve a return on their investment will depend on appreciation in the price of our Common Stock.

We do not intend to pay any cash dividends on our Common Stock for the foreseeable future. We intend to invest our future earnings, if any, to fund our growth. Payment of future cash dividends, if any, will be at the discretion of the board of directors, subject to applicable law and will depend on various factors, including our financial condition, operating results, current and anticipated cash needs, the requirements of current or then-existing debt instruments and other factors the board of directors deems relevant. Therefore, our stockholders are not likely to receive any dividends on their Common Stock for the foreseeable future. Since we do not intend to pay dividends, our stockholders' ability to receive a return on their investment will depend on any future appreciation in the market value of our Common Stock. There is no guarantee that our Common Stock will appreciate or even maintain the price at which our stockholders have purchased it. The terms of our credit facilities limit our ability to pay dividends.

Provisions in our charter documents and under Delaware law could make an acquisition us more difficult and may discourage any takeover attempts the company stockholders may consider favorable, and may lead to entrenchment of management.

Provisions of our amended and restated certificate of incorporation and amended and restated bylaws could delay or prevent changes in control or changes in management without the consent of the board of directors. These provisions will include the following:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of the board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of the board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on the board of directors;
- the ability of the board of directors to authorize the issuance of shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;
- the ability of the board of directors to alter its bylaws without obtaining stockholder approval;
- the required approval of at least 66⅔% of the shares entitled to vote at an election of directors to adopt, amend or repeal its bylaws or repeal the provisions of the amended and restated certificate of incorporation regarding the election and removal of directors;

- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of the stockholders;
- the requirement that a special meeting of stockholders may be called only by the chairman of the board of directors, the chief executive officer, the president or the board of directors, which may delay the ability of the stockholders to force consideration of a proposal or to act, including the removal of directors; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to the board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of the combined company.

These provisions would apply even we were to receive an offer that some stockholders may consider beneficial.

We are also be subject to the anti-takeover provisions contained in Section 203 of the Delaware General Corporation Law, or the DGCL, or Section 203. Under Section 203, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other exceptions, the board of directors has approved the transaction.

Our certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or other employees.

Our certificate of incorporation provides that the Court of Chancery of the State of Delaware is the sole and exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty owed by any of our directors, officers or other employees to us or ours stockholders, any action asserting a claim against us arising pursuant to any provisions of the DGCL, our certificate of incorporation or our bylaws, or any action asserting a claim against we that are governed by the internal affairs doctrine; provided that, the exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Our certificate of incorporation also provides that the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. However, the enforceability of similar federal court choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find this type of provision to be inapplicable or unenforceable. If a court were to find the federal choice of forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions.

The choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with the combined company or its directors, officers or other employees, which may discourage such lawsuits against the combined company and its directors, officers and other employees.

Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law.

In addition, as permitted by Section 145 of the DGCL, our amended and restated bylaws and our indemnification agreements that we have entered into with our directors and officers provide that:

- we will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law

provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful;

- we may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law;
- we are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification;
- we will not be obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification;
- the rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons; and
- we may not retroactively amend our amended and restated bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

Our executive officers, directors and certain of our shareholders who are affiliated with our directors will have the ability to control or significantly influence all matters submitted to our stockholders for approval.

As of December 31, 2019, our executive officers, directors and certain of our shareholders who are affiliated with our directors, in the aggregate, beneficially own approximately 62.1% of our outstanding shares of Common Stock on a fully diluted basis, after giving effect to the Merger and the Concurrent Financing. As a result, if these stockholders were to choose to act together, they would be able to control or significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, if they choose to act together, these persons would control or significantly influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. Within this group, after giving effect to the Merger and the Concurrent Financing, EW Healthcare and its affiliates own approximately 23.5%, HealthQuest and its affiliates own approximately 13.4% and Longitude Venture Partners II, L.P and its affiliates own approximately 12.3% and respectively, of our outstanding shares. This concentration of voting power could delay or prevent an acquisition of the Company on terms that other stockholders may desire.