UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 20-F

(Mark One)

☐ **REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934**

OR

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2019

OR

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

OR

☐ **SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Date of event requiring this shell company report _____

Commission file number 001-38775

Itamar Medical Ltd.

(Exact name of Registrant as specified in its charter)

Not Applicable
(Translation of Registrant's name into English)

Israel
(Jurisdiction of incorporation or organization)

9 Halamish Street
Caesarea 3088900, Israel
(Address of principal executive offices)

Shy Basson
Chief Financial Officer
Telephone: +972-4-6177000; Facsimile: +972-4-6275598
Itamar Medical Ltd.
9 Halamish Street, Caesarea 3088900, Israel
(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
American Depository Shares, each representing 30 Ordinary Shares, par value NIS 0.01 per share (1)	ITMR	The Nasdaq Stock Market LLC (Nasdaq Capital Market)
Ordinary Shares, par value NIS 0.01 per share (2)	ITMR	The Nasdaq Stock Market LLC (Nasdaq Capital Market)

(1) Evidenced by American Depositary Receipts.

(2) Not for trading, but only in connection with the listing of the American Depositary Shares.

Securities registered or to be registered pursuant to Section 12(g) of the Act: None

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act: None

Indicate the number of outstanding shares of each of the issuer's classes of capital stock or common stock as of the close of the period covered by the annual report (December 31, 2019): 335,285,001 ordinary shares.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o No ☒

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. Yes ☐ No ☒

Note—Checking the box above will not relieve any registrant required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 from their obligations under those Sections.

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☒ Emerging growth company ☒

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, 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. ☐

† The term "new or revised financial accounting standard" refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP ☐ International Financial Reporting Standards as issued by the International Accounting Standards Board ☒ Other ☐

If "Other" has been checked in response to the previous question indicate by check mark which financial statement item the registrant has elected to follow. Item 17 ☐ Item 18 ☐

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

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GENERAL INFORMATION

Except where the context otherwise requires or where otherwise indicated in this Annual Report on Form 20-F, or Annual Report, the terms "Itamar," the "Company," "we," "us," "our," "our company" and "our business" refer to Itamar Medical Ltd., together with its consolidated subsidiaries as a consolidated entity.

When the following terms and abbreviations appear in the text of this Annual Report, they have the meanings indicated below:

- "*ADSs*" means our American Depositary Shares, each representing 30 ordinary shares.
- "Companies Law" means the Israeli Companies Law, 1999.
- "convertible notes" or "Series L convertible notes" mean the convertible notes we issued as part of a public offering we conducted in 2013, all of which notes were fully repaid in February 2018.
- "CPAP" means continuous positive airway pressure. CPAP devices are therapy devices used to treat certain sleep apnea conditions.
- "Credit Facility" means that certain Credit Framework Agreement by and between the Company and Mizrahi Tefahot Bank Ltd., dated February 9, 2020.
- "dollars", "U.S. dollars" or "$" mean United States dollars.
- "Endo PAT" means our device that enables testing of endothelial dysfunctions (the failure of the normal function of the inner lining of blood vessels).
- "Exchange Act" means United States Securities Exchange Act of 1934, as amended.
- "euro" or "€" means the currency introduced at the start of the third stage of European economic and monetary union pursuant to the treaty establishing the European Community, as amended.
- "HSAT" means home sleep apnea test.
- "Israeli CPI" means the Israeli consumer price index published by the Israeli Central Bureau of Statistics.
- "MADs" means mandibular advancement devices. MADs are therapy devices used to treat certain sleep apnea conditions, also known as sleep apnea oral or dental appliances.
- "major shareholder" means a shareholder that is the beneficial owner of 5% or more of our outstanding ordinary shares.
- "Nasdaq" means the Nasdaq Stock Market LLC.
- "NIS" means New Israeli Shekels, the official currency of the State of Israel.
- "ordinary shares" means our ordinary shares, par value NIS 0.01 per share.
- "OSA" means obstructive sleep apnea.
- "PAT" or "PAT signal" means Peripheral Arterial Tonometry, or Peripheral Arterial Tone, which measures the arterial volume changes at the fingertip, reflecting the sympathetic nervous system activation.

- "PSG" means polysomnography. PSG is the process of monitoring, recording and analyzing physiologic data during sleep and wakefulness to assist in the assessment and diagnosis of sleep disorders.

- "SEC" means the United States Securities and Exchange Commission.

- "TASE" means the Tel Aviv Stock Exchange.

- "TaaS" means Test as a Service.

- "TSS," "TSS marketing program" or "TSS program" means our Total Sleep Solution. TSS is our marketing program that is designed to allow any medical practice or physician that is not a sleep physician by specialty, easy access to a comprehensive suite of products and services for the diagnosis, treatment and management of patients they suspect suffer from sleep apnea.

- "U.S. Subsidiary" means Itamar Medical, Inc.

- "Viola" means, collectively, Viola Growth II A.V. LP, a limited partnership registered in Israel, Viola Growth II (A) L.P., a limited partnership registered in Cayman Islands, and Viola Growth II (B) L.P., a limited partnership registered in Cayman Islands.

- "Viola Transaction" means the private placement transaction pursuant to the share purchase agreement we entered into with Viola, dated as of August 26, 2015.

- "Viola Warrants" means warrants issued to Viola in November 2015 and January 2016 as part of the Viola Transaction, which expired on May 4, 2019.

- "Warrants (Series 4)" means the warrants issued to certain of our shareholders as part of a rights offering in December 2015, which expired on May 4, 2019.

- "WatchPAT" means our portable diagnostic device that enables HSATs.

EMERGING GROWTH COMPANY STATUS

We qualify as an "emerging growth company," as defined in the JOBS Act, and we may take advantage of certain exemptions, including exemptions from various reporting requirements that are otherwise applicable to public traded entities that do not qualify as emerging growth companies. These exemptions include:

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002; and

- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements (i.e., an auditor discussion and analysis).

Section 107 of the JOBS Act also provides that an emerging growth company can take advantage of the extended transition period provided in Section 13(a) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, for complying with new or revised accounting standards. We have elected to irrevocably opt out of this extended transition period and, as a result, we are required to comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies. Under federal securities laws, our decision to opt out of the extended transition period is irrevocable.

We will remain an emerging growth company until the earliest of: (i) the last day of the first fiscal year in which our annual gross revenues exceed $1.07 billion; (ii) the last day of 2024; (iii) the date that we become a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our ordinary shares, including ordinary shares represented by ADSs, held by non-affiliates exceeds $700 million as of the last business day of our most recently completed second fiscal quarter; or (iv) the date on which we have issued more than $1.0 billion in non-convertible debt securities during any three-year period.

PRESENTATION OF FINANCIAL AND OTHER INFORMATION

Our consolidated financial statements appearing in this Annual Report are prepared in accordance with International Financial Reporting Standards, or IFRS, as adopted by the International Accounting Standards Board, or IASB. None of our financial statements were prepared in accordance with generally accepted accounting principles in the United States. We present our consolidated financial statements in U.S. dollars. We have made rounding adjustments to some of the figures included in this Annual Report. Accordingly, numerical figures shown as totals in some tables may not be an arithmetic aggregation of the figures that preceded them.

On March 24, 2020, the representative exchange rate, or Exchange Rate, between the NIS and the U.S. dollar, as quoted by the Bank of Israel, was NIS 3.658 to $1.00. Unless derived from our financial statements or indicated otherwise by the context, statements in this Annual Report that provide the U.S. dollar equivalent of NIS amounts or provide the NIS equivalent of U.S. dollar amounts are based on the representative exchange rate, as quoted by the Bank of Israel, as of such date (or, if no quote was provided for such date, the next quote provided) or, when the applicable date has yet to be determined, the Exchange Rate. Such U.S. dollar amounts are not necessarily indicative of the amounts of U.S. dollars that could actually have been purchased upon exchange of NIS at the dates indicated.

MARKET, INDUSTRY AND OTHER DATA

Unless otherwise indicated, information contained in this Annual Report concerning our industry and the markets in which we operate, including our competitive position and market opportunity, is based on information from our own management estimates and research, as well as from industry and general publications and research, surveys and studies conducted by third parties. Management estimates are derived from publicly available information, our knowledge of our industry and assumptions based on such information and knowledge, which we believe to be reasonable. Our management estimates have not been verified by any independent source, and we have not independently verified any third-party information. In addition, assumptions and estimates of our and our industry's future performance are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in Item 3.D. "*Risk Factors*" below.

Statements made in this Annual Report concerning the contents of any contract, agreement or other document are summaries of such contracts, agreements or documents and are not complete descriptions of all of their terms. If we filed any of these documents as an exhibit to this Annual Report, you may read the document itself for a complete description of its terms, and the summary included herein is qualified by reference to the full text of the document which is incorporated by reference into this Annual Report.

TRADEMARKS

We have obtained trademark registrations in the U.S. for, among others, PAT, Endo PAT, WatchPAT, EndoScore, ITAMAR, CloudPAT and SLEEPATH and some of them are also registered in additional jurisdictions, including Europe, Japan, Canada, China, India, Russia, Mexico, Korea and Singapore. Although we have omitted the "®" and "TM" trademark designations for such marks in this Annual Report, all rights to such trademarks and service marks are nevertheless reserved. Unless indicated otherwise by the context, any other trademarks and trade names appearing in this Annual Report are owned by their respective holders.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report contains statements that constitute "forward-looking statements" within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. These statements are neither historical facts nor assurances of future performance. Although we believe that these estimates and forward-looking statements are based upon reasonable assumptions, they are subject to numerous risks and uncertainties some of which are beyond our control, and are made in light of information currently available to us.

In some cases, these forward-looking statements can be identified by words or phrases such as "believe," "may," "will," "expect," "estimate," "could," "should," "anticipate," "aim," "estimate," "intend," "plan," "believe," "potential," "continue," "is/are likely to" or other similar expressions. Forward-looking statements contained in this Annual Report include, but are not limited to, statements about:

- the development of our products;
- the potential attributes and benefit of our products and their competitive position;
- our ability to successfully commercialize, or enter into strategic relationships with third parties to commercialize, our products;
- our estimates regarding expenses, future revenues, capital requirements and our need for additional financing;
- our ability to acquire or in-license new product candidates;
- potential strategic relationships; and
- the duration of our patent portfolio.

These forward-looking statements are subject to risks, uncertainties and assumptions, some of which are beyond our control. In addition, these forward-looking statements reflect our current views with respect to future events and are not a guarantee of future performance. Actual outcomes may differ materially from the information contained in the forward-looking statements as a result of a number of important factors, including, without limitation, the important risk factors set forth in Item 3.D. "*Risk Factors*" of this Annual Report.

We operate in an evolving environment. New risks emerge from time to time, and it is not possible for our management to predict all risks, nor can we assess the effect of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

The forward-looking statements made in this Annual Report relate only to events or information as of the date on which the statements are made in this Annual Report. Except as required by law, we undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise, after the date on which the statements are made or to reflect the occurrence of unanticipated events. You should read this Annual Report and the documents that we have filed as exhibits hereto completely and with the understanding that our actual future results or performance may be materially different from what we expect.

PART I

Item 1. Identity of Directors, Senior Management and Advisers

Not applicable.

Item 2. Offer Statistics and Expected Timetable

Not applicable.

Item 3. Key Information

A. Selected Financial Data

We prepare our consolidated financial statements in accordance with IFRS as issued by the IASB.

The following tables present our selected consolidated financial and other data as of and for the periods indicated. The selected consolidated statements of operations data for the years ended December 31, 2019, 2018 and 2017 and the selected consolidated statements of financial position as of December 31, 2019 and 2018 are derived from our audited consolidated financial statements and the notes thereto included elsewhere in this Annual Report. Our audited consolidated financial statements and the notes thereto and other data for the years ended December 31, 2016 and 2015 and as of December 31, 2017, 2016, and 2015 are not included elsewhere in this Annual Report.

The financial data set forth below should be read in conjunction with, and are qualified by reference to, Item 5. "*Operating and Financial Review and Prospects*" and the audited consolidated financial statements and notes thereto included elsewhere in this Annual Report. Our historical results for any prior period do not necessarily indicate our results to be expected for any future period.

	Year Ended December 31,				
	2019	2018	2017	2016	2015
	(in thousands, except per share and share data)				
Consolidated Statements of Operations Data:					
Revenues	$ 31,258	$ 24,189	$ 20,701	$ 18,440	$ 16,807
Cost of revenues	6,984	5,726	5,002	4,979	4,401
Gross profit	24,274	18,463	15,699	13,461	12,406
Operating expenses:					
Selling and marketing	18,294	12,699	12,140	14,035	10,684
Research and development	4,520	3,638	4,129	3,225	2,831
General and administrative	6,354	5,247	5,278	6,213	4,350
Total operating expenses	29,168	21,584	21,547	23,473	17,865
Operating loss	(4,894)	(3,121)	(5,848)	(10,012)	(5,459)
Financial income (expenses) from cash, deposits and investments	454	244	1,591	716	(354)
Financial expenses from leases, notes, loans and other	(1,233)	(1,161)	(4,884)	(4,760)	(4,229)
Gain (loss) from derivative instruments, net	442	2,433	3,925	(216)	7,930
Financial income (expenses), net	(337)	1,516	632	(4,260)	3,347
Loss before income taxes	(5,231)	(1,605)	(5,216)	(14,272)	(2,112)
Taxes on income	(37)	(124)	(85)	(131)	(135)
Net loss	$ (5,268)	$ (1,729)	$ (5,301)	$ (14,403)	$ (2,247)
Loss per share:					
Basic	$ (0.02)	$ (0.01)	$ (0.02)	$ (0.05)	$ (0.01)
Diluted	$ (0.02)	$ (0.01)	$ (0.02)	$ (0.05)	$ (0.02)

	As of December 31,				
	2019	2018	2017	2016	2015
	(in thousands)				
Consolidated Statements of Financial Position Data:					
Cash and cash equivalents	$ 15,115	$ 6,471	$ 7,643	$ 23,358	$ 33,019
Investment in marketable securities	-	-	3,173	2,781	2,710
Working capital	14,951	6,222	3,356	18,843	36,989
Total assets	33,207	18,392	21,227	35,547	43,740
Total non-current liabilities	3,228	1,653	4,133	15,986	22,169
Accumulated deficit	(109,649)	(105,546)	(105,004)	(100,885)	(88,151)
Total equity	16,664	6,688	1,377	5,241	16,951

B. Capitalization and Indebtedness

Not applicable.

C. Reasons for the Offer and Use of Proceeds

Not applicable.

D. Risk Factors

You should carefully consider the important risks described below before making an investment decision. Additional risks not presently known to us or that we currently deem immaterial may also impair our business operations. Our business, financial condition or results of operations could be materially and adversely affected by any of these risks. The trading price and value of our ordinary shares and ADSs could decline due to any of these risks, and you may lose all or part of your investment. This Annual Report also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including the risks faced by us described below and elsewhere in this Annual Report.

Risks Related to Our Business and Operations

We substantially depend on the sales of our WatchPAT family of products.

Building upon our WatchPAT family of products and related services, the key elements of our business strategy and success are to focus on and sell a one-stop sleep apnea solution for the cardiology market, to continue to focus on the core sleep market by calling on sleep physicians, to develop direct to consumer, or DTC, sales channels and to expand into additional countries. In order to do so, we have, among other things, focused and invested substantial time and resources on developing various solutions and WatchPAT related services, such as our TSS program. We also plan to invest resources into developing DTC channels and relationships with distributors and resellers in other countries. While focusing on promoting our WatchPAT family of products, we, at the same time, limited our sales and marketing efforts for our legacy EndoPAT product, whose sales gradually decreased in the years ended December 31, 2017 and 2018. Although EndoPAT sales increased during the year ended December 31, 2019, we currently plan to continue to limit our sales and marketing efforts of the EndoPAT. The sales of our WatchPAT family of products as stand-alone products remain our main source of revenue, representing approximately 92.7%, 92.5% and 87.5% of our total revenues in the years ended December 31, 2019, 2018 and 2017, respectively. If we are not successful in implementing our business strategy to increase the sales of our WatchPAT family of products and related consumables and services to the cardiology market, the core sleep market, through DTC channels and in additional countries, or if we are unable to use our technologies to further develop and enhance our WatchPAT family of products and related services with significant commercial potential, we may not be able to achieve our objectives or build a sustainable or profitable business.

We have a history of losses, may incur future losses and may never achieve profitability.

Since our incorporation in 1997, we have incurred operating and net losses in most of our years of operation. In particular, we incurred operating losses of approximately $4.9 million, $3.1 million and $5.8 million for the years ended December 31, 2019, 2018 and 2017, respectively. We expect to continue to incur operating and net losses for the foreseeable future, as we continue to invest in research and development and marketing and sales operations aimed at growing our business. The extent of our future operating and net losses is highly uncertain and we may never achieve or sustain profitability. Even if we reach and maintain profitability, we cannot assure that future net income will offset our accumulated deficit, which as of December 31, 2019 was approximately $109.6 million. In addition, there is no guarantee that we will be able to benefit from our losses for tax purposes.

There is no certainty that our EndoPAT and WatchPAT family of products and related services will be accepted by the international medical community, in general, and specifically that the WatchPAT family of products will be accepted by the cardiology community and consumers.

Building upon our WatchPAT family of products and related services, one of the key elements of our business strategy and success is to focus on and sell a one-stop sleep apnea solution for the cardiology market. Our success in doing so depends, to a large extent, on recognition by the international medical community, in general, and the cardiology community in particular, of:

- the linkage between sleep apnea and cardiovascular disease and the benefits of diagnostic aids;
- the advantages of shifting the point of care for sleep apnea, mainly in the United States, from sleep centers to the cardiology care point; and
- the advantages of our WatchPAT family of products and related services.

Recognition by the cardiology community of the linkage between sleep apnea and cardiovascular disease depends, among other things, on our ability to promote awareness amongst physicians, primarily cardiologists, to such linkage in a manner consistent with the labeling for our products, including by providing supporting clinical data and studies demonstrating the said linkage and benefits of sleep apnea diagnosis and treatment to their cardiology patients. Recognition by the cardiology community of the advantages of shifting the point of care for sleep apnea, mainly in the United States, from sleep centers to the cardiology care point, in general, and of the advantages of our WatchPAT family of products and related services in particular, depends to a large extent on our ability to demonstrate that (i) our WatchPAT devices are efficient, cost-effective and provides significant improvement in performance and data compared to other diagnostic tools available in the sleep market and (ii) our WatchPAT-related services, such as our TSS program, provide cardiologists with easy access to prescribe HSATs to patients, receive reimbursement for the WatchPAT-related services and increase the diagnosis rate with an effective management and monitoring of sleep apnea.

Even if we succeed in promoting awareness to the linkage between sleep apnea and cardiovascular disease and in proving the advantages of shifting the point of care to the cardiology care point and the advantages of our WatchPAT family of products and related services, there is a risk that healthcare service providers and other prospective customers will avoid purchasing our products and related services for any number of reasons. For example, they may continue to use PSG tests in sleep centers or other traditional HSAT devices because such diagnostic tools are already widely accepted. The failure to gain wide market acceptance of the linkage between sleep apnea and cardiovascular disease and in proving the advantages of shifting the point of care to the cardiology care point or the failure of our WatchPAT family of products and related services to otherwise gain market acceptance may adversely affect our business, financial condition and results of operations.

In addition, during 2019, we began focusing on the DTC market segment, where we will offer our prescription HSAT products and most of the TSS components, through channel partners that have a consumer market presence, directly to patients, and facilitate patient access to real time consultation, advice and prescriptions throughout the care pathway. Although we believe that our digital health platform, which we believe can facilitate the journey of patients from diagnosis to therapy and compliance in an easy, efficient and innovative manner within their homes, positions us for new growth opportunities, if our products and related DTC services fail to gain wide market acceptance among consumers, our business, financial condition and results of operations may be adversely affected.

If healthcare providers are not adequately reimbursed for tests conducted using our products and related services, we may not be successful in marketing and selling our products.

We market our products and related services primarily to healthcare providers, including health facilities and physicians, many of whom rely on reimbursement for the healthcare services they provide to their patients from third-party payors, such as Medicare and Medicaid in the United States, as well as private insurance plans, managed care programs and other domestic and international government programs. These healthcare providers as well as government agencies in the United States and foreign countries are unlikely to purchase our products if they are not adequately reimbursed for the tests conducted using our products. Unless a sufficient amount of conclusive, peer-reviewed clinical data about our products is published and regular clinical use is documented, third-party payors, including insurance companies and government agencies, may refuse to provide reimbursement.

In 2009, the Centers for Medicare and Medicaid Services, or CMS, issued a National Coverage Determination in the United States to extend Medicare coverage to a number of HSATs, including the WatchPAT and other sleep testing devices when used to aid in the diagnosis of OSA in Medicare beneficiaries who have signs and symptoms indicative of OSA if performed unattended in or out of sleep lab facility or attended in a sleep lab facility. Certain commercial third-party payors, including, among others, Aetna, Cigna and UnitedHealthcare, updated their coverage policies to include coverage for these tests, including the WatchPAT. In March 2017, the American Academy of Sleep Medicine, or AASM, published guidelines establishing updated clinical practice recommendations to aid in the diagnosis of OSA in adults, pursuant to which devices that measure a minimum of the following sensors are considered technically adequate to diagnose OSA in uncomplicated adult patients presenting signs and symptoms that indicate an increased risk of moderate-to-severe OSA: (i) nasal pressure, chest and abdominal respiratory inductance plethysmography and oximetry; or (ii) PAT with oximetry and actigraphy, such as our WatchPAT family of products. Since that time, other commercial third-party payors and specialty benefits management companies that manage sleep apnea benefits for other United States health insurance plans determined that devices utilizing the combination of peripheral arterial tone, actigraphy, EKG/heart rate and oxygen saturation are considered medically necessary when certain clinical criteria are met.

Nevertheless, certain commercial payors and most Medicaid programs currently do not cover certain HSATs, including our WatchPAT. Other third-party payors that cover WatchPAT may require that our customers meet certain accreditation and certification requirements to receive reimbursement for administering or interpreting the test, which can limit our ability to obtain new customers. It is difficult to predict at this time what third-party payors and government agencies in the United States and abroad will decide with respect to the coverage and reimbursement for tests using our products. We cannot provide assurance that we will be successful in any efforts we may potentially undertake to reverse such non-coverage decisions. If we are not successful in reversing non-coverage policies, or if third-party payors that currently cover or reimburse certain tests reverse or limit their coverage of such tests in the future, or if other third-party payors issue similar policies, our business could be adversely impacted.

Even if coverage is available for tests using our products, reimbursement may not be adequate to fully compensate the health facilities and physicians. Third-party payors regularly update reimbursement amounts and also from time to time revise the methodologies used to determine reimbursement amounts. This includes annual updates to payments to physicians for tests using our products. Because the cost of our products generally is recovered by our customers as part of the payment for performing the test and not separately reimbursed, these updates could directly impact the demand for our products. An example of payment updates in the United States is the Medicare program's updates to physician payments under the Medicare Physician Fee Schedule, or MPFS, which are done on an annual basis using a prescribed statutory formula. In November 2019, CMS issued final revisions to its payment policies under the MPFS, effective January 1, 2020, reducing the payment associated with certain HSAT procedures. It is unclear what impact, if any, these payment reductions will have on our customers' willingness to adopt the broad use of our WatchPAT and other devices. Any changes in coverage and reimbursement that further restrict coverage of our products or lower reimbursement for tests using our devices could materially affect our business.

In addition, in the United States, our TSS program relies, to some extent, on the reimbursement available for sleep apnea treatment devices, such as CPAP devices, and on the desire of durable mobile equipment, or DME, suppliers to sell such devices. If healthcare providers cannot obtain sufficient reimbursement from third-party payors for such third-party treatment devices, our business may suffer. For example, in the past several years, Medicare has gradually reduced the reimbursement levels of CPAP devices through competitive bidding. In addition, under the Patient Protection and Affordable Care Act, or ACA, as amended by the Health Care and Education Affordability Reconciliation Act of 2010, in 2016, CMS adjusted Medicare reimbursement amounts in non-competitive bidding areas to competitive bidding prices. On March 7, 2019, CMS announced it would initiate a new round of competitive bidding, named Round 2021, with contracts expected to become effective on January 1, 2021 and extend through December 31, 2023. In addition to adopting new bidding processes, CMS expanded the product categories included in competitive bidding to include non-invasive ventilators, in addition to oxygen, CPAP and respiratory assist devices, and related supplies and accessories, which had been included in prior rounds of competitive bidding. Competitive bidding has generally reduced the Medicare reimbursement to DME suppliers compared with reimbursement before the program was implemented. A further reduction of reimbursement levels or institution of burdensome restrictions and procedures on such reimbursements may also cause DME suppliers to lose interest in selling such devices, in which case, our TSS program and business would suffer. Reimbursement, funding and healthcare payment systems vary significantly by country and we may not obtain approvals for reimbursement in a timely manner, or at all. For example, in Japan, our second largest market for the past two years, our WatchPAT family of products was approved by local authorities and medical institutions that use our WatchPAT test for diagnosis of sleep apnea, at a fixed reimbursement amount per test. Nevertheless, local authorities have limited such clearance to diagnose OSA for the purpose of prescribing therapy only to those patients who are categorized as severe and, to our knowledge, PSG tests remain the dominant means of sleep apnea diagnosis. If our efforts to convince local authorities in Japan to remove such limitations fail, our growth prospects in Japan may be adversely affected. Similarly, our potential expansion in other countries may depend to a large extent on our ability to obtain reimbursement and coverage of our products by local payors and government agencies.

There is no certainty that our WatchPAT family of products will be included in, or recommended by, any clinical practice guidelines or other guidelines and standards relevant to our business.

Professional associations publish clinical practice guidelines from time to time, suggesting processes and procedures intended for various medical conditions, as well as other guidelines and standards for the dispatch, prescription and billing procedures for tests using medical devices. Such guidelines and standards have significant importance and influence decisions by various health plans administrators, clinicians, government agencies and hospital administrators. In addition, many physicians consider clinical practice guidelines and act according to the recommendations included therein. For example, the clinical practice guidelines to aid in the diagnosis of OSA published by the AASM included the PAT-based technology used by our WatchPAT family of products in March 2017, whereas AIM Specialty Health, or AIM, an organization which manages the insurance reimbursement policies for some insurance companies and payors in the United States, updated its guidelines to medical insurers to include sleep apnea diagnostic aids using the PAT-based technology, only in November 2017. There is no assurance that all medical insurers, in the United States as well as in other countries, will follow the AASM and AIM guidelines and provide reimbursement for our WatchPAT family of products and related services. There is also no certainty that our product will continue to be included in such guidelines, or recommended by additional clinical guidelines or that the methods by which we offer our products and related services for sale will be consistent with guidelines and standards related to the dispatch, prescription and billing procedures for medical devices.

If we fail to have our products included in clinical practice guidelines in the United States or in other countries into which we wish to expand (or, in the case of the AASM and AIM guidelines, continue to be included in such guidelines) or if we fail to offer our products and related services for sale in a manner consistent with guidelines and standards related to dispatch, prescription and billing, it could have an adverse effect on our business, financial condition and results of operations.

The loss of one or more of our material customers or a decline in demand from one or more of these customers could harm our business.

Historically, a limited number of customers accounted for a substantial portion of our total sales. For example, our three largest customers, Kaiser Foundation Health Plan, Inc., or Kaiser, Philips Respironics GK, a subsidiary of Koninklijke Philips NV (also known as Royal Philips), or Philips Japan, and the Department of Veterans Affairs, or VA, accounted for 22.4%, 11.0% and 6.6%, respectively, of our total revenues, in the year ended December 31, 2019, compared with 18.9%, 13.3% and 11.9%, respectively, of our total revenues in the year ended December 31, 2018. There can be no assurance that such customers will continue to order our products at the same level, or at all. A reduction or delay in orders from such customers, including reductions or delays due to market, economic or competitive conditions, could have a material adverse effect on our business, operating results and financial condition.

We depend on our proprietary PAT-based technology.

Our PAT-based technology is designed to provide a non-invasive window to the cardiovascular system and autonomic nervous system by monitoring the PAT signal and analyzing it for diagnostic aid purposes. Since our products are mainly based on our PAT-based technology, we are dependent on such technology that has taken us many years to develop. We have benefited from the fact that the type of proprietary technology equivalent to our PAT-based technology has not been widely available to, or used by, our competitors. If our technology becomes more widely available to our current or future competitors for any reason, or if our competitors are able to develop similar technology or present their products as using similar technology, our operating results may be adversely affected. Additionally, adoption or development of similar or more advanced technologies by our competitors may require that we devote substantial resources to the development of more advanced technology to remain competitive.

The market for our WatchPAT family of products and related services is highly competitive. If we are unable to compete successfully, this would adversely impact our business, revenues and results of operation.

The market for our WatchPAT family of products is highly competitive and is characterized by frequent product improvements and evolving technology. Our competitors range from small privately held companies to multinational corporations and their product offerings vary in scope and breadth, and some of our competitors may have certain competitive advantages, including:

- significant brand name recognition;
- established relationships with healthcare professionals, customers and third-party payors;
- established distribution networks and channels;
- additional product lines and the ability to offer rebates or bundle products to offer higher discounts or other incentives to gain a competitive advantage; and
- greater financial and human resources for product development, sales and marketing, customer support and intellectual property litigation.

Also, while we are not aware of any competitors offering products and services similar to our TSS program and other WatchPAT related services targeted at the cardiology community, we believe that competitors who possess robust financial resources and sales and regulatory personnel may be able to overcome the barriers to entry into this market and offer products and service models similar to our TSS program.

Our ability to compete successfully depends, in part, on our ability to continuously develop, improve and market our WatchPAT family of products and related services. Consequently, we may need to increase our efforts, and related expenses for research and development, clinical studies and sales and marketing, to maintain or improve our market position. Additionally, our efforts to educate the medical community, specifically the cardiology community, and third-party payors on the linkage between sleep apnea and cardiovascular conditions, the advantages of shifting the point of care for sleep apnea from sleep centers to the cardiology care point as well as on the diagnostic aid benefits of the WatchPAT and related services may require significant resources and may not be successful.

The development of innovative new products and services by our competitors for the same or similar indications as our product offerings, which competitive products and services may be less costly, more effective, or more widely accepted by the medical community, may also adversely affect the sales of our products and related services and could result in our products and services being noncompetitive or obsolete. Also, our competitors may attempt to present their products as providing features and advantages similar or superior to those provided by the WatchPAT family of products or as being based on similar technology, thus adversely affecting our ability to differentiate our WatchPAT family of products. In addition, our WatchPAT family of products may be subject to pricing pressures as a result of competition with other HSATs or with PSG tests.

If we are unable to support our plans for continued growth, our business could suffer.

We intend to continue our investment in research and development activities and to expand our sales and marketing activities in the United States and in other countries through our own field sales force as well as through local distributors and DTC channel partners. If we continue to grow, the complexity of our operations is likely to increase, placing greater demands on our management. Our ability to manage our growth effectively depends on our ability to implement and improve our financial and management information systems on a timely basis and to effect other changes in our business, including the ability to monitor and improve our manufacturing systems, and align our information, quality and regulatory compliance systems, among others. Unexpected difficulties during expansion, the failure to attract and retain qualified employees and subcontractors, the failure to successfully replace or upgrade our management information systems, the failure to manage costs or our inability to respond effectively to growth or plan for future expansion could halt our growth. If we fail to manage our growth effectively and efficiently, our costs could increase faster than our revenues and our business results could suffer.

We depend on strategic relationships with our distributors, channel partners and other business partners and our revenues may be reduced if such relationships are not successful or are terminated.

Our products and services are offered through both direct and indirect channels, including distributors, channel partners in the cardiology and DTC segments and other business partners in the United States and in other countries. Specifically, we rely on strategic relationships with distributors and other business partners, such as Philips Japan, which acts as the exclusive distributor of our WatchPAT family of products in Japan, to sell our products, and these relationships account for a large portion of our revenues. In addition, in order to promote our TSS program in the United States, we are also developing partnerships with various business partners whose products or services are complimentary to ours. Additionally, we have entered into an agreement with a wholly-owned subsidiary of SoClean Inc., or SoClean, for the sale of our WatchPAT ONE via SoClean's DTC marketing channels. Any failure of these relationships, whether to market our products effectively or generate significant revenues for us or our inability to sell products and services that are complimentary to ours, a termination of any of these relationships, or if we are unable to form additional strategic alliances in the future that will prove beneficial to us, could have a material adverse effect on our business, operating results and financial condition.

Natural disasters and other states of emergency, such as the novel coronavirus outbreak, could adversely impact our business, financial condition and results of operations.

Natural disasters and other states of emergency affecting the countries in which we operate, or the global economic markets may have an adverse impact on our business. For example, in December 2019, a strain of novel coronavirus surfaced in Wuhan, China and, in January 2020, the World Health Organization, or the WHO, declared the novel coronavirus outbreak a "Public Health Emergency of International Concern" and the U.S. Department of State instructed travelers to avoid all nonessential travel to China. Since then, the WHO declared the novel coronavirus as a pandemic and many countries, including the U.S., Israel, Japan and certain states in Europe have imposed various measures designed to minimize the spread of the coronavirus, such as restrictions on international travel, domestic commute, public gatherings and employment and business operations, as well as limitations on the presence of employees in any work place at a given time. Such measures, designed to limit the spread of the coronavirus, have impacted our operations and may continue to impact our operations, primarily in connection with our manufacturing facility in Israel.

In compliance with regulations enacted in Israel as a response to the coronavirus, we moved most of our office employees in Israel to work from their homes and have changed the structure of our manufacturing facility shifts in order to comply with the said regulations. Our supply chain has also been interrupted, particularly our suppliers in China, who have halted their operations for a few weeks. While our safety inventory has allowed us to meet demand for the first quarter of 2020, and our suppliers in China are in the process of resuming operations, with first deliveries already arrived in Israel recently, and while our current shift structure allows us to continue our manufacturing activities in full capacity, there is no assurance that more stringent regulations, limiting our suppliers ability to deliver or limiting our ability to operate our manufacturing facility at its current pace, will not be enacted. The coronavirus has also impacted the global economy and may impact our business, operations and sales and marketing efforts. If, as a result of the outbreak or a second or continued outbreak and related governmental orders and regulations, certain of our suppliers and subcontractors, primarily in China, continue to be affected and experience closures and labor shortages, this could disrupt their activities. We could therefore face difficulty sourcing key components and materials necessary to produce supply of our products, which may negatively affect our ability to meet demand for our products. Even if we are able to find alternate sources for some of these components and materials, qualification processes of such suppliers are lengthy and they may cost more, which could adversely affect our business, results of operations and financial position.

In addition, because the outbreak has spread to Israel, where our headquarters and single manufacturing facility are located, as well as to the U.S., where our U.S. headquarters and products warehouse are located, we have restricted access and may continue to restrict access, including of some of our own employees, to our facilities. Also, our employees in the various countries in which we operate may be infected by the coronavirus or quarantined for purposes of containing its spread. While employees whose access to our facilities was restricted are currently working remotely from their homes, these restrictions, could negatively impact our employees' productivity. While current regulations allow us to operate our manufacturing facility in full capacity, subject to certain restrictions, we have applied for a special permit from the Israeli Ministry of Health and from the Israeli Ministry of Economics, that will allow some of our employees, who are most critical to our ability to continue production at the Israeli facility, to continue to have access to such facility, in case a complete shutdown is imposed in Israel. However, there is no assurance that we will obtain such permit and, even if we do obtain such permit, whether it will suffice in order to maintain production at the same level.

Moreover, the measures imposed by many countries to minimize the spread of the coronavirus, including restrictions on international travel, domestic commutes, public gatherings, entrance to medical facilities and the number of personnel present in a work place at a given time, may also adversely affect our sales and marketing efforts. In addition, the coronavirus outbreak could delay enrollment in our clinical trials due to prioritization of hospital resources toward the outbreak, and some patients may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Also, as governments, regulators, healthcare systems and payors in the various counties in which we operate focus on containing the recent coronavirus outbreak, and prioritize their work and resources accordingly, there is no guarantee that submissions of our products for approval for sale or for inclusion in payor's policies in such counties will be completed within standard time frames, which could adversely affect the execution of our business goals. Similarly, interruption or delays in the operations of the U.S. Food and Drug Administration, or the FDA, may also impact review and approval timelines.

Lastly, at this point in time, there is significant uncertainty relating to the potential effect of the novel coronavirus on our business and, while we maintain business continuity plans, they might not adequately protect us. Infections may become more widespread, including in countries where we manufacture key components of our products or in which we sell our products, and manufacturing closures, travel restrictions and other restrictions may remain or worsen, all of which would have a negative impact on our business, financial condition and results of operations.

We are dependent on a single facility that houses the majority of our manufacturing operations.

We are dependent on the uninterrupted and efficient operations of our leased manufacturing facility, located in Caesarea, Israel. If operations at the plant were to be disrupted or halted as a result of equipment failures, earthquakes and other natural disasters (including public health emergencies, such as the novel coronavirus and related governmental orders and regulations), fires, accidents, work stoppages, power outages, acts of war, terrorism or other reasons, we will likely need to use subcontractors or stop manufacturing activities until we are able to set up and qualify an alternative facility or subcontractor, and our business could be materially adversely affected. Lost sales, our inability to meet our delivery obligations or customers' demand or increased costs that we may experience during the disruption or halting of operations may not be recoverable under our insurance policies, and longer-term business disruptions could result in a loss of customers, customers' claims and loss of sales. If this were to occur, our business could be materially adversely affected.

We are dependent upon third-party manufacturers and suppliers, which makes us vulnerable to supply disruptions.

In addition to manufacturing our products in our own manufacturing facility, we also engage third-party manufacturers and suppliers. the majority of which are located in China and Israel, for the assembly and manufacture of our products and components of our products as well as to provide us with software licenses for IT platforms and other applications which we use as part of our CloudPAT and related services. Some of our suppliers and third-party manufacturers are not obligated to continue to supply us. We have relatively few sources of supply for some of the components and materials used in our products and IT platforms and other applications and, in some cases, we rely entirely on sole-source suppliers. In addition, the lead-time involved in manufacturing some of these components can be lengthy. Our third-party suppliers and manufacturers may encounter problems during manufacturing or supply or suffer a complete stoppage of operations for long periods of time, due to a variety of reasons, including, among others, failure to follow specific protocols and procedures, failure to comply with applicable regulatory requirements, equipment or software malfunctions, environmental factors, natural disasters, including public health emergencies, such as the novel coronavirus and related governmental orders and regulations, or work force stoppages, any of which could delay or impede their ability to meet our demand for components or ongoing support. Our sole-source suppliers, and any of our other suppliers or our third-party contract manufacturers, may be unwilling or unable to supply the necessary materials and components or manufacture and assemble our products reliably and at the levels we anticipate or that are required by the market. Our ability to supply our products and related services commercially and to develop any future products and related services depends, in part, on our ability to timely obtain these materials, components and products in accordance with regulatory requirements and in sufficient quantities for commercialization and clinical testing. For example, we rely upon a single supplier who provides us with development services and database management services used for our CloudPAT platform.

While our suppliers and other contract manufacturers have generally met our demand for their products and services on a timely basis in the past, there have been occasions when our suppliers, particularly in China, during the recent novel coronavirus outbreak, have completely halted their operations resulting in a disruption of supply of components and materials to us. While we generally maintain relatively high inventory levels of components, materials and complete products, to allow us to meet customers' demand despite potential supply disruption by our suppliers and contract manufacturers, we cannot guarantee that such inventory levels will be sufficient in the face of long term supply disruptions or stoppages or that our suppliers and contract manufacturers will be able to meet our demand for their products and services in the future, either because of acts of nature, emergency situations and the nature of our agreements with those suppliers and other manufacturers or our relative importance to them as a customer., Our suppliers and other manufacturers may also decide in the future to discontinue or reduce the level of business they conduct with us. While we believe we can engage alternative suppliers, license or purchase our requirements or develop an alternative independently, changing suppliers or contract manufacturers due to any change in, or termination of, our relationships with these third parties may be a lengthy and expensive process and, consequently, we may lose sales, experience manufacturing or other delays, incur increased costs or otherwise experience impairment to our customer relationships. We cannot guarantee that we will be able to establish alternative relationships on adequate terms and without delays. Our reliance on third-party suppliers also subjects us to additional risks that could harm our business, including, among others:

- our third-party suppliers or third-party manufacturers, especially new suppliers or manufacturers, may make manufacturing errors that may not be detected by our quality assurance testing, which could negatively affect the efficacy or safety of our products or cause shipment delays or product recalls;

- our suppliers or third-party manufacturers may encounter financial or other hardships unrelated to our demand, such as a result of equipment failures, earthquakes and other natural disasters (including public health emergencies, such as the novel coronavirus and related governmental orders and regulations), which could inhibit their ability to fulfill our orders and meet our requirements; and

- our suppliers or third-party manufacturers may not maintain their regulatory clearances, authorizations or approvals and as a result, we may not be able use their products or services, which may result in delays and reduction of our production capacity.

In addition, replacement or alternative sources might not be readily obtainable due to regulatory requirements and other factors applicable to our manufacturing operations. Incorporation of components or services from new suppliers or new third-party manufacturers into our products and related services may require a new or supplemental filing with applicable regulatory authorities and clearance or approval of the filing before we could resume product manufacturing. This process may take a substantial period of time, and we may not be able to obtain the necessary regulatory clearance or approval. This could also create supply disruptions that would harm our ability to meet our delivery obligations to our customers, may impede product sales and could have a material adverse effect on our business, financial condition and results of operations.

Our Credit Facility contains restrictive covenants that may limit our operating flexibility.

In February 2020, we secured a line of credit from an Israeli bank of up to $20 million, subject to the terms of the Credit Facility, from which we withdrew $5 million on February 20, 2020, which are due on May 20, 2020, unless extended with the consent of the bank. In order to secure our obligations under the Credit Facility, we pledged and granted to the bank a first priority floating charge on all of our assets and a first priority fixed charge on (i) our intellectual property, goodwill, holdings in our subsidiaries and certain other assets; and (ii) all of the assets of our U.S. subsidiary. We refer to the agreements relating to such charges and other security interests as the Security Agreements.

The Security Agreements contain a number of customary restrictive terms and covenants that limit our operating flexibility, such as limitations on the creation of additional liens, on the incurrence of indebtedness, on the provision of loans and guarantees, on engagement in certain fundamental transactions including mergers and consolidations, on the sale and transfer of assets and on distributions of dividends. The Security Agreements also grant the bank the ability to accelerate repayment in certain events, such as breach of covenants, liquidation and a change of control of our Company. In addition, our right to make any draws under the Credit Facility is conditioned upon us having cash balances in our account with the lending bank of not less than 30% of the total amount drawn for draws of up to $10 million in the aggregate and 40% of the aggregate amount exceeding $10 million. Such provisions may hinder our future operations or the manner in which we operate our business, which could have a material adverse effect on our business, financial condition or results of operations. A breach of any of these covenants could result in a default under the Credit Facility, which could cause all of the outstanding indebtedness under our Credit Facility to become immediately due and payable and terminate all commitments to extend further credit. These covenants could also limit our ability to seek capital through the incurrence of new indebtedness or, if we are unable to meet our obligations, require us to repay any outstanding amounts with sources of capital we may otherwise use to fund our business, operations and strategy.

Defects or failures associated with our products or our quality system could lead to the filing of adverse event reports, product recalls or safety alerts with associated negative publicity and could also subject us to regulatory actions.

Manufacturing flaws, component failures, design defects, off-label uses or inadequate disclosure of product-related information could result in an unsafe condition or bodily injury of a patient. These problems could lead to a recall of, issuance of a safety alert relating to, or need for us to submit applications for new marketing authorizations for, our products and result in significant costs and negative publicity. An adverse event involving one of our products could result in reduced market acceptance and demand for all products within that brand, and could harm our reputation and our ability to market our products in the future. In some circumstances, adverse events arising from or associated with the design, manufacture or marketing of our products could result in the suspension of current regulatory clearances or approvals of our products or delays in regulatory reviews of our applications for new product approvals or clearances. The FDA, and foreign regulatory authorities have the authority to require the recall of commercialized products in certain circumstances, such as where the FDA finds that there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death. We may also voluntarily undertake a recall of our products, temporarily shut down production lines or place products on a shipping hold based on internal safety and quality monitoring. We may also face litigation brought against us as a result of any of the foregoing instances, by customers and patients, and there is no assurance that our insurance policies will fully cover such claims. A government-mandated or voluntary recall or other shutdown by us could occur as a result of an unacceptable health risk, component failure, malfunction, manufacturing defect, labeling or design deficiency, packaging defect, or other deficiency or failure to comply with applicable regulations. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. We may initiate voluntary withdrawals for our products in the future that we determine do not require notification to the FDA. If the FDA disagrees with our determinations, it could require us to report those actions as recalls and we may be subject to enforcement action. Any corrective action, whether voluntary or involuntary, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results. Moreover, depending on the corrective action we take to redress a product's deficiencies or defects, the FDA may require, or we may decide, that we will need to obtain new clearances or approvals for the device before we may market or distribute the corrected device. Seeking such clearances or approvals may delay our ability to replace the recalled devices in a timely manner.

We are subject to the FDA's medical device reporting, or MDR, regulations and similar foreign regulations, which require us to report to the FDA or foreign regulatory bodies when we receive or become aware of information that reasonably suggests that one or more of our products may have caused or contributed to a death or serious injury or malfunctioned in a way that, if the malfunction were to recur, 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 or malfunction, 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 the product. If we fail to comply with our reporting obligations, the FDA could take action, including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our device clearances, seizure of our products or delay in clearance or approval of future products.

Our future operating results will depend on our ability to sustain an effective quality control system and effectively train and manage our employee base, suppliers and subcontractors with respect to our quality system. Our quality system plays an essential role in determining and meeting customer requirements, preventing defects and improving our products and services. While we have a network of quality systems throughout our business lines and facilities, quality and safety issues may occur with respect to any of our products. A quality or safety issue may result in, among other things, product recalls, a public warning letter, a public safety communication or potentially a consent decree from the FDA in the United States and from similar regulatory bodies elsewhere. In addition, we may be subject to product recalls or seizures, monetary sanctions, injunctions to halt manufacturing and distribution of products, civil or criminal sanctions, import detentions of our products and restrictions on operations. Any of the foregoing events could disrupt our business and have an adverse effect on our results of operations and financial condition.

The misuse or off-label use of our products may harm our reputation in the marketplace, result in injuries that lead to product liability suits or result in costly investigations, fines or sanctions by regulatory bodies if we are deemed to have engaged in the promotion of these uses, any of which could be costly to our business.

Our currently marketed products have been cleared by the FDA for specific indications. We train our marketing personnel and direct sales force to not promote our devices for uses outside of the FDA-cleared indications for use, known as "off-label uses." We cannot, however, prevent a physician from using our devices off-label, when in the physician's independent professional medical judgment and practice of medicine he or she deems it appropriate. There may be increased risk of injury to patients if physicians attempt to use our devices off-label. Furthermore, the use of our devices for indications other than those cleared by the 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 the 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 the issuance of an untitled letter, which is used for violators that do not necessitate a warning letter, issuance of a warning letter or imposition of an injunction, seizure, civil fine 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.

In addition, physicians may misuse our products or use improper techniques if they are not adequately trained, potentially leading to injury and an increased risk of product liability. If our devices are misused or used with improper technique, we may become subject to costly litigation by our customers or their patients. As described below, product liability claims could divert management's attention from our core business, be expensive to defend and result in sizeable damage awards against us that may not be covered by insurance.

We face the risk of product liability claims that could be expensive, divert management attention and harm our reputation and business. We may not be able to maintain adequate product liability insurance.

Our business exposes us to the risk of product liability claims that are inherent in the testing, manufacturing and marketing of medical devices. This risk exists even if a device is cleared or approved for commercial sale by the FDA or other applicable foreign regulatory authority and manufactured in facilities regulated by the FDA or other applicable foreign regulatory authority. Our products are designed to test, and future products may be designed to test, important bodily functions and processes. Any adverse effects, manufacturing defects, misuse or abuse associated with our devices could result in patient injury. The medical device industry has historically been subject to extensive litigation over product liability claims, and we cannot offer any assurance that we will not face product liability suits. We may be subject to product liability claims if our devices cause, or merely appear to have caused, patient injury. In addition, we may be subject to claims related to our DTC business through the online marketplace that we plan to create, which will connect patients in demand for clinical services with physicians. Further, an injury that is caused by the activities of our suppliers, such as those who provide us with components and raw materials, may be the basis for a claim against us either as manufacturers or resellers of third-party devices. Product liability claims may be brought against us by patients, physicians, healthcare providers or others selling or otherwise coming into contact with our products or, while less likely, the products we resell.

In addition, we facilitate the provision of home sleep apnea test interpretation, and also plan to facilitate the provisions of prescriptions and on-line consultations via our digital health platform, the CloudPAT, by licensed physicians in line with acceptable medical standards. We take precautions to assure that all of the physicians which provide services via CloudPAT are duly licensed and intend to require all such physicians to procure appropriate professional malpractice insurance, however, there is no assurance that patients receiving such physician services, facilitated by our CloudPAT platform do not suffer from malpractice by such physicians, which may be the basis for a claim against us.

If we cannot successfully defend ourselves against product liability claims, we will incur substantial liabilities and reputational harm. In addition, regardless of merit or eventual outcome, product liability and medical malpractice claims may result in:

- cost of litigation;
- distraction of management's attention from our primary business;

- the inability to commercialize our products and related services;
- decreased demand for our products and related services, including through our digital health platform;
- damage to our business reputation;
- product recalls or withdrawals from the market;
- withdrawal of clinical trial participants;
- substantial monetary awards to patients or other claimants; and
- loss of sales.

While we may attempt to manage our product liability exposure by proactively recalling or withdrawing from the market any defective products, any recall or market withdrawal of our products may delay the supply of those products to our customers and may negatively impact our reputation. We can provide no assurance that we will be successful in initiating appropriate market recall or market withdrawal efforts that may be required in the future or that these efforts will have the intended effect of preventing product malfunctions and the accompanying product liability that may result. Such recalls and withdrawals may also be used by our competitors to harm our reputation for safety or be perceived by patients as a safety risk when considering the use of our products, either of which could have a material adverse effect on our business, financial condition and results of operations.

Although we have product liability and clinical study liability insurance that we believe is appropriate, this insurance is subject to deductibles and coverage limitations. Our current product liability insurance may not continue to be available to us on acceptable terms, if at all, and, if available, coverage may not be adequate to protect us against any future product liability claims. If we are unable to obtain insurance at an acceptable cost or on acceptable terms or otherwise protect against potential product liability claims, we could be exposed to significant liabilities. A product liability claim, recall or other claim with respect to uninsured liabilities or for amounts in excess of insured liabilities could have a material adverse effect on our business, financial condition and results of operations.

Our use of "open source" software could adversely affect our ability to offer our services and subject us to possible litigation.

We may use open source software in connection with our products and services. Companies that incorporate open source software into their products have, from time to time, faced claims challenging the use of open source software and/or compliance with open source license terms. As a result, we could be subject to suits by parties claiming ownership of what we believe to be open source software or claiming noncompliance with open source licensing terms. Some open source software licenses require users who distribute software containing open source software to publicly disclose all or part of the source code to such software and/or make available any derivative works of the open source code, which could include valuable proprietary code of the user, on unfavorable terms or at no cost. While we plan to monitor the use of open source software and try to ensure that none is used in a manner that would require us to disclose our proprietary source code or that would otherwise breach the terms of an open source agreement, such use could inadvertently occur, in part because open source license terms are often ambiguous. Any requirement to disclose our proprietary source code or pay damages for breach of contract could have a material adverse effect on our business, financial condition and results of operations, and could help our competitors develop products and services that are similar to or better than ours. In addition, there can be no assurance that the security characteristics of open source software would be sufficient to keep our products or services compliant with applicable security and privacy requirements and regulations.

We have limited data and experience regarding the safety and efficacy of our products. Results of earlier studies may not be predictive of future clinical trial results, or the safety or efficacy profile for such products.

The results of preclinical studies and clinical trials of our products conducted to date and ongoing or future studies and trials of our current, planned or future products may not be predictive of the results of later studies or clinical trials, and interim results of a study or clinical trial do not necessarily predict final results. Our interpretation of data and results from our studies or clinical trials do not ensure that we will achieve similar results in future studies or clinical trials in other patient populations. In addition, preclinical and clinical data are often susceptible to various interpretations and analyses, and many companies that have believed their products performed satisfactorily in preclinical studies and earlier clinical trials have nonetheless failed to replicate results in later clinical trials. Products in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through nonclinical studies and earlier clinical trials.

If we receive a significant number of warranty claims or our products require significant post-sale support, our costs will increase and our business and financial results will be adversely affected.

Sales of our products typically include a warranty on our part, generally for a period of 12 months from the date the product is delivered to the customer's facility (and, in some cases, for extended periods of 24 and 36 months). While we have not experienced many warranty claims in the past and the cost of repairing or replacing our products has not been material thus far, if product returns or warranty claims are significant or exceed our expectations, we could incur unanticipated reductions in sales or additional expenditures for parts and service. In addition, our reputation could be damaged and our products may not achieve market acceptance.

Long lead-times required by certain suppliers could prevent us from meeting the demand for our products. As such, if we do not accurately forecast such demand, our operating results could be adversely affected.

Market uncertainty makes it difficult for us, our customers, our distributors and our suppliers to accurately forecast future product demand trends, which could cause us to order or produce excess products that can increase our inventory costs and result in obsolete inventory. Alternatively, this forecasting difficulty could cause a shortage of products, or components and materials used in our products, that could result in an inability to satisfy demand within a timeframe acceptable by our customers for our products and a resulting material loss of potential revenue.

In addition, some of our suppliers, such as suppliers of components, may require extensive advance notice of our requirements in order to produce products in the quantities we desire and may not guarantee the final price in advance. This long lead-time, which in some cases can be between six and twelve months, and price fluctuations may require us to place orders far in advance of the time when certain products will be offered for sale, thereby also making it difficult for us to accurately forecast supply of our products and their cost of manufacturing, exposing us to risks relating to shifts in consumer demand and trends, cost fluctuations and adversely affecting our operating results.

Our competitive position may be adversely affected if we fail to develop additional products and applications or enhance existing products.

We plan to develop and manufacture additional products and applications using our PAT-based technology, continue enhancing our existing line of products and further develop and enhance our digital health platform in order to remain competitive. There is no certainty that we will meet the technological, clinical and regulatory requirements or any other requirements applicable to the development process of such new products or applications. In addition, we may not have the financial resources necessary for the completion of such development. If we fail to develop additional products and applications, enhance our existing line of products or further develop and enhance our digital health platform in a manner that is acceptable to our partners and consumers, it may have an adverse effect on our competitive position, reputation, growth prospects and business results, and our operating results may decline or fail to grow as expected. In addition, if we fail to develop and deploy new products, enhancements of our products and our digital health platform on a timely basis or if we fail to gain market acceptance of our new products, our revenues may decline and we may lose market share to our competitors.

The risks and uncertainties inherent in conducting clinical trials could delay or prevent the development and commercialization of new products, or new indications for our existing products, which could have a material adverse effect on our results of operations, financial condition and growth prospects.

Manufacturers may be required to conduct clinical trials prior to obtaining regulatory authorizations to market and sell a medical device in any given territory, or may conduct clinical trials to support the marketing of their products. Clinical trials are experiments conducted or observations made in clinical research of medical devices on human participants. Such trials are designed to answer particular questions about novel medical devices or new indications that require further study and provide data about the product's safety and efficacy, and are subject to stringent oversight by regulatory authorities and/or institute ethics committees. Clinical testing is difficult to design and implement, can take many years, can be expensive and carries uncertain outcomes.

We have been required to provide data from clinical trials in connection with our submissions for marketing authorizations, and we may be required to support our marketing authorization submissions with clinical data in the future. There are a number of risks and uncertainties associated with conducting clinical trials. Clinical trials vary in scale and scope and may entail significant costs. They are also often conducted with patients having advanced stages of disease and, as a result, during the course of the trial, these patients may suffer adverse medical effects for reasons that may not be related to the product being tested, but which nevertheless affect the clinical trial results. In addition, side effects experienced by the patients may cause a delay of clearance or approval or limited profile of a cleared or approved product. Moreover, clinical trials may not provide sufficient safety and efficacy data to support FDA clearance or approval, or the approval or marketing authorization of applicable foreign regulatory authorities. Regulatory authorities may disagree with our interpretation of data and results from our clinical trials.

Failure can occur at any time during the clinical trial process, and the results from early clinical trials may not be predictive of results obtained in later and larger clinical trials. Product candidates in later clinical trials may fail to show the desired safety or efficacy despite having progressed successfully through earlier clinical testing. In the future, the completion of clinical trials, if required, for our new products or new indications of current products may be delayed or halted for many reasons, including:

- we may be required to submit an IDE application to the FDA, which must become effective prior to commencing certain human clinical trials of medical devices, and the FDA may reject our IDE application and notify us that we may not begin clinical trials;

- regulators may disagree as to the design or implementation of our clinical trials, and regulators or institutional review boards or ethics committees may not allow us to commence or continue a clinical trial;

- we may not reach agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;

- the number of subjects required for clinical trials may be larger than we anticipate, enrollment in these clinical trials may be insufficient or slower than we anticipate, the number of clinical trials being conducted at any given time may be high and result in fewer available subjects for any given clinical trial or subjects may drop out of these clinical trials at a higher rate than we anticipate;

- risks associated with trial design, which may result in a failure of the trial to show statistically significant results;

- clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;

- our third-party contractors, including those manufacturing products or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;

- safety issues, including adverse events associated with product candidates, occurring during clinical trials;

- the failure of patients to complete clinical trials due to adverse side effects, dissatisfaction with the product candidate or other reasons;

- clinical sites may not adhere to the clinical protocol or may drop out of a clinical trial; and

- governmental or regulatory delays or changes in regulatory requirements, policy, guidelines or interpretations.

Clinical trials must be conducted in accordance with the laws and regulations of the FDA and other applicable regulatory authorities' legal requirements, regulations or guidelines, and are subject to oversight by these governmental agencies and ethics committees or institutional review boards at the medical institutions where the clinical trials are conducted. In addition, clinical trials must be conducted with supplies of our devices produced under current good manufacturing practice, or cGMP, requirements and other regulations. Furthermore, we may rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials, and while we have agreements governing their committed activities, we have limited influence over their actual performance. We depend on our collaborators and on medical institutions to conduct our clinical trials in compliance with good clinical practice, or GCP, requirements. To the extent our collaborators or the CROs fail to enroll participants in our clinical trials, fail to conduct the study to GCP standards or are delayed for a significant time in the execution of trials, including achieving full enrollment, we may be affected by increased costs, program delays, or both. In addition, clinical trials that are conducted in countries outside the United States may subject us to further delays and expenses as a result of increased shipment costs, additional regulatory requirements and the engagement of non-U.S. CROs, as well as expose us to risks associated with clinical investigators who are unknown to the FDA, and different standards of diagnosis, screening and medical care.

Any failure or delay in completing clinical trials for new products or new indications of our products would prevent or delay the commercialization of our product or the introduction of new indications for our products, which could result in significant expenses and materially adversely affect our business. In addition, disruptions caused by the coronavirus pandemic may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical trials. There is no certainty that our expenses related to clinical trials will lead to the development of products or new product indications that will receive regulatory clearance or approval and generate revenues in the near future, or ever.

Delays or failure in the development and commercialization of our products could have a material adverse effect on our results of operations, liquidity, financial condition and growth prospects. Negative results of clinical trials performed by us or by third parties regarding the use of our products may also adversely affect the medical community's and customers' acceptance of our products.

Our revenues and operating results could fluctuate significantly.

Our revenues and operating results may vary significantly from year-to-year and quarter-to-quarter. Variations may result from, among other factors:

- the timing of product launches, and market acceptance of such products launched;
- changes in the amount we spend to research, develop, acquire, license or promote new products;
- the outcome of our research, development and clinical trial programs, as well as independent trials conducted without our involvement which could be published in peer-reviewed journals;
- serious or unexpected health or safety concerns related to our products or our product candidates;
- the introduction of new products by others that render our products obsolete or noncompetitive;
- the ability to maintain selling prices and high gross margins on our products;
- changes in coverage and reimbursement policies of health plans and other health insurers, including changes to Medicare, Medicaid and similar state programs;
- increases in the cost of components or raw materials used to manufacture our products;

- manufacturing and supply interruptions, including product rejections or recalls due to failure to comply with manufacturing specifications or inability to meet demand due to interruptions in our supply chain;
- the timing of FDA or any other foreign regulatory authority clearances, authorizations or approvals;
- the ability to protect our intellectual property and avoid infringing the intellectual property of others;
- the timing and quantities of our customers' purchases of our products, which may be affected by factors out of our control including, among others, their budget constraints; and
- the outcome and cost of possible litigation over patents with third parties.

We are an international business, and we are exposed to various global risks that could have a material adverse effect on our financial condition and results of operations.

As an international business, which operates in multiple jurisdictions, we are exposed to trends and financial risks of international markets, and are also required to comply with varying legal and regulatory requirements in such multiple jurisdictions. Profitability from international operations may be limited by risks and uncertainties related to regional and global economic conditions, regulatory clearances and approvals and reimbursement approvals, and our ability to implement our overall business strategy in various jurisdictions. We expect these risks will increase as we pursue our strategy to expand operations into new geographic markets. We may not succeed in developing and implementing effective policies and strategies in each location where we conduct business. Any failure to do so may harm our business, results of operations and financial condition.

International sales and operations are subject to a variety of risks, including:

- foreign currency exchange rate fluctuations;
- potential adverse changes in laws and regulatory practices, including export license requirements, trade barriers, tariffs and tax laws;
- burdens and costs of compliance with a variety of foreign laws;
- foreign tax laws and potential increased costs associated with overlapping tax structures;
- greater difficulty in staffing and managing foreign operations;
- greater risk of uncollectible accounts;
- longer collection cycles;
- logistical and communications challenges;
- changes in labor conditions;
- political and economic instability, including, without limitation, due to natural disasters or other catastrophic events, such as terrorist attacks, pandemic diseases, such as the novel coronavirus, hurricanes, fire, floods, pollution and earthquakes;
- greater difficulty in protecting intellectual property;

- the risk of third-party disputes over ownership of intellectual property and infringement of third-party intellectual property by our products; and

- general economic and political conditions in these foreign markets.

International markets are also affected by economic pressure to contain reimbursement levels and healthcare costs. Profitability from international operations may be limited by risks and uncertainties related to regional economic conditions, regulatory clearances and approvals and reimbursement approvals, competing products, infrastructure development, intellectual property rights protection and our ability to implement our overall business strategy. We expect these risks will increase as we pursue our strategy to expand operations into new geographic markets. We may not succeed in developing and implementing effective policies and strategies in each location where we conduct business. Any failure to do so may harm our business, results of operations and financial condition.

Exchange rate fluctuations, primarily between the U.S. dollar and the NIS, may negatively affect our liquidity, financial condition and results of operation.

We currently generate a substantial portion of our revenues in U.S. dollars whereas we currently incur a significant portion of our expenses in other currencies, predominantly NIS. Since our functional and reporting currency is the U.S. dollar, our financial results may be affected by fluctuations in the exchange rates of currencies in the countries in which we transact business. For example, during 2019, we witnessed a strengthening of the average exchange rate of the NIS against the U.S. dollar, which increased the U.S. dollar value of Israeli expenses. If the NIS strengthens against the U.S. dollar, as it did in 2019, the U.S. dollar value of our Israeli expenses, mainly personnel and facility-related, will increase. It is possible that such fluctuation of the average exchange rate of the NIS against the U.S. dollar may continue in 2020, including as a result of the effect of the coronavirus outbreak on global economy, including on currencies exchange rates. While we engage, from time to time, in currency hedging transactions intended to reduce the effect of fluctuations in foreign currency exchange rates on our results of operations, we cannot guarantee that such measures will adequately protect us against currency fluctuations in the future. Although exposure to currency fluctuations to date has not had a material adverse effect on our business, there can be no assurance such fluctuations in the future will not have a material adverse effect on our operating results and financial condition.

Changing or severe global economic conditions may materially adversely affect our business.

Our business and financial condition are affected by global economic conditions and their impact on levels of spending by customers, which may be disproportionately affected by economic downturns. The global economy is subject to uncertainties surrounding its strength in many regions. For example, the recent outbreak of the coronavirus is already affecting the global economy and international trade (see also above under "*Natural disasters and other states of emergency, such as the novel coronavirus outbreak could adversely impact our business, financial condition and results of operations*") and, at this point in time, there is significant uncertainty relating to the potential effect thereof on our business. In addition, the recent escalating disagreements between the United States and certain European states, as well between the United States and China, with respect to placing tariffs and other trade barriers, may adversely affect international trade and we cannot predict the implications of such barriers on our business. Uncertainty about current global economic conditions continues to pose a risk as customers may postpone or reduce spending in response to restraints on credit or concerns about restraints on credit. Should an economic slowdown resume and/or companies in our target markets reduce capital expenditures, it may cause our customers to reduce or postpone their spending significantly, which could result in reductions in sales of our products, longer sales cycles, slower adoption of new technologies and increased price competition.

In addition, if the market is flat and customers experience low visibility, we may not be able to increase our sales (whether direct sales or indirect sales through our distributors). Each of the above scenarios would have a material adverse effect on our business, operating results and financial condition.

Our ability to retain and attract qualified senior management, including our President and Chief Executive Officer, as well as employees with the expertise required for our business is key to our success.

Our success largely depends on our ability to retain and attract qualified senior management, in particular Mr. Gilad Glick, our President and Chief Executive Officer, who also acts as President of our wholly-owned U.S. subsidiary, Itamar Medical, Inc., as well as on our ability to retain and attract qualified personnel, including personnel with expertise in research and development and sales and marketing, and to effectively provide for the succession of senior management. There is intense competition from numerous biotechnology, medical device and other companies seeking to employ qualified individuals in the business fields in which we operate, and we may not be able to attract and retain the qualified personnel necessary for the achievement of our business objectives.

We do not maintain life insurance on any of our personnel. Regardless, the loss of senior management employees, the failure of any senior management employee to perform or our inability to attract and retain skilled employees, as needed, or an inability to effectively plan for and implement a succession plan for senior management could harm our business. In particular, the loss of the services of Mr. Glick could result in a significant loss in the knowledge and experience that we possess and could significantly delay or prevent successful implementation of our business objectives.

Under applicable employment laws, we may not be able to enforce covenants not to compete.

Our employment agreements generally include covenants not to compete. These agreements prohibit our employees, if they cease working for us, from competing directly with us or working for our competitors for a limited period. We may be unable to enforce these agreements under the laws of the jurisdictions in which our employees work. For example, Israeli courts have required employers seeking to enforce covenants not to compete to demonstrate that the competitive activities of a former employee will harm one of a limited number of material interests of the employer, such as the secrecy of a company's confidential commercial information or the protection of its intellectual property. If we cannot demonstrate that such an interest will be harmed, we may be unable to prevent our competitors from benefiting from the expertise of our former employees or consultants and our competitiveness may be diminished, which could materially adversely affect our business, results of operations and ability to capitalize on our proprietary information.

Our employees, independent contractors, consultants, partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of employee fraud or other illegal activity by our employees, former employees, independent contractors, consultants, partners and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to comply with the regulations of the FDA, the European Medicines Agency, or the EMA, and comparable foreign regulatory authorities, provide true, complete and accurate information to the FDA, EMA and comparable foreign regulatory authorities, comply with manufacturing standards we have established, comply with healthcare fraud and abuse laws in Israel, the United States and similar foreign fraudulent misconduct laws, report financial information or data accurately or disclose unauthorized activities to us. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs. We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter misconduct by our employees, independent contractors, consultants, partners and vendors, and the precautions we take to detect and prevent such activities 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 comply with these laws or regulations. If any actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of civil, criminal and administrative penalties, damages, monetary fines, imprisonment, disgorgement, possible exclusion from participation in government healthcare programs, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm, diminished profits and future earnings and the curtailment of our operations.

Cyber security attacks or breaches of our data could adversely affect our reputation and business.

The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by criminal hackers, hacktivists, state-sponsored intrusions, industrial espionage, employee malfeasance and human or technological error are constantly evolving. Computer hackers and others routinely attempt to breach the security of high profile companies, governmental agencies, technology products, services and systems. Such risk may be enhanced if a significant portion of our personnel were to work remotely, as is currently done due to the coronavirus outbreak.

In the ordinary course of our business, we collect and store personal, financial, proprietary and other confidential information related to our business, employees, customers and their patients and partners on our IT systems. We rely on said systems to manage our business, operations and research and development and, in some cases, to provide services to our customers. For example, sensitive data is stored using our CloudPAT digital health cloud-based platform. This includes, where required or permitted by applicable laws, personally identifiable information of our customers, as well as records of home sleep tests conducted by our WatchPAT devices and the interpretation records of such tests. The CloudPAT platform facilitates the upload, storage and transfer of such data as part of the services provided via the CloudPAT platform. We also plan to enhance our CloudPAT platform to facilitate on-line physician consults and transferring of related medical documentation. Certain third parties with whom we collaborate also collect and store such data. The secure maintenance of this information is important to our operations and business strategy. Despite the implementation of security measures, our internal computer systems, and those of third parties on which we rely, are vulnerable to damage from, among others, computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization or similar disruptive problems. Any such breach could compromise information stored on our networks or those of our partners and may result in significant data losses or theft of personally identifiable information. 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. A cybersecurity breach could also hurt our reputation by adversely affecting the patients' perception of the security of their information. A number of proposed and enacted federal, state and international laws and regulations obligate companies to notify individuals of security breaches involving particular personally identifiable information, which could result from breaches experienced by us or by third parties, including collaborators, vendors, contractors or other organizations with which we expect to form strategic relationships.

We are subject to strict data privacy laws and regulations in the United States, European Union and other jurisdictions in which we operate, governing the collection, transmission, storage and use of data and personally identifying information, such as the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, or HIPAA, in the United States and the General Data Protection Regulation, or GDPR, in Europe. Any breach, unauthorized access, disclosure or other loss of information could result in legal claims or proceedings, liability under data privacy laws and regulations, disruption of our operations, including delays in our efforts to obtain regulatory clearances or approvals of our products, criminal penalties or civil liabilities, any of which would damage our reputation and adversely affect our business. See also below under "*Risks Related to Our Industry—Privacy regulations may impose costs and liabilities on us, limit our use of information, and adversely affect our business.*"

We can provide no assurance that our current IT systems are fully protected against cyber security threats or that any breach of our IT system will be detected. Even when a security breach is detected, the full extent of the breach may not be determined immediately. An increasing number of companies have disclosed security breaches of their IT systems and networks. We believe such incidents are likely to continue, and we are unable to predict the direct or indirect impact of these future attacks on us. In addition, although we maintain cyber security insurance that we believe is appropriate, this insurance is subject to deductibles and coverage limitations and there can be no assurances that our insurance coverage will be sufficient, or that insurance proceeds will be paid to us in a timely manner.

We rely on Internet infrastructure, cloud services and other third-party providers and our own systems for providing services to our clients via our CloudPAT digital platform, and any failure or interruption in the services provided by these third parties or our own systems could expose us to litigation and negatively impact our relationships with clients, adversely affecting our brand and our business.

Our ability to deliver and facilitate services through our cloud-based CloudPAT digital health platform is dependent, in part, on the development and maintenance of the infrastructure of the Internet, telecommunications services, cloud services and other third-party services. This includes maintenance of a reliable infrastructure and network connection with the necessary speed, data capacity and security for providing reliable Internet access and services.

Our services are designed to operate without interruption, however, there is no assurance that we will not experience infrastructure failures which may adversely affect the level of our services in the future. We rely on internal systems as well as on third-party suppliers and service providers to provide our services. Interruptions in these systems could affect the security, availability or level of our services and prevent or inhibit the ability of our customers and partners to access our services. If a catastrophic event occurs with respect to one or more of these systems, we may experience an extended period during which service level decreases or service is not available, which could result in substantial remedial costs, a negative impact on our relationship with our clients and partners as well as on our reputations, resulting in an adverse effect on our business, results of operations and financial condition.

Any failure of or by our own systems or third-party providers' systems to handle current or higher volume of use could significantly harm our business. We exercise limited control over our third-party suppliers, which increases our vulnerability to disruptions of the services they provide. Any errors, failures, interruptions or delays experienced in connection with these third-party service providers or our own systems could negatively impact our relationships with clients and partners, adversely affect our business and expose us to third-party liabilities.

The reliability and performance of our Internet connection may be harmed by increased usage or by denial-of-service attacks. The Internet has experienced a variety of outages and other delays as a result of damages to portions of its infrastructure, and it could face outages and delays in the future. These outages and delays could reduce the level of Internet usage as well as the availability of the Internet to us for delivery of our cloud-based services.

Consolidation in the healthcare industry or group purchasing organizations could lead to demands for price concessions.

Healthcare costs have risen significantly over the past decade, which has resulted in or led to numerous cost reform initiatives by legislators, regulators and third-party payors. Cost reform may also trigger a consolidation trend in the healthcare industry to aggregate purchasing power, which may create more requests for pricing concessions in the future. Additionally, group purchasing organizations, independent delivery networks and large single accounts may continue to use their market power to consolidate purchasing decisions for hospitals and our other targeted customers. We expect that market demand, government regulation, third-party coverage and reimbursement policies and social pressures will continue to change the healthcare industry worldwide, resulting in further business consolidations and alliances among our customers, which may exert further downward pressure on the prices of our products.

We face risks associated with acquisition of businesses and technologies.

As part of our growth strategy, we intend to evaluate and may pursue acquisitions of, or significant investments in, complementary companies or technologies to increase our technological capabilities and expand our product offerings. Acquisitions and the successful integration of new technologies, products, assets or businesses that we may acquire in the future will require significant attention from our management and could result in a diversion of resources from our existing business, which in turn could have an adverse effect on our business operations. Other risks typically encountered with acquisitions include disruption of our ongoing business; difficulties in integration of the acquired operations and personnel; inability of our management to maximize our financial and strategic position by the successful implementation or integration of the acquired technology into our product offerings; being subject to known or unknown contingent liabilities, including taxes, expenses and litigation costs; and inability to realize expected synergies or other anticipated benefits which may, among other things, also lead to goodwill impairments or other write-offs. We cannot assure you that we will be successful in overcoming these risks or any other problems we may encounter in connection with potential future acquisitions. Our inability to successfully integrate the operations of an acquired business, including a successful implementation of the technologies we acquire, and realize anticipated benefits associated with an acquisition could have a material adverse effect on our business, financial condition, results of operations and cash flows. Acquisitions or other strategic transactions may also result in dilution to our existing shareholders if we issue additional equity securities as consideration or partial consideration as well as in the incurrence of indebtedness if we borrow funds to finance such transactions.

We may face both reputational and SEC enforcement risks with respect to conflict minerals obligations.

Because of the listing of our ADSs on the Nasdaq Capital Market, we are subject to disclosure requirements under Section 102 of the Dodd-Frank Wall Street Reform and Consumer Protection Act regarding the source of certain minerals for which such conflict minerals are necessary to the functionality or production of a product manufactured, or contracted to be manufactured which are mined from the Democratic Republic of Congo, and adjoining countries, including: Angola, Burundi, Central African Republic, the Republic of the Congo, Rwanda, South Sudan, Tanzania, Uganda and Zambia. These rules require reporting companies to file a conflict minerals report as an exhibit to a Form SD report with the SEC. The conflict minerals report is required to set out the due diligence efforts and procedures exercised on the source and chain of custody of such conflict minerals, in accordance with internationally recognized due diligence framework, and a description of our products containing such conflict minerals. Although we expect that we will be able to comply with the SEC rules and timely file our initial Form SD report with the SEC, in preparing to do so we are dependent upon information supplied by certain suppliers of products that contain, or potentially contain, conflict minerals. Such preparation may be costly. To the extent that the information that we receive from our suppliers is inaccurate or inadequate or our processes in obtaining that information do not fulfill the SEC's requirements, we could face both reputational and SEC enforcement risks.

We may require additional funds to support our strategy and long-term operational plans, and, if additional funds are not available, we may need to significantly scale back or even cease our planned operations.

We plan to expand our business, which would require us to increase our investment in research and development as well as require expansion of our sales and marketing activities, including investing significant resources in further developing our sales work force and in obtaining insurance reimbursement of our products in additional territories, to support and drive our sales and marketing efforts. Our ability to take these and other actions may be limited by our available liquidity. As a result, in the future, we may seek additional financing to meet our working capital and capital expenditure requirements.

Additional debt or equity financing that we may need may not be available on terms favorable to us, or at all, and if additional funds are raised through an equity financing, the percentage ownership of our then-current shareholders would be diluted. Additionally, certain financing we obtain may contain restrictive covenants or other unfavorable terms that limit our operating flexibility or our ability to secure additional financing in the future. If we are unable to obtain such additional financing on a timely basis, we may have to curtail our development activities and growth plans or be forced to sell assets, perhaps on unfavorable terms, which would have a material adverse effect on our business, financial condition and results of operations. Further, we may not be able to continue operating if we do not generate sufficient revenues to finance our operations. In addition, we may incur substantial costs in pursuing capital financing, including investment banking fees, legal fees, accounting fees, securities law compliance fees, printing and distribution expenses and other costs.

Risks Related to Our Intellectual Property

We depend on our intellectual property, and our future success is dependent on our ability to protect our intellectual property and not infringe on the rights of others.

Our success depends, in part, on our abilities to obtain patent protection for our products, register our trademarks in the geographic locations in which we operate, protect against any infringement or misuse of our patents and trademarks, maintain the confidentiality of our trade secrets and know-how, operate without infringing on the proprietary rights of others and prevent others from infringing our proprietary rights. We try to protect our proprietary rights by, among other things, filing United States and foreign patent applications related to our products, inventions and improvements that may be important to the continuing development of our products and applying for the registration of our trademarks in certain geographic locations in which we operate. However, we cannot assure you that:

- any of our future processes or products will be patentable;
- we will identify all patentable aspects of the inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them;
- our processes or products will not infringe upon the patents of third parties;
- our patents will protect us in the jurisdictions where our patents have been granted;

- all of the potentially relevant prior art that may be used to invalidate our patents or that may prevent a patent from issuing from one of our pending patent applications has been found and been provided to the relevant patent examining authorities; or

- we will have the resources to defend against charges of patent infringement or other violation or misappropriation of intellectual property by third parties or to protect our own intellectual property rights against infringement, misappropriation or violation by third parties.

Because the patent position of medical device companies involves complex legal and factual questions, we cannot predict the validity and enforceability of our patents, or provide any assurances that any of our patent applications will be found to be patentable, with certainty. Our issued patents may not provide us with any competitive advantages, may be held invalid or unenforceable as a result of legal challenges by third parties or could be circumvented. Our competitors may also independently develop processes, technologies or products similar to ours or design around or otherwise circumvent any patents issued to, or licensed by, us. Thus, any patents that we own or license from others may not provide adequate protection against competitors. Our pending patent applications, those we may file in the future or those we may license from third parties may not result in patents being issued. If these patents are issued, they may not provide us with proprietary protection or competitive advantages. The degree of future protection to be afforded by our proprietary rights is uncertain because legal means afford relatively limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. After the completion of development and registration of our patents, third parties may still manufacture or market our products despite our patent protected rights. If the protection of our proprietary rights is inadequate to prevent use or appropriation by third parties, the value of our brand and other intangible assets may be diminished and competitors may be able to more effectively mimic our technology. If competitors were to mimic our technology, it may result in loss of sales and material litigation expenses. Such infringement of our patent protected rights is likely to cause us damage and lead to a reduction in the prices of our products, thereby reducing our anticipated profits.

The patent application and approval process is expensive and time-consuming. We may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. In addition, due to the extensive time needed to develop, test and obtain regulatory approval for our products, any patents that protect our products may expire early during commercialization. For example, our original United States patent and corresponding foreign patents, covering our PAT-based technology and certain embodiments thereof, expired during 2017. Since our products have undergone substantial development since then, we believe they should be protected by newer patents. However, we cannot be sure that these patents will be commercially useful in protecting our technology and, even if they are, our granted patents and any patents issued from our currently pending patent applications, should they issue without terminal disclaimers or other term shortening restrictions, are scheduled to expire between 2020 and 2037. This may reduce or eliminate any market advantages that such patents may give us. Following patent expiration, we may face increased competition through the entry of competing products into the market and a subsequent decline in market share and profits.

Changes in patent laws or patent jurisprudence could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

The Leahy-Smith America Invents Act, or AIA, which was passed in September 2011, resulted in significant changes to the United States patent system. An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned from a “first-to-invent” to a “first-to-file” system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. Under a “first-to-file” system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a patent on the invention regardless of whether another inventor had made the invention earlier. A third party that filed or files a patent application in the United States Patent and Trademark Office, or USPTO, after March 16, 2013 but before us could therefore be awarded a patent covering an invention of ours even if we made the invention before it was made by the third-party. This will require us to be cognizant going forward of the time from invention to filing of a patent application and be diligent in filing patent applications, but circumstances could prevent us from promptly filing patent applications on our inventions.

Among some of the other changes introduced by the AIA are changes that alter where a patentee may file a patent infringement suit and that provide opportunities for third parties to challenge any issued patent in the USPTO. This applies to all of our United States patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action.

Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third-party as a defendant in a district court action. It is not clear what, if any, impact the AIA will have on the operation of our business. However, the AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our or any licensors' patent applications and the enforcement or defense of our or any licensors' issued patents.

Additionally, the United States Supreme Court has ruled on several patent cases in recent years either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations, and there are other open questions under patent law that courts have yet to decisively address. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways and could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. In addition, the European patent system is relatively stringent in the type of amendments that are allowed during prosecution, and the complexity and uncertainty of European patent laws has also increased in recent years. Complying with these laws and regulations could limit our ability to obtain new patents in the future that may be important for our business.

Obtaining and maintaining our 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, European and other 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 and annuity fees on any issued patent are due to be paid to the USPTO, European and other patent agencies over the lifetime of the patent. While an unintentional failure to make payment of such fees or to comply with such provisions can in many cases be cured by additional payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance with such provisions will result in the abandonment or lapse of the patent or patent application, and the 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 failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents within prescribed time limits. If we or any licensors fail to maintain the patents and patent applications covering our product candidates or if we or any licensors otherwise allow our patents or patent applications to be abandoned or lapse, it can create opportunities for competitors to enter the market, which would hurt our competitive position and could impair our ability to successfully commercialize our product candidates in any indication for which they are approved.

It is possible that defects of form in the preparation, filing or prosecution of our patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope or requests for patent term adjustments. If we fail to establish, maintain or protect such patent rights and other intellectual property rights, such rights may be reduced or eliminated. If there are material defects in the form, preparation, prosecution or enforcement of our patents or patent applications, such patents may be invalid and/or unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

Foreign patent protection is particularly uncertain, and if we are involved in opposition proceedings in foreign countries, we may have to expend substantial sums and management resources.

Patent rights are territorial; thus, the patent protection we currently have will extend only to those countries in which we have issued patents. Even so, the laws of certain countries do not protect our intellectual property rights to the same extent as do the laws of the United States. For example, certain countries do not grant patent claims that are directed to the treatment of humans. Competitors may successfully challenge our patents, produce similar devices that circumvent and do not infringe our patents, or manufacture devices in countries where we have not applied for patent protection or that do not respect our patents. Furthermore, it is difficult to predict the scope of claims that will be allowed in pending applications and it is also difficult to predict which claims of granted patents, if any, will be deemed enforceable in a court of law. We may participate in opposition proceedings to determine the validity of our foreign patents or our competitors' foreign patents, which would result in substantial costs and diversion of our management's efforts, thus adversely affecting our results of operations.

If we are unable to protect the confidentiality of our trade secrets or know-how, such proprietary information may be used by others to compete against us.

In addition to filing patent applications, we protect our trade secrets, know-how and technology by entering into confidentiality or non-disclosure agreements with parties that have access to our proprietary information, such as our development or commercialization partners, employees, contractors and consultants. We also enter into agreements that purport to require the disclosure and assignment to us of the rights to the ideas, developments, discoveries and inventions of our employees, advisors, research collaborators, contractors and consultants while we employ or engage them. However, we cannot ensure that all such agreements have been duly executed. Moreover, these agreements can be difficult and costly to enforce or may not provide adequate remedies. Any of these parties may breach the confidentiality agreements and willfully or unintentionally disclose our confidential information, or our competitors might learn of the information in some other way. The disclosure to, or independent development by, a competitor of any trade secret, know-how or other technology not protected by a patent could materially adversely affect any competitive advantage we may have over any such competitor.

To the extent that any of our employees, advisors, research collaborators, contractors or consultants independently develop, or use independently developed, intellectual property in connection with any of our projects, disputes may arise as to the proprietary rights to this type of information. If a dispute arises with respect to any proprietary right, enforcement of our rights can be costly and unpredictable and a court may determine that the right belongs to a third party, which could materially adversely affect our business, results of operations and ability to capitalize on our proprietary information.

Legal proceedings or third-party claims of intellectual property infringement and other challenges may require us to spend substantial time and money and could prevent us from developing or commercializing our products.

The development, manufacture, use, sale, offer for sale or importation of our products may infringe third-party patents or other intellectual property rights. The nature of claims contained in unpublished patent applications around the world is unknown to us and it is not possible to know which countries patent applicants may choose for the extension of their filings under the Patent Cooperation Treaty, or other mechanisms. Our competitors may seek or may have already obtained patents that will limit, interfere with or eliminate our ability to make, use and sell our products. We may also be subject to claims based on the actions of employees and consultants with respect to the usage or disclosure of intellectual property learned at other employers. In addition, a third party may claim an ownership interest in one or more of our patents or other intellectual property rights. A third party could bring legal actions against us and seek monetary damages and/or to enjoin testing, manufacturing and marketing of the affected product or products. While we are presently unaware of any claims or assertions by third parties with respect to our patents or other intellectual property, we cannot guarantee that a third-party will not assert a claim or an interest in any such patents or intellectual property. The cost to us of any intellectual property litigation or other infringement proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively because of their greater financial resources. Uncertainties resulting from the initiation and continuation or defense of intellectual property litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Intellectual property litigation and other proceedings may also absorb significant financial resources and management time. Consequently, there is no assurance that we will be able to develop or commercialize a product in line with our business objectives, in the event of an infringement action. In the event of patent infringement claims, or to avoid potential claims, we may choose or be required to seek a license from a third party and would most likely be required to pay license fees or royalties, or both. These licenses may not be available on acceptable terms, or at all. Even if we were able to obtain a license, the rights may be non-exclusive, which could potentially limit our competitive advantage. Ultimately, we could be prevented from completing the development or commercialization of a product if, as a result of actual or threatened patent infringement or other claims, we are unable to enter into licenses on acceptable terms. This inability to enter into licenses could harm our business significantly. Further, the outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance, including the demeanor and credibility of witnesses and the identity of any adverse party. This is especially true in intellectual property cases that may turn on the testimony of experts as to technical facts upon which experts may reasonably disagree.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful.

Our ability to protect our products from unauthorized making, using, selling, offering to sell or importing by third parties or to protect against third parties purporting to offer their products based on the same or similar technology as our products is dependent on the extent to which we have rights under valid and enforceable patents that cover these activities and on the extent to which such third parties may circumvent such rights or present their products as non-infringing. To counter infringement, unauthorized use by our competitors or other third parties of our patents, trademarks, copyrights or other intellectual property, or the promotion of products as based on the same or similar technology as our products in order to gain marketing advantages based on the association with our technology, we may be required to file infringement or other claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. Any claims we assert against perceived infringers or other third parties could provoke these parties to assert counterclaims against us alleging, among other allegations, that we infringe their patents or other proprietary rights, in addition to counterclaims asserting that our patents or trademarks are invalid or unenforceable, or both. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of any patent is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention. An adverse outcome in a litigation or proceeding involving one or more of our patents could limit our ability to assert those patents against those parties or other competitors, and may curtail or preclude our ability to exclude third parties from making or selling similar or competitive products. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are unenforceable, that the alleged infringing mark does not infringe our trademark rights or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this last instance, we could ultimately be forced to cease use of such trademarks.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy for the loss and damages which may be associated with such infringement, including damage to our brand name and loss of sales to infringing competitors. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If security analysts or investors perceive these results to be negative, it could adversely affect the price of our ordinary shares and the ADSs. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, nor to defend against counterclaims that may be filed against us, both of which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary costs of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

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.

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 may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our unregistered trademarks or trade names. Over the long term, if we are unable to successfully register our trademarks and trade names and establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely impact our financial condition or results of operations.

We may become subject to claims for remuneration or royalties for assigned 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 in the course of their employment for us. Under the Israeli Patent Law, 1967, or the Patent Law, inventions conceived by an employee in the course and as a result of or arising from his or her employment with a company 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 regarding consideration for service inventions, the Israeli Compensation and Royalties Committee, or the Committee, a body constituted under the Patent Law, shall determine whether the employee is entitled to remuneration for his inventions and the scope and conditions for such remuneration. Prior decisions by the Committee created uncertainty, as it was held that employees may be entitled to remuneration for their service inventions despite having waived any such rights. We generally enter into assignment-of-invention agreements with our employees pursuant to which such individuals assign to us all rights to any inventions created in the scope of their employment or engagement with us, without further compensation. Although our employees have agreed to assign to us service invention rights and have specifically waived their right to receive any special remuneration for such assignment beyond their regular salary and benefits, as a result of the uncertainty under Israeli law with respect to the efficacy of waivers of service invention rights, we may face claims demanding remuneration in consideration for assigned inventions. If such claims are successful, we may be required to pay remuneration to our current and/or former employees which could negatively affect our results of operations.

Risks Related to Our Industry

Our ability to market and sell products depends upon receipt of domestic and foreign regulatory clearances or approvals of our products and, as required, manufacturing facilities and operations. We and our products are also subject to extensive government regulation and oversight both in the United States and abroad even after regulatory approvals and clearances are obtained. Our failure to timely obtain or maintain regulatory clearances and approvals and to maintain compliance with regulatory requirements could negatively affect our business.

Our products are regulated as medical devices. Accordingly, our products and operations are subject to extensive regulation by governmental authorities such as the FDA in the United States, the European Union National Competent Authorities of the Member States of the European Economic Area, or EEA, and numerous other national or state governmental authorities in the countries in which we manufacture and sell our products. These regulations govern, among other things, the research, testing, manufacturing, safety, clinical efficacy, effectiveness and performance, product standards, packaging requirements, labeling requirements, import/export restrictions, storage, recordkeeping, promotion, distribution, production, post-marketing surveillance and handling of complaints, tariffs, duties and tax requirements. Our products and operations are also often subject to the rules or norms of industrial standards bodies, such as the International Standards Organization, or ISO, or the rules of associations of healthcare professionals.

In the United States, our products are medical devices subject to regulation by the FDA pursuant to its authority under the federal Food, Drug and Cosmetic Act, or FDCA, and its implementing regulations. In addition, future products, or components thereof, may also be subject to other regulatory requirements, including regulation by the Federal Communications Commission, or the FCC. Many of the laws and regulations applicable to our products in other countries, such as the EU Medical Devices Regulation, or MDR, are generally comparable to those of the FDCA in their aim to ensure safety and effectiveness of medical devices, but the applicable standards and proceedings are not globally harmonized. 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. The FDA and other regulators enforce these regulatory requirements through, among other means, periodic unannounced inspections. There appears to be a trend toward more stringent regulatory oversight throughout the world. We do not anticipate this trend to diminish in the near future. Due to the movement towards harmonization of standards in the European Union, we expect a changing regulatory environment in Europe characterized by a shift from a country-by-country regulatory system to a European Union-wide harmonized regulatory system, while such harmonized regulatory system would not necessarily preclude state specific requirements with which we may have to comply. We cannot predict the timing of this harmonization and its effect on us. The changing regulatory environment may have a material impact on existing device marketing authorizations as well as future device registration applications, requirements and timing, which may, in turn, have material impacts upon our ability to continue or begin to market existing and new devices. Our failure to obtain or maintain regulatory clearances and approvals and to ensure compliance with regulatory requirements could negatively affect our business.

Modifications to our currently FDA-cleared products or the introduction of new products may require new regulatory clearances or approvals or require us to recall or cease marketing of our current products until clearances or approvals are obtained. Our products are regulated as medical devices.

In general, unless an exemption applies, each medical device, or new use of or significant modification to an existing medical device, intended to be marketed in the United States must first receive one of the following types of FDA premarket review authorizations:

- clearance via Section 510(k) of the FDCA, or 510(k); or

- approval of a premarket approval application, or PMA.

All of our medical device products (excluding one 510(k)-exempt product) have received a 510(k) clearance. In the 510(k) clearance process, before a device may be marketed the FDA must determine if it 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) or a device that was originally on the United States market pursuant to an approved premarket approval and later down-classified. 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.

The PMA process is much more costly, lengthy and uncertain than the 510(k) process, and generally must be supported by extensive data from clinical trials. In the PMA process, the FDA must determine that the proposed device is safe and effective for its intended use based, in part, on extensive data, including, but not limited to, technical, pre-clinical, clinical and manufacturing 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. We have not received PMA approval for any of our devices, as they are all subject to either the 510(k) process or are exempt from the requirements of 510(k) clearance. The FDA may not grant future 510(k) clearances or any PMAs for any future product or product modification we propose to market. Further, any modification to a 510(k)-cleared device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design or manufacture, requires a new 510(k) clearance or, possibly, approval of a PMA. The FDA requires every manufacturer to make this determination in the first instance, but the FDA may review any manufacturer’s decision and may disagree with that manufacturer’s conclusion as to whether a 510(k) or PMA was required for the change. We have made modifications to our 510(k)-cleared 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. If the FDA requires us to seek 510(k) clearance or premarket approval of a PMA for modifications to a previously cleared product for which we have concluded that new clearances or approvals are not required, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval, and we may be subject to significant regulatory fines or penalties. Further, our products could be subject to recall if we determine that our products have a defect or do not comply with applicable regulatory authorities’ requirements or if the FDA determines, for any reason, that our products are not safe or effective.

The application process to receive clearances or approvals of our products by the pertinent regulatory authorities is costly and generally lasts between approximately three to 24 months. Delays in receipt of, or failure to receive, clearances or approvals, the loss of previously received clearances or approvals, or the failure to comply with existing or future regulatory requirements could adversely impact our operating results.

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

- our inability to demonstrate to the satisfaction of the FDA or the applicable regulatory entity or notified body that our products are safe or effective for their intended uses;
- the disagreement of the FDA or the applicable foreign regulatory body with the design or implementation of our clinical trials or the interpretation of data from pre-clinical studies or clinical trials;
- serious and unexpected adverse effects experienced by participants in our clinical trials;
- the data from our pre-clinical studies and clinical trials may be insufficient to support clearance or approval, where required;
- our inability to demonstrate that the clinical and other benefits of the device outweigh the risks;
- the manufacturing process or facilities we use may not meet applicable requirements; and
- the potential for clearance or approval policies or regulations of the FDA or applicable foreign regulatory bodies to change significantly in a manner rendering our clinical data or regulatory filings insufficient for clearance or approval.

If the FDA or a foreign regulatory authority finds that we have failed to comply with these requirements, such authority may institute a wide variety of enforcement actions, ranging from a public warning letter to more severe sanctions such as:

- fines, injunctions and civil penalties;
- recall or seizure of our products;
- issuance of public notices or warnings;
- imposition of operating restrictions, partial suspension, or total shutdown of production;
- refusal of our requests for Section 510(k) clearance or premarket approval of new products;
- withdrawal of Section 510(k) clearance or premarket approvals already granted; or
- criminal prosecution.

Countries outside of the United States regulate medical devices in a manner similar to that of the FDA. The marketing and distribution of our products in the European Union, for example, is subject to the European Union's Medical Device Directive described above. Devices that comply with the requirements of the Medical Devices Directive are entitled to bear the CE conformity mark, or the CE Mark, indicating that the device meets minimum standards of performance, safety and quality (i.e., the essential requirements) and, accordingly, can be commercially distributed throughout the EEA, Turkey and other countries outside Europe that have accepted the CE marking as a certification of efficiency and safety of medical devices. In Japan, we must comply with Japan's Pharmaceuticals and Medical Devices Act, or the PMD Act, and are subject to the Pharmaceutical Medical Devices Authority, or the PMDA, the regulatory body supervising and regulating the marketing and sale of medical devices such as our products. We currently hold PMDA authorizations to market and sell our WatchPAT200 Unified and EndoPAT 2000 in Japan. Such authorizations are held by an in-country representative, also known as MAH/ D-MAH, with whom we maintain a contractual engagement.

Even though we have received FDA clearance, CE Mark certification, PMDA authorizations and other marketing authorizations or regulatory approvals for our products, there can be no assurance that we will be able to continue to comply with the required annual compliance and auditing requirements or other international regulatory requirements that may be applicable. Adverse events, manufacturing faults or failures to comply with regulatory requirements may result in voluntary actions as well as actions imposed by regulators, such as voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any medical device we manufacture or distribute, fines, suspension of regulatory clearances or approvals, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects. In addition, there can be no assurance that government regulations applicable to our products or the interpretation of those regulations will not change or that we will be able to obtain required regulatory clearances and approvals for our new products. The extent of potentially adverse government regulation that might arise from future legislation or administrative action and the impact on our business and results of operations cannot be predicted.

Failure to comply with post-marketing regulatory requirements could subject us to enforcement actions, including substantial penalties, and might require us to recall or withdraw a product from the market.

We are subject to ongoing and pervasive regulatory requirements governing, among other things, the manufacture, marketing, advertising, medical device reporting, sale, promotion, import, export, registration and listing of devices. Even after we have obtained the proper regulatory clearance or approval to market a device, we have ongoing responsibilities under FDA regulations and applicable foreign laws and regulations. The FDA, state and foreign regulatory authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA, state or foreign regulatory authorities, which may include any of the following:

- untitled letters or warning letters;
- fines, injunctions, consent decrees and civil penalties;
- recalls, termination of distribution, administrative detention or seizure of our products;
- customer notifications or repair, replacement or refunds;
- operating restrictions or partial suspension or total shutdown of production;
- delays in or refusal to grant our requests for future clearances or approvals or foreign regulatory approvals of new products, new intended uses or modifications to existing products;
- withdrawals or suspensions of our current 510(k) clearances, resulting in prohibitions on sales of our products;
- FDA refusal to issue certificates to foreign governments needed to export products for sale in other countries; and
- criminal prosecution.

Any of these actions could result in higher than anticipated costs or lower than anticipated sales and have a material adverse effect on our reputation, business, financial condition and results of operations.

In addition, regulators may determine 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. Principal investigators for our clinical trials may serve as speakers or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or other regulatory authority. The FDA or other regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or other regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in clearance or approval, or rejection, of our marketing applications by the FDA or other regulatory authority, as the case may be, and may ultimately lead to the denial of marketing clearance or approval of one or more of our product candidates.

In addition, the FDA or other regulatory authority may change its clearance or approval policies, adopt additional regulations or revise existing regulations, or take other actions, which may prevent or delay clearance or approval of our future products under development or impact our ability to modify our currently cleared products on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain new clearances or approvals, increase the costs of compliance or restrict our ability to maintain our clearances of our current products.

Our products must be manufactured in accordance with federal and state regulations, and we or any of our suppliers or third-party manufacturers could be forced to recall products or terminate production if we fail to comply with these regulations.

The methods used in, and the facilities used for, the manufacture of our products must comply with the FDA's Quality System Regulation, or QSR, which is a complex regulatory scheme that covers the procedures and documentation of the design, testing, production, process controls, quality assurance, labeling, packaging, handling, storage, distribution, installation, servicing and shipping of medical devices (also referred to as cGMPs). Furthermore, we are required to verify that our suppliers maintain facilities, procedures and operations that comply with our quality standards and applicable regulatory requirements. The FDA enforces the QSR through periodic announced or unannounced inspections of medical device manufacturing facilities, which may include the facilities of subcontractors. Our products are also subject to similar state regulations and various laws and regulations of foreign countries governing manufacturing.

Our third-party manufacturers may not take the necessary steps to comply with applicable regulations, which could cause delays in the delivery of our products. In addition, failure to comply with applicable FDA requirements or later discovery of previously unknown problems with our products or manufacturing processes could result in, among other things, warning letters or untitled letters, fines, injunctions or civil penalties, suspension or withdrawal of clearances or approvals, seizures or recalls of our products, total or partial suspension of production or distribution, administrative or judicially imposed sanctions, the FDA's refusal to grant pending or future clearances or approvals for our products, clinical holds, refusal to permit the import or export of our products and criminal prosecution of us or our employees.

Any of these actions could significantly and negatively affect supply of our products. If any of these events occurs, our reputation could be harmed, we could be exposed to product liability claims and we could lose customers and experience reduced sales and increased costs.

Legislative or regulatory reforms may make it more difficult and costly for us to obtain regulatory clearances or approvals for our products or to manufacture, market or distribute our products after clearance or approval is obtained.

From time to time, legislation is drafted and introduced in various countries that could significantly change the statutory provisions governing the regulation of medical devices. In the U.S., the FDA may change its clearance and approval policies, adopt additional regulations or amend existing regulations, or take other actions, which may prevent or delay clearance or approval of our future products under development or impact our ability to modify our currently cleared products on a timely basis. For example, in November 2018, FDA officials announced forthcoming steps that the FDA intends to take to modernize the premarket notification pathway under Section 510(k) of the Federal Food, Drug, and Cosmetic Act. Among other things, the FDA announced that it plans to develop proposals to drive manufacturers utilizing the 510(k) pathway toward the use of newer predicates. These proposals include plans to potentially sunset certain older devices that were used as predicates under the 510(k) clearance pathway, and to potentially publish a list of devices that have been cleared on the basis of demonstrated substantial equivalence to predicate devices that are more than 10 years old. In May 2019, the FDA solicited public feedback on these proposals. These proposals have not yet been finalized or adopted, and the FDA may work with

Congress to implement such proposals through legislation. Accordingly, it is unclear the extent to which any proposals, if adopted, could impose additional regulatory requirements on us that could delay our ability to obtain new 510(k) clearances, increase the costs of compliance, restrict our ability to maintain our current clearances or otherwise create competition that may negatively affect our business.

More recently, in September 2019, the FDA finalized guidance describing an optional "safety and performance based" premarket review pathway for manufacturers of "certain, well-understood device types" to demonstrate substantial equivalence under the 510(k) clearance pathway by showing that such device meets objective safety and performance criteria established by the FDA, thereby obviating the need for manufacturers to compare the safety and performance of their medical devices to specific predicate devices in the clearance process. The FDA intends to develop and maintain a list device types appropriate for the "safety and performance based" pathway and will continue to develop product-specific guidance documents that identify the performance criteria for each such device type, as well as the testing methods recommended in the guidance documents, where feasible. The FDA may establish performance criteria for classes of devices for which we or our competitors seek or currently have received clearance, and it is unclear the extent to which such performance standards, if established, could impact our ability to obtain new 510(k) clearances or otherwise create competition that may negatively affect our business.

In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new statutes, regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of any future products or make it more difficult to obtain clearance or approval for, manufacture, market or distribute our products. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require: additional testing prior to obtaining clearance or approval; changes to manufacturing methods; recall, replacement or discontinuance of our products; or additional record keeping. The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory clearance or approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States 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 a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine oversight activities such as implementing statutes through rulemaking, issuing guidance, and reviewing and issuing marketing authorizations. It is difficult to predict how these executive actions will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose restrictions on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. 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 lose any marketing clearances or approvals that we may have obtained and we may not achieve or sustain profitability.

On April 5, 2017, the European Parliament passed the Medical Devices Regulation (Regulation 2017/745), which repeals and replaces the EU Medical Devices Directive and the Active Implantable 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 ensure a high level of safety and health while supporting innovation.

The Medical Devices Regulation will, however, only become applicable three years after publication (in 2020). 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 the 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 effect on the way we conduct our business in the EEA.

There is also no assurance that legislative or regulatory reforms which may make it more difficult and costly for us to obtain regulatory clearances or approvals for our products or to manufacture, market or distribute our products, will not be introduced in Japan or in other countries where we may wish to commercialize our products.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new products and services from being developed, cleared, approved or commercialized in a timely manner, which could negatively impact our business.

The ability of the FDA to review and clear or approve new products can be affected by a variety of factors, including government budget and funding levels; statutory, regulatory and policy changes; ability to hire and retain key personnel and accept the payment of user fees; and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new devices to be reviewed and/or cleared or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the United States government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the global pandemic of novel coronavirus, on March 10, 2020 the FDA announced its intention to postpone most inspections of manufacturing facilities and products through April 2020, and regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the coronavirus pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

We expect the healthcare industry to face increased limitations on coverage and reimbursement by third-party payors as a result of healthcare reform, which could adversely how much or under what circumstances healthcare providers will order or administer tests using our products.

In both the United States and other countries, sales of our products will depend in part upon the availability of coverage and reimbursement from third-party payors, which include governmental authorities, managed care organizations and other private health insurers. Third-party payors are increasingly challenging the price and examining the cost effectiveness of medical products and services. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

Increasing expenditures for healthcare have been the subject of considerable public attention in the United States. Both private and government entities are seeking ways to reduce or contain healthcare costs. Numerous proposals that would effect changes in the United States healthcare system have been introduced or proposed in Congress and in some state legislatures, including reducing reimbursement for prescription products.

In the U.S., the ACA was signed into law and designed to reform the American healthcare system. Among other things, the ACA:

- established a 2.3% excise tax on sales of medical devices with respect to any entity that manufactures or imports specified medical devices offered for sale in the United States, which, through a series of legislative amendments, was suspended, effective January 1, 2016, and subsequently repealed altogether on December 20, 2019;

- established a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research;

- implemented payment system reforms, including a national pilot program to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain health care services through bundled payment models; and

- created an independent payment advisory board that will submit recommendations to reduce Medicare spending if projected Medicare spending exceeds a specified growth rate.

There have been a number of significant changes to the ACA and its implementation. By way of example, the Tax Cuts and Jobs Act of 2017, or Tax Act, effective January 1, 2019, included a provision repealing the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate.” On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, or the Texas District Court Judge, ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. On December 18, 2019, the Fifth Circuit Court of Appeals also struck down the individual mandate and remanded to the Northern District of Texas the decision as to whether the remainder of the ACA is valid. It is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA and our business. Litigation and legislation over the ACA are likely to continue with unpredictable and uncertain results. We will continue to evaluate the effect that the ACA and its possible repeal and replacement has on our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, reduced Medicare payments to providers by 2% per fiscal year, effective on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2029 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. The Medicare Access and CHIP Reauthorization Act of 2015, or MACRA, enacted on April 16, 2015, repealed the formula by which Medicare made annual payment adjustments to physicians and implemented fixed annual updates and a new system of incentive payments that began in 2019 that are based on various performance measures and physicians’ participation in alternative payment models such as accountable care organizations. It is unclear what effect new quality and payment programs, such as MACRA, may have on our business, financial condition, results of operations or cash flows.

In response to perceived increases in healthcare costs in recent years, there have been and continue to be proposals by the presidential administrations, members of Congress, state governments, regulators and third-party payors to control these costs and, more generally, to reform the United States healthcare system, including by repealing or replacing the ACA. Other elements of health care reform such as comparative effectiveness research, an independent payment advisory board, payment system reforms including shared savings pilots and other provisions could meaningfully change the way healthcare is developed and delivered, and may materially adversely impact numerous aspects of our business, results of operations and financial condition.

We expect additional state and federal healthcare policies and reform measures to be adopted in the future, any of which could limit reimbursement for healthcare products and services or otherwise result in reduced demand for our products or other products we may commercialize in the future or additional pricing pressure and have a material adverse effect on our industry generally and on our customers. Any changes of, or uncertainty with respect to, future coverage or reimbursement rates could affect demand for our products or other products we may commercialize in the future, which in turn could impact our ability to successfully commercialize our products or other products we may commercialize in the future and could have a material adverse effect on our business, financial condition and results of operations.

We are subject to United States and foreign fraud and abuse laws and regulations. Our failure to comply with these laws and regulations could have adverse consequences.

We are subject to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act, which may constrain the business or financial arrangements and relationships through which we sell, market and distribute our products. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry (e.g., healthcare providers, physicians and third-party payors), are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. These laws impact, among other things, our sales, marketing, support and education programs and constrain our business and financial arrangements and relationships with third-party payors, physicians and other customers, and marketing partners, and include, but are not limited to, the following:

- the United States federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order, or arranging for or recommending the purchase, lease or order of, any item or service, for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Violations of the federal Anti-Kickback Statute may result in civil monetary penalties, plus up to three times the remuneration involved. Violations of the Federal Anti-Kickback Statute can also result in criminal penalties, including criminal fines and imprisonment. In addition, violations can result in exclusion from participation in government healthcare programs, including Medicare and Medicaid. In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution;

- the United States federal false claims laws, including the civil False Claims Act (which can be enforced through "qui tam," or whistleblower actions, by private citizens on behalf of the federal government), which prohibits any person from, among other things, knowingly presenting, or causing to be presented false or fraudulent claims for payment of government funds or knowingly making, using or causing to be made or used, a false record or statement material to an obligation to pay money to the government or knowingly and improperly avoiding, decreasing or concealing an obligation to pay money to the United States federal government. Manufacturers can be held liable under the False Claims Act even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. DME companies that submit claims directly to payors may be liable under the False Claims Act for the direct submission of such claims. When an entity is determined to have violated the federal civil False Claims Act, the government may impose civil fines and penalties ranging from for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;

- HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for healthcare benefits, items or services by a healthcare benefit program, which includes both government and privately funded benefits programs. Similar to the United States federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the Physician Payments Sunshine Act, created under the ACA, implemented as the Open Payments program, and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to the CMS information related to certain payments made in the preceding calendar year and other transfers of value to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made to certain non-physician providers such as physician assistants and nurse practitioners. Violations of the Physician Payments Sunshine Act may result in annual civil penalties of up to $1,150,000, adjusted annually, for payments omitted from each annual report;

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm customers; and

- analogous state and foreign laws and regulations, including state anti-kickback and false claims laws, that may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require medical device companies to comply with the medical device industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the United States federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and state laws and regulations that require drug and device manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; state and local laws that require the licensure of sales representatives; and state laws related to insurance fraud in the case of claims involving private insurers.

The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance or reporting requirements in multiple jurisdictions increase the possibility that a healthcare or medical device company may fail to comply fully with one or more of these requirements. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities may conclude that our business practices, including, without limitation, our Cost per Test sales model, the TSS model, the DTC segment model, rebates, competitive trade-in programs and other sales and marketing practices, or co-marketing arrangements, do not comply with applicable fraud and abuse or other healthcare laws and regulations or guidance. Further, despite our efforts, we have not timely reported certain of our payments to covered recipients under the Physician Payments Sunshine Act and similar state laws. We therefore may be subject to the civil penalties described above.

To enforce compliance with healthcare regulatory laws, certain enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Responding to investigations can be time- and resource-consuming and can divert management's attention from the business. Additionally, as a result of these investigations, healthcare providers and entities may also have to agree to additional compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlements could increase our costs or otherwise have an adverse effect on our business. Even an unsuccessful challenge or investigation into our practices could cause adverse publicity and be costly to respond to.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities, could, despite efforts to comply, be subject to challenge under one or more of such laws. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and our ability to contract with government entities, including the Department of Veteran Affairs, additional oversight and reporting requirements if we become subject to a corporate integrity agreement to resolve allegations of non-compliance with these laws and the curtailment or restructuring of our operations. If any of the physicians or other providers, marketing partners or other entities with whom we expect to do business is found not to be in compliance with applicable laws, they may be subject to the same criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Privacy regulations may impose costs and liabilities on us, limit our use of information, and adversely affect our business.

Our products generate medical information about patients and certain of our services are provided by way of a cloud service. Privacy of personal information has become a significant issue in the United States, Europe, Israel and many other countries where we operate. There are numerous federal, state and international laws and regulations regarding privacy, data protection, information security, and the collection, storing, sharing, use, processing, transfer, disclosure and protection of personal information and other data, and the scope of such laws and regulations may change, be subject to differing interpretations and be inconsistent among countries and regions we intend to operate in (e.g., the United States, the European Union and Israel), or conflict with other laws and regulations. The regulatory framework for privacy and data protection worldwide is, and is likely to remain for the foreseeable future, uncertain and complex, and this or other actual or alleged obligations may be interpreted and applied in a manner that we may not anticipate or that is inconsistent from one jurisdiction to another and may conflict with other rules or practices including ours. Further, any significant change to applicable laws, regulations, or industry practices regarding the collection, use, retention, security, or disclosure of data, or their interpretation, or any changes regarding the manner in which the consent of relevant users for the collection, use, retention or disclosure of such data must be obtained, could increase our costs and require us to modify our services and candidate products, possibly in a material manner, which we may be unable to complete, and may limit our ability to store and process patients' data or develop new services and features.

In the United States, we are subject to data protection laws (i.e., laws and regulations that address data privacy and security) at both the federal and state levels. The legislative and regulatory landscape for data protection continues to evolve, and in recent years there has been an increasing focus on privacy and data security issues. Numerous federal and state laws, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws, govern the collection, use and disclosure of health-related and other personal information. Failure to comply with such laws and regulations could result in government enforcement actions and create liability for us (including the imposition of significant civil or criminal penalties), private litigation and/or adverse publicity that could negatively affect our business. For instance, California enacted the California Consumer Privacy Act, or CCPA, on June 28, 2018, which took effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal data. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability, and many similar laws have been proposed at the federal level and in other states. State laws governing the privacy and security of health information, many of which differ from each other in significant ways and may not have the same effect, may complicate our compliance efforts.

We are subject to the privacy and security rules established under HIPAA, which establish national standards to protect individually identifiable health information by health plans, health care clearinghouses and certain health care providers, referred to as "covered entities," and their respective business associates, individuals or entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HIPAA also provides patients with certain rights over their health information, including rights to examine and obtain a copy of their health records, and to request corrections. HIPAA requires covered entities and business associates to develop and maintain policies and procedures with respect to protected health information that is used or disclosed, including the adoption of administrative, physical and technical safeguards to protect such information. The Health Information Technology for Economic and Clinical Health Act, or HITECH, expands the notification requirement for breaches of patient-identifiable health information, restricts certain disclosures and sales of patient-identifiable health information and provides for civil monetary penalties for HIPAA violations. HITECH also increased the civil and criminal penalties that may be imposed against covered entities and business associates and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and its implementing regulations and seek attorneys' fees and costs associated with pursuing federal civil actions. Additionally, certain states have adopted comparable privacy and security laws and regulations, some of which may be more stringent than HIPAA.

Internationally, many jurisdictions have or are considering enacting privacy or data protection laws or regulations relating to the collection, use, storage, transfer, disclosure and/or other processing of personal data, as well as certification requirements for the hosting of health data specifically. Such laws and regulations may include data hosting, data residency or data localization requirements (which generally require that certain types of data collected within a certain country be stored and processed within that country), data export restrictions, international transfer laws (which prohibit or impose conditions upon the transfer of such data from one country to another), or may require companies to implement privacy or data protection and security policies, enable users to access, correct and delete personal data stored or maintained by such companies, inform individuals of security breaches that affect their personal data or obtain individuals' consent to use their personal data. For example, the GDPR became effective on May 25, 2018, and European legislators are now in the process of finalizing the ePrivacy Regulation to replace the European ePrivacy Directive (Directive 2002/58/EC as amended by Directive 2009/136/EC). The GDPR, supplemented by national laws and further implemented through binding guidance from the European Data Protection Board, imposes more stringent European Union data protection requirements and provides for significant penalties for noncompliance. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. Additionally, following the United Kingdom's withdrawal from the European Union, we will have to comply with the GDPR and the United Kingdom GDPR, each regime having the ability to fine up to the greater of €20 million/ £17.5 million or 4% of global turnover. The relationship between the United Kingdom and the European Union in relation to certain aspects of data protection law remains unclear, for example around how data can lawfully be transferred between each jurisdiction, which exposes us to further compliance risk.

Changes to laws or regulations affecting privacy in the United States and in other jurisdictions in which we operate could impose additional costs and liability on us and could limit our use of such information to add value to our customers. If we were required to change our business activities or revise or eliminate services, or to implement burdensome compliance measures, we may face additional expenditures. In addition, we may be subject to fines, penalties and potential litigation if we fail to comply with applicable privacy regulations. Regulatory burdens of this sort increase our costs and harm our financial results.

We are subject to various laws relating to trade, export controls and foreign corrupt practices, the violation of which could adversely affect our reputation, operations, business, prospects, operating results and financial condition.

We must comply with all applicable international trade, export and import laws and regulations of the United States and other countries, and we are subject to export controls and economic sanctions laws and embargoes imposed by the United States Government. Changes in trade sanctions laws may restrict our business practices, including cessation of business activities in sanctioned countries or with sanctioned entities, and may result in modifications to compliance programs. Among others, we are subject to the Foreign Corrupt Practices Act, or FCPA, and other anti-bribery and anti-corruption laws that generally prohibit the offering, promising, giving or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls.

Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. We have implemented safeguards and policies to discourage prohibited practices by our employees and agents that would violate applicable anti-bribery and anti-corruption laws. However, we cannot ensure that our compliance controls, policies and procedures will in every instance protect us from acts committed by our employees, agents, contractors or collaborators that may violate the laws or regulations of the jurisdictions in which we operate.

Violations of these laws and regulations could result in significant fines, criminal sanctions against us, our officers, or our employees, requirements to obtain export licenses, disgorgement of profits, cessation of business activities in sanctioned countries, implementation of compliance programs, exclusion from government programs, prohibitions on the conduct of our business and our inability to market and sell our products in one or more countries. Additionally, any such violations could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees and our business, prospects, operating results and financial condition.

If we do not comply with laws regulating the protection of the environment and health and human safety, our business could be adversely affected.

Our research and development and manufacturing involve the use of hazardous materials and chemicals and related equipment. If an adverse safety incident occurs, we could be held liable for resulting damages, which could be substantial. We are also subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures and the handling of biohazardous materials. We are also subject to domestic and foreign waste treatment laws and regulations which may be applicable to waste produced in our manufacturing processes, as well as in the discarding of our disposable single use WatchPAT ONE and probes. Insurance may not provide adequate coverage against these potential liabilities and we do not maintain insurance for environmental liability claims that may be asserted against us. Moreover, additional foreign and local laws and regulations affecting our operations may be adopted in the future. We may incur substantial costs to comply with such regulations and pay substantial fines or penalties if we violate any of these laws or regulations.

With respect to environmental, safety and health laws and regulations, we cannot accurately predict the outcome or timing of future expenditures that we may be required to make in order to comply with such laws as they apply to our operations and facilities. We are also subject to potential liability for the remediation of contamination associated with both present and past hazardous waste generation, handling, and disposal activities. We will be periodically subject to environmental compliance reviews by environmental, safety and health regulatory agencies. Environmental laws are subject to change and we may become subject to stricter environmental standards in the future and face larger capital expenditures in order to comply with environmental laws which could have a material adverse effect on our business.

Risks Related to Our Ordinary Shares and ADSs

Prior to the listing of ADSs on Nasdaq there had been no prior public market in the United States for our ordinary shares or ADSs, and an active trading market in the United States may not develop.

We listed ADSs on the Nasdaq Capital Market in February 2019. Prior to such listing, there was no public market in the United States for ADSs. An active trading market in the United States may not develop following the aforementioned listing or, if developed, may not be sustained. The lack of an active market may impair the ability of ADS holders to sell their ADSs at the time they wish to sell them or at a price that they would consider reasonable. The lack of an active market may also reduce the fair market value of such ADSs. An inactive market may also impair our ability to raise capital by selling shares of capital stock and may impair our ability to acquire other companies by using our shares as consideration.

Our ordinary shares and ADSs are traded on different markets and this may result in price variations.

Our ordinary shares have been traded on the TASE, since March 2007. We also listed ADSs on the Nasdaq Capital Market in February 2019. Price variations may result due to this dual listing. Trading in ordinary shares and ADSs on these markets is in different currencies, U.S. dollars on the Nasdaq Capital Market and NIS on the TASE and at different times (resulting from different time zones, different trading days and different public holidays in the United States and Israel). Given these and other factors, such as differences in exchange rates, ordinary shares and ADSs may trade at different prices on the TASE and the Nasdaq Capital Market. In addition, market influences in one market may influence the price in the other.

The price of our ordinary shares and ADSs may be volatile and could be substantially affected by various factors.

The market prices of our ordinary shares and ADSs have been, and may in the future be, highly volatile and fluctuate substantially. For example, since the listing of our ADSs on Nasdaq in February 2019, the market price of our ADSs on the Nasdaq Capital Market varied between a high price of $18.33 and a low price of $7.66. Numerous factors, many of which are beyond our control, may cause our market price and trade volume to fluctuate and decrease in the future, including the following factors:

- actual or anticipated fluctuations in our results of operations;
- changes in expectations as to our future financial performance and cash position, including financial estimates by securities analysts and investors;
- announcements of technological innovations, medical findings or new products by us or our competitors;
- announcements by us or our competitors of significant business developments, changes in distributor relationships, strategic partnerships, joint ventures, capital commitments, acquisitions or expansion plans;
- changes in the prices of our raw materials or the products we sell;
- changes in the status of our intellectual property rights;
- our involvement in significant claims or proceedings;
- our sales of ordinary shares and ADSs or other securities in the future;
- market conditions in our industry;
- changes in key personnel;

- the trading volume of our ordinary shares and ADSs;
- changes in the estimation of the future size and growth rate of our markets;
- general economic and market conditions; and
- any of the events underlying any of the other risks or uncertainties set forth elsewhere in this Annual Report actually occurs.

In addition, the stock markets have experienced extreme price and volume fluctuations. Broad market and industry factors may materially harm the market price of our ordinary shares and ADSs, regardless of our operating performance. In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been instituted against that company. If we were involved in any similar litigation, we could incur substantial costs and our management's attention and resources could be diverted.

Low trading volume may also increase the price volatility of our ordinary shares and ADSs. A thin trading market could cause the price of our ordinary shares and ADSs to fluctuate significantly more than the stock market as a whole. In addition, domestic and international stock markets and electronic trading platforms often experience extreme price and volume fluctuations. Market fluctuations, as well as general political and economic conditions, such as a recession or interest rate or currency rate fluctuations or political events or hostilities in or surrounding Israel or other countries in which we operate, could also adversely affect the price of our ordinary shares and ADSs.

Holders of ADSs are not treated as shareholders of our Company.

Holders of ADSs are not treated as shareholders of our Company unless they withdraw the ordinary shares underlying the ADSs from the depositary, which holds the ordinary shares underlying the ADSs. Holders of ADSs therefore do not have any rights as shareholders of our Company, other than the rights that they have pursuant to the deposit agreement with the depositary. For example, under the deposit agreement, if a holder of ADSs does not provide the depositary with voting instructions for an agenda item in our shareholders meeting in a timely manner, we may instruct the depositary, if we reasonably do not know of any substantial opposition to such agenda item and the matter is not materially adverse to the interests of shareholders, to treat the holder as giving a discretionary proxy to a person designated by us as to that matter.

Our directors and executive officers own a substantial percentage of our ordinary shares.

As of March 15, 2020, our directors and executive officers beneficially own approximately 12.1% of our outstanding ordinary shares (or, when taken together with the holdings of Viola Growth II A.V. LP, Viola Growth II (A) L.P. and Viola Growth II (B) L.P., or, collectively, Viola, and MS Pace LP, which are affiliated with certain of these directors, approximately 38.8% of our outstanding ordinary shares). As a result, if these shareholders acted together, they could exert significant influence on the election of our directors and on decisions by our shareholders on matters submitted to a shareholder vote, including mergers, consolidations and the sale of all or substantially all of our assets. This concentration of ownership of our ordinary shares could delay or prevent proxy contests, mergers, tender offers or other purchases of our ordinary shares and ADSs that might otherwise give our shareholders and ADS holders the opportunity to realize a premium over the then-prevailing market price for our securities and, as a result, may also adversely affect the price of our ordinary shares and ADSs.

In addition, in connection with the public offering we completed in February 2020, certain of our shareholders and ADS holders, directors and executive officers, who beneficially own, in the aggregate, approximately 38.8% of our outstanding ordinary shares, have agreed not to sell any of our ordinary shares or ADSs without the prior written consent of the representatives of the underwriters until July 29, 2020. The representatives of the underwriters may, however, in their sole discretion and without notice, release all or any portion of these securities from the restrictions in the lock-up agreements. After these agreements expire, these securities will be eligible for sale in the public market and if these shareholders or holders of our options or RSUs sell substantial amounts of our ordinary shares or ADSs, the market price of our ordinary shares and ADSs may be adversely affected. Any substantial sales of our ordinary shares or ADSs in the public market might also make it more difficult for us to sell equity or equity-related securities in the future at a time and on terms we deem appropriate. Even if there are not a substantial number of sales, the mere existence of this "market overhang" could have a negative impact on the market for, and the market price of, our ordinary shares and ADSs.

If equity research analysts do not publish research or reports about our business or if they issue unfavorable commentary or downgrade our ordinary shares and ADSs, the price of our ordinary shares and ADSs could decline.

The trading market for our ordinary shares and ADSs will rely in part on the research and reports that equity research analysts publish about us and our business. The price of our ordinary shares and ADSs could decline if one or more securities analysts downgrade our ordinary shares or ADSs or if those analysts issue other unfavorable commentary or cease publishing reports about us or our business.

As a foreign private issuer with ADSs listed on the Nasdaq Capital Market, we follow certain home country corporate governance practices instead of certain Nasdaq requirements.

As a foreign private issuer whose ADSs are listed on the Nasdaq Capital Market, we are permitted to follow certain home country corporate governance practices instead of certain requirements of the Nasdaq rules. As permitted under the Companies Law, our articles of association provide that the quorum for any meeting of shareholders is two shareholders who hold or represent between them at least 331⁄3% of the voting rights in our Company, similar to Nasdaq requirements; however, if the meeting is adjourned for lack of quorum, the quorum for such adjourned meeting will be two shareholders who hold or represent between them at least 10% of the issued and outstanding share capital in our Company, instead of 331⁄3% of the issued share capital. We also intend to adopt and approve material changes to equity incentive plans in accordance with the Companies Law, which does not impose a requirement of shareholder approval for such actions and we will not have a nominating committee composed entirely of independent directors with a written charter addressing the committee's purpose and responsibilities. In addition, we intend to follow the Companies Law in respect of private placements instead of Nasdaq requirements to obtain shareholder approval for certain dilutive events (such as issuances that will result in a change of control, certain transactions other than a public offering involving issuances of a 20% or greater interest in us and certain acquisitions of the stock or assets of another company). Accordingly, our shareholders may not be afforded the same protection as provided under Nasdaq corporate governance rules for domestic issuers.

We may in the future elect to follow Israel corporate governance practices in lieu of Nasdaq corporate governance rules with regard to other matters.

Following our home country governance practices as opposed to the requirements that would otherwise apply to a United States company listed on the Nasdaq Capital Market may provide less protection than is accorded to investors of domestic issuers.

As a "foreign private issuer", our disclosure and reporting requirements are different than those of a United States domestic reporting company.

In addition, as a foreign private issuer, we are exempt from the rules and regulations under the Exchange Act related to the furnishing and content of proxy statements, and our officers, directors and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we will not be required under the Exchange Act to file annual, quarterly and current reports and financial statements with the SEC as frequently or as promptly as domestic companies whose securities are registered under the Exchange Act.

We incur additional increased costs as a result of the listing of ADSs for trading on the Nasdaq Capital Market, and our management is required to devote substantial time to compliance initiatives and reporting requirements associated therewith.

As a public company in the United States, we incur additional significant accounting, legal and other expenses as a result of the listing of ADSs on the Nasdaq Capital Market. These include costs associated with corporate governance requirements of the SEC and the Marketplace Rules of Nasdaq, as well as requirements under Section 404 and other provisions of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act. These rules and regulations increase our legal and financial compliance costs, introduce new costs such as those relating to investor relations, stock exchange listing fees and shareholder reporting, and make some activities more time consuming or costly, such as increased costs for directors' and officers' liability insurance. Any future changes in the laws and regulations affecting public companies in the United States and Israel, including Section 404 and other provisions of the Sarbanes-Oxley Act, the rules and regulations adopted by the SEC and the rules of Nasdaq, as well as applicable Israeli reporting requirements, for so long as they apply to us, will result in increased costs to us as we respond to such changes. These laws, rules and regulations could make it more difficult or more costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our Board of Directors, our committees of our Board of Directors or as executive officers.

If we are unable to satisfy the requirements of Section 404 as they apply to us, or our internal controls over financial reporting are not effective, the reliability of our financial statements may be questioned and the price of ADSs may suffer.

We are subject to the requirements of the Sarbanes-Oxley Act in light of the listing of ADSs on the Nasdaq Capital Market. Section 404 of the Sarbanes-Oxley Act, or Section 404, requires companies subject to the reporting requirements of the United States securities laws to complete a comprehensive evaluation of its and its subsidiaries' internal controls over financial reporting. To comply with this statute, we will be required to document and test our internal control procedures and our management will be required to assess and issue a report concerning our internal controls over financial reporting. Pursuant to the JOBS Act, we will be classified as an "emerging growth company." Under the JOBS Act, emerging growth companies are exempt from certain reporting requirements, including the independent auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act. Under this exemption, our independent auditor will not be required to attest to and report on management's assessment of our internal controls over financial reporting during a five-year transition period. We will need to prepare for compliance with Section 404 by strengthening, assessing and testing our system of internal controls to provide the basis for our report. However, the continuous process of strengthening our internal controls and complying with Section 404 is complicated and time-consuming. Furthermore, we believe that our business will grow both domestically and internationally, in which case our internal controls will become more complex and will require significantly more resources and attention to ensure our internal controls remain effective overall. During the course of its testing, our management may identify material weaknesses or significant deficiencies, which may not be remedied in a timely manner to meet the deadline imposed by the Sarbanes-Oxley Act. If our management cannot favorably assess the effectiveness of our internal controls over financial reporting, or our independent registered public accounting firm identifies material weaknesses in our internal controls, investor confidence in our financial results may weaken, and the market price of our securities may suffer.

There can be no assurance that we will not be classified as a passive foreign investment company, which could result in adverse United States federal income tax consequences to United States Holders of our ordinary shares and ADSs.

We would be a passive foreign investment company, or PFIC, for any taxable year if, after the application of certain look-through rules, either: (i) 75% or more of our gross income for such year is "passive income" (as defined in the relevant provisions of the Internal Revenue Code of 1986, as amended), or (ii) 50% or more of the value of our assets (determined on the basis of a quarterly average) during such year is attributable to assets that produce or are held for the production of passive income. Based on our anticipated market capitalization and the composition of our income, assets and operations, we do not expect to be a PFIC for United States federal income tax purposes for the current taxable year or in the foreseeable future. However, this is a factual determination that must be made annually after the close of each taxable year. Moreover, the value of our assets for purposes of the PFIC determination may be determined by reference to the public price of our ordinary shares and ADSs, which could fluctuate significantly. Therefore, there can be no assurance that we will not be classified as a PFIC in the future. Certain adverse United States federal income tax consequences could apply to a United States Holder (as defined in Item 10.E. "*Taxation— United States Federal Income Tax Considerations*") if we are treated as a PFIC for any taxable year during which such United States Holder holds ADSs.

If a United States person is treated as owning at least 10% of our ordinary shares, such holder may be subject to adverse United States federal income tax consequences.

If a United States person is treated as owning (directly, indirectly or constructively) at least 10% of the value or voting power of our ordinary shares, such person may be treated as a "United States shareholder" with respect to each controlled foreign corporation, or CFC, in our group (if any). In addition, because our group includes one or more United States subsidiaries, under recently-enacted rules, certain of our non-U.S. subsidiaries could be treated as CFCs, regardless of whether or not we are treated as a CFC (although there is currently a pending legislative proposal to significantly limit the application of these rules). A United States shareholder of a CFC may be required to report annually and include in its United States taxable income its pro rata share of "Subpart F income," "global intangible low-taxed income" and investments in United States property by CFCs, regardless of whether we make any distributions. An individual who is a United States shareholder with respect to a CFC generally is not allowed certain tax deductions or foreign tax credits that would be allowed to a United States shareholder that is a United States corporation. Failure to comply with these obligations may subject a United States shareholder to significant monetary penalties and may prevent the statute of limitations with respect to such shareholder's United States federal income tax return for the year for which reporting was due from starting. We cannot provide any assurances that we will assist investors in determining whether any of our non-U.S. subsidiaries are treated as CFCs or whether such investor is treated as a United States shareholder with respect to any such CFCs or furnish to any United States shareholders information that may be necessary to comply with the aforementioned reporting and tax paying obligations. The United States Internal Revenue Service has provided limited guidance on situations in which investors may rely on publicly available information to comply with their reporting and tax paying obligations with respect to foreign-controlled CFCs. A United States investor should consult its advisors regarding the potential application of these rules to an investment in the ADSs.

The market price of our ordinary shares and ADSs could be negatively affected by future sales of our ordinary shares and ADSs.

As of March 24, 2020, we had approximately 423.1 million ordinary shares issued and outstanding (including ordinary shares underlying the ADSs) and approximately 52.0 million of additional ordinary shares which are issuable upon exercise of outstanding warrants, stock options and vesting of RSUs. The issuance of a significant amount of additional ordinary shares or ADSs on account of these outstanding securities will dilute our current shareholders' holdings and may depress the price of our ordinary shares and ADSs.

If our existing shareholders and ADS holders or holders of our warrants, options or RSUs sell substantial amounts of our ordinary shares or ADSs, either on the TASE or Nasdaq, the market price of our ordinary shares and ADSs may be adversely affected. Any substantial sales of our ordinary shares or ADSs in the public market might also make it more difficult for us to sell equity or equity-related securities in the future at a time and on terms we deem appropriate. Even if there are not a substantial number of sales, the mere existence of this "market overhang" could have a negative impact on the market for, and the market price of, our ordinary shares and ADSs.

In 2015, we agreed to grant Viola, our largest shareholder, registration rights that require that we register under the Securities Act the resale of their shares into the public markets. The market price of our ordinary shares and ADSs may be adversely affected when the restrictions on resale by our existing shareholders lapse and these shareholders are able to sell our ordinary shares or ADSs into the market or, in the case of Viola, if Viola were to exercise its registration rights. In connection with our registered public offering in February 2020, we and certain of our shareholders and ADS holders, directors and officers have agreed not to sell any of our ordinary shares or ADSs without the prior written consent of the representatives of the underwriters until July 29, 2020. The representatives of the underwriters may, however, in their sole discretion and without notice, release all or any portion of these securities from the restrictions in the lock-up agreements. After these agreements expire, these securities will be eligible for sale in the public market.

Provisions of our articles of association and Israeli law as well as the terms of some of our equity-based grants and the Security Agreements may delay, prevent or make difficult an acquisition of us, which could prevent a change of control and negatively affect the price of our ordinary shares and ADSs.

Israeli corporate law regulates mergers, requires tender offers for acquisitions of shares or voting rights above specified thresholds, requires special approvals for certain transactions involving directors, officers or significant shareholders and regulates other matters that may be relevant to these types of transactions. These provisions of Israeli law may delay, prevent or make difficult an acquisition of us, which could prevent a change of control and therefore depress the price of our ordinary shares and ADSs. For example, under the Companies Law, upon the request of a creditor of either party to a proposed merger, the court may delay or prevent the merger if it concludes that there exists a reasonable concern that as a result of the merger the surviving company will be unable to satisfy the obligations of any of the parties to the merger. In addition, our executive officers and certain other key employees are entitled to certain benefits in connection with a change of control of our Company and the Security Agreements allow the lender bank to accelerate repayment of outstanding debt upon a change of control of our Company. These provisions could cause our ordinary shares and ADSs to trade at prices below the price for which third parties might be willing to pay to gain control of us. Third parties who are otherwise willing to pay a premium over prevailing market prices to gain control of us may be unable or unwilling to do so because of these provisions of Israeli law.

Furthermore, Israeli tax considerations may make potential transactions unappealing to us or to our shareholders, especially for those shareholders whose country of residence does not have a tax treaty with Israel which exempts such shareholders from Israeli tax. For example, Israeli tax law does not recognize tax-free share exchanges to the same extent as United States tax law. With respect to mergers, Israeli tax law allows for tax deferral in certain circumstances but makes the deferral contingent on the fulfillment of a number of conditions, including, in some cases, a holding period of two years from the date of the transaction during which sales and dispositions of shares of the participating companies are subject to certain restrictions. Moreover, with respect to certain share swap transactions, the tax deferral is limited in time, and when such time expires, the tax becomes payable even if no disposition of the shares has occurred.

We have never paid cash dividends on our share capital, and we do not anticipate paying any cash dividends in the foreseeable future.

We have never declared or paid cash dividends on our share capital, nor do we anticipate paying any cash dividends on our share capital in the foreseeable future. We currently intend to retain all available funds and any future earnings to fund the development and growth of our business. As a result, capital appreciation, if any, of our ordinary shares and ADSs will be investors' sole source of gain for the foreseeable future. Moreover, the Security Agreements contain limitations on the distribution of dividends and repurchase of our shares. In addition, Israeli law limits our ability to declare and pay dividends, and may subject our dividends to Israeli withholding taxes. Furthermore, our payment of dividends (out of tax-exempt income) may retroactively subject us to certain Israeli corporate income taxes, to which we would not otherwise be subject.

You may not receive dividends or other distributions on our ordinary shares and you may not receive any value for them, if it is illegal or impractical to make them available to you.

The depositary for the ADSs has agreed to pay you the cash dividends or other distributions it or the custodian receives on our ordinary shares or other deposited securities underlying the ADSs, after deducting its fees and expenses. You will receive these distributions in proportion to the number of ordinary shares your ADSs represent. However, the depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any holders of ADSs. For example, it would be unlawful to make a distribution to a holder of ADSs if it consists of securities that require registration under the Securities Act but that are not properly registered or distributed under an applicable exemption from registration. The depositary may also determine that it is not feasible to distribute certain property through the mail. Additionally, the value of certain distributions may be less than the cost of mailing them. In these cases, the depositary may determine not to distribute such property. We have no obligation to register under United States securities laws any ADSs, ordinary shares, rights or other securities received through such distributions. We also have no obligation to take any other action to permit the distribution of ADSs, ordinary shares, rights or anything else to holders of ADSs. This means that you may not receive distributions we make on our ordinary shares or any value for them if it is illegal or impractical for us to make them available to you. These restrictions may cause a material decline in the value of the ADSs.

ADSs holders may not be entitled to a jury trial with respect to claims arising under the deposit agreement relating to the ADSs or ordinary shares, which could result in less favorable outcomes to the plaintiffs in any such action.

The deposit agreement governing the ADSs representing our ordinary shares provides that, to the fullest extent permitted by law, ADS holders waive the right to a jury trial of any claim they may have against us or the depositary arising out of or relating to our shares, the ADSs or the deposit agreement, including any claim under the United States federal securities laws. If we or the depositary opposed a jury trial demand based on such jury trial waiver, the court would determine whether the waiver was enforceable based on the facts and circumstances of that case in accordance with the applicable state and federal law. To our knowledge, the enforceability of a contractual pre-dispute jury trial waiver in connection with claims arising under the federal securities laws has not been finally adjudicated by the United States Supreme Court. However, we believe that a contractual pre-dispute jury trial waiver provision is generally enforceable, including under the laws of the State of New York, which govern the deposit agreement, by a federal or state court in the City of New York, which has non-exclusive jurisdiction over matters arising under the deposit agreement. In determining whether to enforce a contractual pre-dispute jury trial waiver provision, courts will generally consider whether a party knowingly, intelligently and voluntarily waived the right to a jury trial. We believe that this is the case with respect to the deposit agreement and the ADSs.

If you or any other holders or beneficial owners of ADSs bring a claim against us or the depositary in connection with matters arising under the deposit agreement, including claims under federal securities laws, you or such other holder or beneficial owner may not be entitled to a jury trial with respect to such claims, which may have the effect of limiting and discouraging lawsuits against us and the depositary. If a lawsuit is brought against either or both of us and the depositary under the deposit agreement relating to the ADSs or ordinary shares, it may be heard only by a judge or justice of the applicable trial court, which would be conducted according to different civil procedures and may result in different outcomes than a trial by jury would have, including results that could be less favorable to the plaintiffs in any such action.

Nevertheless, if this jury trial waiver provision is not permitted by applicable law, an action could proceed under the terms of the deposit agreement with a jury trial. No condition, stipulation or provision of the deposit agreement or ADSs serves as a waiver by any holder or beneficial owner of ADSs or by us or the depositary of compliance with the United States federal securities laws and the rules and regulations promulgated thereunder.

Risks Related to Our Operations in Israel

Our headquarters, manufacturing and other significant operations are located in Israel and, therefore, our business and operation may be adversely affected by political, economic and military conditions in Israel.

We are incorporated under the laws of the State of Israel, and our principal offices and research and development and production facilities are located in Israel. In addition, the majority of our key employees, officers and directors are residents of Israel. Accordingly, political, economic and security conditions in the Middle East in general, and in Israel in particular, directly affect our business and operations.

Over the past several decades, a number of armed conflicts have taken place between Israel and its Arab neighbors and a state of hostility, varying in degree and intensity, has existed between Israel and certain other countries or militant groups in the region. Since late 2000, there has also been an increase in violence and unrest between Israel and the Palestinians, including during the summer of 2014, when Israel was engaged in an armed conflict with Hamas, a militia and political group operating in the Gaza Strip. This conflict has strained Israel's relationship with its Arab citizens, Arab countries and, to some extent, with other countries around the world. In addition, since the end of 2010, several countries in the region have been experiencing increased political instability, which has led to changes in government in some of these countries and increases in violence and turbulence, including the ongoing civil war in Syria which shares a common border with Israel, the effects of which are currently difficult to assess. In addition, Israel faces threats from more distant neighbors, such as Iran (which has previously threatened to attack Israel and is believed to have influence over Hamas in Gaza and Hezbollah, a militia and political group operating in Lebanon) and the militant group known as the Islamic State of Iraq and Syria. This situation may potentially escalate in the future and may also lead to deterioration of the political and trade relationships that exist between the State of Israel and these countries. Any armed conflicts or political instability in the region, including acts of terrorism as well as cyber-attacks or any other hostilities involving or threatening Israel, would likely negatively affect business conditions and could make it more difficult for us to conduct our operations in Israel, which could increase our costs and adversely affect our financial results. 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 currently covers the reinstatement value of direct damages that are caused by terrorist attacks or acts of war, we cannot be assured that this government coverage will be maintained or will be adequate in the event we submit a claim. Any losses or damages incurred by us could have a material adverse effect on our business. Any armed conflict involving Israel could adversely affect our operations and results of operations.

Furthermore, some neighboring countries, as well as certain companies, organizations and movements, continue to participate in a boycott of Israeli firms and others doing business with Israel or with Israeli companies. In the past several years, there have been increased efforts by activists to cause companies and consumers to boycott Israeli goods based on Israeli government policies. Similarly, Israeli companies are limited in conducting business with entities from several countries. For example, in 2008, the Israeli legislature passed a law forbidding any investments in entities that transact business with Iran. Restrictive laws, policies or practices directed towards Israel or Israeli businesses could have an adverse impact on our operating results, financial condition or the expansion of our business.

Some of our officers and employees are obligated to perform annual military reserve duty, and in the event of a military conflict, these persons could be called to active duty at any time, for extended periods of time and on very short notice. The absence of a number of our officers and employees for significant periods could materially adversely affect our business and results of operations. We cannot assess the full impact of these obligations on our workforce or business if conditions should change.

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.

The Israeli government grants that we have received require us to meet several conditions and restrict our ability to manufacture products and transfer know-how outside of Israel and require us to satisfy specified conditions.

We have in the past received, and in the future may apply for, royalty-bearing grants from the Israeli Innovation Authority (formerly known as the Office of the Chief Scientist of the Israeli Ministry of Economy and Industry), or the IIA, for research and development programs that meet specified criteria pursuant to the Law for the Encouragement of Research, Development and Technological Innovation in Industry, 1984 (formerly known as the Law for Encouragement of Research and Development in Industry, 1984), and the regulations promulgated thereunder, or the R&D Law. The terms of the IIA grants limit our ability to manufacture products outside of Israel or transfer technologies to any third party if such products or technologies were developed using know-how developed with or based upon IIA grants. Under the R&D Law, we are prohibited from manufacturing products developed using these grants outside of the State of Israel without special approvals. We may not receive the required approvals for any proposed transfer of manufacturing activities. Even if we do receive approval to manufacture products developed with government grants outside of Israel, the royalty rate may be increased and we may be required to pay up to three times the grant amounts plus interest, depending on the manufacturing volume that is performed outside of Israel. This restriction may impair our ability to outsource manufacturing or engage in our own manufacturing operations for those products or technologies.

Additionally, under the R&D Law, we are prohibited from transferring (including by way of license), the IIA-financed technologies and related rights (including know-how and other intellectual property rights) outside of the State of Israel, except under limited circumstances and only with the approval of the IIA Research Committee. We may not receive the required approvals for any proposed transfer and, even if received, we may be required to pay the IIA a portion of the consideration that we receive upon any transfer of such technology to a non-Israeli entity up to 600% of the grant amounts plus interest. In addition, a change of control in us and the acquisition of 5% or more of our ordinary shares by a non-Israeli may require notification to the IIA and the provision of an undertaking to comply with the R&D Law, some of the principal restrictions and penalties of which are the transferability limits described above and elsewhere in this Annual Report.

Further, the IIA grants may be terminated in the future or the available benefits may be reduced or impacted, including, among other possible circumstances, should we transfer certain research and development or manufacturing activities outside the State of Israel. The termination or curtailment of these programs or the loss or reduction of such benefits could have a material adverse effect on our business, financial condition and results of operations. In addition, the IIA may establish new guidelines regarding the R&D Law, which may affect our existing and/or future IIA programs and incentives for which we may be eligible. We cannot predict what changes, if any, the IIA may make.

As of December 31, 2019, we have received royalty-bearing grants from the IIA in a total amount of $1.06 million (including interest accrued through December 31, 2019) for the development of EndoPAT 3000 (the development of which was discontinued before its completion with no sales to date). In 2009, the IIA notified us that under the terms of such grant, we must pay royalties on the sale of all of our products commencing as of 2012. We believe that under the terms of the said grant we are not required to repay these grants to the IIA from the sale of our past and currently marketed products. There is no assurance that we will prevail in our efforts opposing the IIA's position. We anticipate that, in 2021, we will begin selling our newly developed EndoPATX, for which we recently received authorization to affix a CE mark. We developed EndoPATX using some of the know-how developed under the EndoPAT 3000 grant program, and therefore anticipate paying royalties on sales of EndoPATX against the grants received for the development of EndoPAT 3000.

Enforcing a United States judgment against our Company and our executive officers and directors, or asserting United States securities law claims in Israel may be difficult.

We are incorporated in Israel, our corporate headquarters is located in Israel and several of our current officers and directors reside in Israel. Service of process upon us, our directors and officers and the Israeli experts, if any, named in this Annual Report, substantially all of whom reside outside the United States, may be difficult to obtain within the United States. Furthermore, because the majority of our assets and investments, and substantially all of our directors, officers and such Israeli experts are located outside the United States, any judgment obtained in the United States against us or any of them may be difficult to collect within the United States and may not be enforced by an Israeli court.

We have been informed by our legal counsel in Israel that it may also be difficult to assert United States securities law claims in original actions instituted in Israel. Israeli courts may refuse to hear a claim based on an alleged violation of United States securities laws if they determine that Israel is not the most appropriate forum to bring such a claim. In addition, even if an Israeli court agrees to hear a claim, it may determine that Israeli law and not United States law is applicable to the claim. There is little binding case law in Israel addressing these matters. If United States law is found to be applicable, the content of applicable United States law must be proven as a fact, which can be a time-consuming and costly process. Certain matters of procedure will also be governed by Israeli law.

Subject to specified time limitations and legal procedures, under the rules of private international law currently prevailing in Israel, Israeli courts may enforce a United States judgment in a civil matter, including a judgment based upon the civil liability provisions of United States securities laws, as well as a monetary or compensatory judgment in a non-civil matter, provided that the following key conditions are met:

- subject to limited exceptions, the judgment is final and non-appealable;
- the judgment was given by a court competent under the laws of the state of the court and is otherwise enforceable in such state;

- the judgment was rendered by a court competent under the rules of private international law applicable in Israel;
- the laws of the state in which the judgment was given provide for the enforcement of judgments of Israeli courts;
- adequate service of process has been effected and the defendant has had a reasonable opportunity to present his arguments and evidence;
- the judgment is enforceable under the laws of State of Israel and its enforcement are not contrary to the law, public policy, security or sovereignty of the State of Israel;
- the judgment was not obtained by fraud and does not conflict with any other valid judgment in the same matter between the same parties; and
- an action between the same parties in the same matter was not pending in any Israeli court at the time the lawsuit was instituted in the United States court.

Your rights and responsibilities as a shareholder will be governed by Israeli law, which differs in some material respects from the rights and responsibilities of shareholders of United States companies.

The rights and responsibilities of the holders of our ordinary shares and ADSs are governed by our amended and restated articles of association and by Israeli law. These rights and responsibilities differ in some material respects from the rights and responsibilities of shareholders in United States corporations. For example, a shareholder of an Israeli company has a duty to act in good faith and in a customary manner in exercising its rights and performing its obligations towards the company and other shareholders, and to refrain from abusing its power in the company, including, among other things, voting at a general meeting of shareholders on matters such as amendments to a company's articles of association, increases in a company's authorized share capital, mergers and acquisitions and related party transactions requiring shareholder approval. In addition, a shareholder who is aware that it possesses the power to determine the outcome of a shareholder vote or to appoint or prevent the appointment of a director or executive officer in the company has a duty of fairness toward the company. There is limited case law available to assist us in understanding the nature of these duties or the implications of these provisions. These provisions may be interpreted to impose additional obligations and liabilities on holders of our ordinary shares and ADSs that are not typically imposed on shareholders of United States corporations.

Item 4. Information on the Company

A. History and Development of the Company

Corporate Information

We are a limited company incorporated under the laws of the State of Israel under the name Itamar Medical (CM) 1997 Ltd. on January 15, 1997 as a company limited by shares. We changed our name to our current name in July 2000. Since March 2007, our ordinary shares have been traded on the TASE under the symbol "ITMR." We also listed ADSs, each representing 30 ordinary shares, on the Nasdaq Capital Market in February 2019, also under the symbol "ITMR."

Our registered office address is 9 Halamish Street, Caesarea 3088900, Israel and our telephone number is +972-4-6177000. Our agent for service of process in the United States is Itamar Medical, Inc., which maintains its principal offices at 3290 Cumberland Club Drive, Atlanta, GA 30339 and its telephone number is 1-888-748-2627.

Our website address is www.itamar-medical.com. The information contained on, or that can be accessed from, our website does not form part of this Annual Report. The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers, such as we, that file electronically, with the SEC at www.sec.gov.

Recent Business Developments

Below is a summary of important business developments in Itamar Medical since January 1, 2019:

- In response to anticipated changes in the sleep apnea tests market, resulting from the coronavirus outbreak, we are changing our manufacturing mix to prioritize WatchPAT ONE production. For more information see Item 5. "*Operating and Financial Review and Prospects — Trend Information*."

- On February 4, 2020, we completed a registered public offering of 2,927,267 ADSs at a price of $13.75 per ADS, for total gross proceeds of approximately $40.25 million. For additional details, see Item 5.B. "*Operating and Financial Review and Prospects — Liquidity and Capital Resources*."

- On December 4, 2019, we announced that we entered into a collaboration agreement with a wholly-owned subsidiary of SoClean, Inc. to offer WatchPAT ONE and other digital health services through DTC channels to the U.S. sleep apnea market. For additional details, see Item 4.B. "*Business Overvoew — Sales and Marketing*."

- On February 27, 2019, we announced the first day of trading of our ADSs on the Nasdaq Capital Market under the ticker symbol "ITMR".

- On January 16, 2019 and January 28, 2019, we entered into agreements with several investors as part of a private placement for gross proceeds of approximately $14.7 million, which was completed in March 2019, whereby we issued ADSs and ordinary shares representing a total of approximately 46.1 million ordinary shares to the investors. For additional details, see Item 5.B. "*Operating and Financial Review and Prospects — Liquidity and Capital Resources*."

Principal Capital Expenditure and Divestitures

During the year ended December 31, 2019, our capital expenditures and capitalized development costs totaled $0.5 million, compared to $0.3 million during the year ended December 31, 2018 and $0.3 million during the year ended December 31, 2017, most of which were used for the purchase of production and research and development equipment, office furniture and equipment and computers and self-manufactured equipment (WatchPAT devices that are used by our customers). Except as described in this Annual Report, we have no significant capital expenditures in progress. For more information regarding the process of constructions and adjustment of our new manufacturing facilities, see under "*Property, Plants and Equipment*" below.

We did not affect any principal divestitures in the past three years.

B. Business Overview

Overview

We are a medical technology company focused on the development and commercialization of non-invasive medical devices and solutions to aid in the diagnosis of respiratory sleep disorders. We use a digital healthcare platform to facilitate the continuum of care for effective sleep apnea management with a focus on the core sleep, cardiology and direct to consumer, or DTC, markets. We offer a TSS to help physicians provide comprehensive sleep apnea management in a variety of clinical environments to optimize patient care and reduce healthcare costs. In addition, we have recently begun offering our WatchPAT family of products and certain components of TSS to the DTC market.

Sleep apnea is a chronic disease impacting 54 million people in the United States and 26% of adults over the age of 40 in the United States. While sleep apnea used to be perceived as a lifestyle disease, with snoring and tiredness as the main implications, it is now known to be a major underlying risk factor and disease progression accelerator for most cardiovascular diseases, and many cognitive and neurodegenerative diseases. Despite the availability of easy to use and cost-effective diagnostic technology for over a decade, approximately 80% of people in the United States suffering from sleep apnea have never been diagnosed. In recent years, awareness of the importance of sleep in general, and the devastating effects that could result from sleep apnea, has been on the rise both in medical professional circles as well as with patients.

We believe a key competitive differentiator for us is the ability to measure and help diagnose sleep apnea through our proprietary software and algorithms which analyze the PAT biological signal with other measurements, including actigraphy, heart rate, chest motion, body position and snoring. Our PAT-based technology is available throughout our prescription WatchPAT family of durable or disposable products. These simple to use, non-invasive watch-like devices utilize finger positioned bio-sensors to measure and record the patient's PAT signal. This signal is transferred to our local software product, zzzPAT, or our cloud-based software product, CloudPAT, for analysis and reporting of sleep apnea diagnosis. These proprietary analyses' results are automatically populated into an easy to read report that allows physicians to accurately diagnosis sleep apnea.

We keep developing our base core sleep business which consists of sleep physicians and practices, including independent diagnostic testing facilities, in order to provide services to patients who are suspected of suffering from sleep apnea. We believe that a substantial market share and broad stakeholders support from this segment are required foundations for success in the Cardiology and DTC markets. We believe that the WatchPAT technology, which is backed by a large body of evidence and was described by the 2017 American Academy of Sleep Medicine, or AASM, Clinical Practice Guideline as technically adequate, is positioned as the easiest to use and most comprehensive home sleep apnea test, or HSAT, in the market. We believe that through education, local sales and support field force and continued investment in traditional and online marketing as well as solid science and innovation programs, we will continue to gain market share and position WatchPAT as a leading HSAT device.

Our TSS is a comprehensive marketing program we offer to physicians that combines products and services, including our proprietary diagnostic aid and data analytics, logistic solutions and access to third-party sleep apnea treatment devices and their therapy compliance data and a network of independent diagnostics testing facilities, or IDTFs, and durable mobile equipment, or DME, providers. TSS is designed to allow any medical practice or physician that does not specialize in sleep, easy access to a comprehensive suite of products and services to aid in the diagnosis, transportation and handling, treatment and management of patients they suspect suffer from sleep apnea. We believe the combination of our proprietary test combined with the ease of having a single point of contact management of the diagnosis and treatment of sleep apnea provided by TSS has been a driver of the increased usage of our tests. Specific products and services included in the TSS program include CloudPAT, including remote interpretation and remote consultation, and SleePath for cloud-based data and information mobilization solutions, access to sleep apnea therapeutic products such as continuous positive airway pressure, or CPAP, devices, patient adherence management services and Mandibular Advancement Devices, or MADs, related services and logistic solutions such as WatchPAT Direct.

We focus on offering TSS to the cardiology market primarily through our TaaS, also known as Cost per Test model, which is the primary model we have utilized to date. The medical practice or physician ordering the TaaS pays a fixed fee per HSAT, that includes all the components associated with the test, including the disposable biosensor, hardware rental fees and access to our CloudPAT platform. We may collaborate with other providers in the cardiology or sleep market to attempt to leverage their sales force presence at accounts which are of interest to us. For example, in June 2019, we launched a limited program in two states with BioTel Heart, a division of BioTelemetry, Inc., or BioTel, the largest provider of ambulatory Holter and event monitoring services in the United States pursuant to which our TSS program is offered to BioTel's clients in said accounts, namely cardiologists and cardiology practices and departments, through BioTel Heart. This allows us to capitalize on the significantly larger presence of BioTel sales force in the United States at cardiology outpatient offices. In addition, the fact that BioTel Heart is already an established provider to cardiologists and cardiology practices and departments, eliminates the need for commercial and business associate contracting with such cardiologists and cardiology practices and departments, reduces the burden of IT clearances and streamlines ordering from a single portal. Under this model, cardiologists and cardiology practices and departments benefit from outsourcing the ownership, handling and billing of HSAT.

In 2019, we began focusing on the DTC market segment in order to address the recent surge in awareness of sleep apnea, harnessing the trend of consumers to seek more accessible and cost-effective solutions that bypass traditional physician referral systems. In this market segment, we offer our HSAT products and most of the TSS components, through channel partners, including SoClean Inc., or SoClean, that have a consumer market presence (whether online or offline) and the desire to identify and treat consumers at risk for sleep apnea, a full digital health sleep apnea solution which can be used by patients suspected to have sleep related breathing disorders at their home in accordance with a physician's instructions, as authorized by qualified medical personnel. This solution is based on our HSAT products and most of the TSS components. We provide high quality digital health patient pathway management services through these partners. To facilitate the clinical oversight of the patients in this process, we have added remote online consultation capabilities to our CloudPAT system and created an online marketplace that connects patients in demand for clinical services with board certified physicians that offer their expertise. As a result, we will facilitate patient access to real time consultation, advice and prescriptions throughout the care pathway. In addition, we will facilitate access to reputable sleep practices and DME providers that have demonstrated their ability to set up CPAP therapeutic solutions remotely, as well as monitor and coordinate compliance. We believe that our digital health platform, which can facilitate the journey of patients from diagnosis to therapy and compliance in an easy, efficient and innovative manner within their homes, positions us for new growth opportunities.

Our Solutions

Our prescription WatchPAT proprietary product, which utilizes the PAT signal, is designed to enable patients to easily conduct sleep apnea tests in the comfort of their home while delivering the treating physicians with comprehensive, accurate and reliable results to aid in the diagnosis of sleep apnea. We believe that WatchPAT provides several key advantages over both PSG testing as well as other HSAT devices by offering the following key benefits: ease of use and patient comfort; accuracy; comprehensiveness; reliability; cost-effectiveness; and immediate and easy-to-read results.

We believe these advantages enable a shift in the "point of care" (the focal point at which the disease is being managed) of simple sleep apnea from sleep centers to the cardiology care point and directly to consumers. In particular, through our WatchPAT-related services, including CloudPAT, our cloud-based IT platform, and our TSS program, we offer physicians, including those in the cardiology market, an effective solution to manage the entire care pathway for patients suffering from sleep apnea by covering both the screening and diagnosis stage of sleep apnea, using our WatchPAT family of products, as well as, through the resale of devices of our business partners, treatment thereof.

Our Competitive Strengths

Our goal is to become a global leader in sleep apnea diagnostic aids and solutions as we continue to focus on advancing the standard of care in at-home respiratory sleep disorders. We believe that our technology platform, combined with the following competitive strengths, will allow us to grow our presence and expand our market opportunity:

- *An emerging market leader in at-home diagnosis of respiratory sleep disorders*. We have developed and are commercializing a novel, non-invasive medical device to aid in the diagnosis of sleep disorders. Our market leading TSS is optimized in a variety of clinical environments to optimize patient care and reduce healthcare costs. We believe that we are the market leader in at-home respiratory sleep disorder diagnostic aids. We also believe we have a significant and scaled first mover advantage over competitors, as our physicians have utilized our technology for more than 1.5 million patients.

- *Proprietary technology with unique advantages over competitive devices*. Our solutions leverage innovative technological advancements that we believe give us a competitive advantage in the marketplace. We believe that there are several key advantages over in-lab PSG testing as well as other HSAT devices, including ease of use, patient comfort, comprehensiveness, enhanced accuracy and reliability with immediate results. The ease of use in which we are able to measure over seven sleep parameters, including true sleep time, is unmatched by most of our competitors and a significant differentiator within the HSAT device market.

- *Significant body of clinical evidence and key opinion leader support*. We have developed a significant body of clinical data that demonstrates the effectiveness, success rate and potential long-term sustained benefits of respiratory sleep disorder diagnosis with our products compared to PSG tests. Peer-reviewed study results utilizing our products have been consistent across both funded and independent clinical studies that have evaluated tests from more than nine hundred patients. In recognition of the clinical evidence, the AASM changed their clinical guidelines in March 2017 to include PAT-based technology as technically adequate for use in HSAT devices to diagnose obstructive sleep apnea.

- *Extensive reimbursement coverage and experience*. We work closely with governmental and private payors to educate them on our innovative features, technology differentiation, and cost benefits. We also work directly with clinicians to help them understand payor requirements for our products. Our solutions are broadly covered and recognized by third-party payors under Current Procedural Terminology, or CPT, codes, which are used by the Medicare program to describe sleep apnea testing services and establish payment amounts for those services. The CPT code that describes PAT-based HSAT services, 95800, is listed by the Medicare reimbursement fee schedule in 2020 at a rate approximately 40% greater than another CPT code describing HSAT devices that do not have sleep time technology, CPT code 95806. Based on our estimates, our solutions have provider coverage for approximately 220 million lives in the United States. In addition to the United States, WatchPAT is also covered in Japan, the United Kingdom and other European regions.

- *Demonstrated healthcare systems cost savings*. We believe our solutions offer meaningful cost savings for the healthcare system and patients, as compared to traditional respiratory sleep disorder diagnostic technologies. As demonstrated by the Health Provider System Study published in 2014, a transition from in-lab testing to unattended home sleep testing improved Obstructive sleep apnea, or OSA, test accessibility, reduced waiting time, and reduced overall OSA diagnosis costs while maintaining patient satisfaction.

- *Strong research and development activities*. We are committed to continued technology innovation and investment which will allow us to achieve significant product improvements. For example, in March 2019 we began commercializing in the United States our latest WatchPAT 300, a new generation of the WatchPAT line of products which is designed to expedite data transfer and allow the use of a lighter and smaller watch. In June 2019 we received FDA 510(k) clearance for what we believe to be the first and only fully disposable home sleep apnea test, the WatchPAT ONE, a prescription device for use with patients suspected to have sleep related breathing disorders. The WatchPAT ONE is indicated as a diagnostic aid for the detection of sleep related breathing disorders, sleep staging, snoring level and body position.

Our Growth Strategy

Our goal is to become a world leader in innovative technology platforms for home-based sleep apnea diagnostic aids and solutions. The key elements of our strategy include:

- *Expand our market presence and focus on our primary call-points*. We plan to leverage our technology platforms to focus on capitalizing on our four main immediate markets:

    - *Core sleep market*. We will continue to call on sleep physicians and practices, including independent diagnostic testing facilities, in order to serve patients suspected of suffering from sleep apnea.

    - *Cardiology market*. According to published literature there are approximately 92 million cardiovascular patients in the United States, of which approximately 40-60% are estimated to suffer from sleep apnea. We will continue to call on cardiologists and cardiology practices, leveraging our digital health platforms and partnerships to facilitate the care continuum at the cardiology care point.

    - *Countries outside of the United States*. We will continue to build relationships with local channel partners as well as establish, and expand upon existing, foreign strategic collaborations with international companies.

    - *Direct to consumer market*. We began focusing on the DTC market in 2019, in an attempt to circumvent the barriers of traditional healthcare systems and increase consumer awareness and adoption. We plan to service this market by highlighting the advantages of our digital health platforms and our market specific WatchPAT ONE, our disposable home sleep apnea test device. Additionally, we intend to continue to form collaborative relationships with partners who have direct to consumer scale and demonstrated marketing expertise.

- *Position our products as the leading sleep apnea solution for cardiologists*. We intend to continue to capitalize on the linkage between sleep apnea and cardiovascular disease by adding a point of early diagnosis for sleep apnea at both the cardiology care point and at home. We plan to continue promoting our WatchPAT family of products and the CloudPAT and SleePath digital health platforms to cardiologists. We will continue to streamline sleep apnea screening, diagnosis therapy and compliance monitoring with our comprehensive TSS program. We will continue collaborations with IDTFs and DME service providers and CPAP data sharing and integration with Philips and ResMed Inc., or ResMed, to maintain a high degree of product availability and benefit patients throughout the continuum of care.

- *Lead in the DTC market segment*. We intend to leverage our WatchPAT family of products, including our disposable WatchPAT ONE, our relationships with DTC channel partners, and continued investment in digital health to become a leader in Sleep Apnea Digital Patient Pathway Management. We will continue to enable an easy, efficient and innovative patient pathway management platform that will help manage the patient journey from diagnosis to treatment. Additionally, we expect to continue to collaborate with channel partners who have proven direct to consumer expertise. We believe these endeavors will both accelerate our existing business of TaaS while also generating new revenue opportunities in the online DTC segment demonstrated by our recently announced SoClean collaboration.

- *Commercialize our technology platforms through expansion of our sales force and enhanced strategic relationships*. We currently maintain a direct sales force in the United States and indirect sales channels through distributors in Europe, Japan and Asia Pacific. We intend to continue focusing on commercializing our technology platforms by expanding our United States sales and marketing infrastructure and broadening our reach into additional segments and countries. As of December 31, 2019, we had 27 territories (Including three verticals — Kaiser, VA and Dental) in the United States, which are supported by 42 employees in our United States direct commercial organization, and we plan to open six to eight additional territories by the end of 2020. We also maintain strategic relationships with various third parties, such as Philips in Japan. We will continue expanding our strategic collaborative relationships to increase adoption of our technology.

- *Broaden Medical Insurer Coverage*. We seek to continue our efforts in securing broad and differentiated insurance reimbursement for our WatchPAT family of products in the United States and internationally. We plan to leverage data demonstrating the health economic benefit of integrating sleep apnea management to the cardiovascular care pathway to enable innovative payor programs.

- *Invest in Research and Development*. We will continue to make investments in research and development to enhance our WatchPAT family of products, develop additional applications and indications using our proprietary technologies, expand on our compendium of clinical evidence to substantiate our claims, enhance our CloudPAT and SleePath platforms, and develop further innovative digital health platforms.

Market Overview

Cardiovascular Disease

Cardiovascular disease, to which we sometimes refer to as CVD or cardiac disease, is a class of diseases that involves the heart or blood vessels, such as hypertension, heart disease, arrhythmias (including atrial fibrillation) and congestive heart failure.

CVD is highly prevalent and, quite often, a severe and potentially fatal, medical condition. According to reports published by the American Heart Association, approximately 92 million (nearly 37.0%) adults in the United States are living with some form of CVD or the after-effects of stroke, and, by 2035, approximately 130 million adults in the United States are projected to have some form of CVD.

It has been shown through several peer-reviewed, published studies that sleep apnea is a direct contributing factor to the incidence of various forms of CVD. Accordingly, cardiologists have become increasingly aware and focused on the diagnosis and treatment of sleep apnea. In addition, according to published reports, there were approximately 32,000 cardiologists in the United States in 2019 that practice in approximately 7,800 cardiology offices.

Sleep Apnea

Sleep apnea is a serious and chronic sleep breathing disorder that negatively impacts a patient's sleep, health and quality of life. There are two types of sleep apnea:

- OSA, the most common form of sleep apnea, occurs when a person's breathing is interrupted during sleep by a partially or completely blocked airway. When the airway becomes blocked, the brain detects a stress signal from various biological sources including the chest muscles, lungs and, at times, also a drop in blood oxygen content, which causes the individual to awaken unconsciously (a micro-arousal), just enough to tighten the airway muscles and allow normal breathing to resume. While regular breathing is restored temporarily, the obstruction typically occurs again which restarts the apnea cycle. This cycle of obstructions and waking can repeat dozens of times per hour throughout the night, disrupting the rapid eye movement, or REM, and deep, restorative sleep that are critical to good health as well as creating negative pressure in the abdomen that causes damage to the organs; and

- Central sleep apnea, or CSA, a less common form of sleep apnea, occurs when a person's breathing is impacted by lack of brain stimulation of the lungs and diaphragm muscles rather than obstruction. CSA is usually mixed with OSA and rarely appears in a pure form. CSA is known to be prevalent in heart failure patients as well as residents of high altitudes and opiates addicts and a specific pattern of it is called Cheyne-Stokes Respiration. To our knowledge, there is a continuing debate in the scientific community and among clinical practitioners whether this diagnosis impacts the treatment pathway.

A 2014 American Journal of Epidemiology study reported that 26% of adults suffer from sleep apnea. Additionally, according to a 2019 study published by the American Journal of Respiratory and Critical Care Medicine, sleep apnea impacts more than 936 million people worldwide. At the same time, and despite the growing awareness of the consequences of OSA, it was estimated in a 2015 study published by the American Thoracic Society that over 80% of patients with OSA have never been diagnosed.

A 2010 report published by Harvard Medical School estimated the annual economic costs (including the cost of diagnosis and treatment, public safety costs from OSA-related traffic accidents, and the incremental medical costs of OSA co-morbidities) of untreated moderate to severe OSA in the United States to be between $65 billion and $165 billion annually, potentially greater than the cost of asthma, heart failure, stroke or hypertensive disease, which range from $20 billion to $80 billion according to estimates. At the same time, according to an estimate published by Fisher & Paykel Healthcare, the sleep apnea diagnostic and treatment worldwide market was estimated to exceed $3 billion.

The severity of sleep apnea is typically measured by:

- the number of partial or complete airway blockages in an hour, referred to as the apnea-hypopnea index, or AHI. For example, moderate OSA patients have an AHI of 15 to 30 events per hour, while severe OSA patients have an AHI of more than 30 events per hour; or

- the average number of respiratory disturbances and related arousals, or RERAs, per hour of sleep, referred to as the respiratory disturbance index, or RDI.

Left untreated, sleep apnea increases the risk of serious chronic conditions, such as high blood pressure, cardiac arrhythmias (such as atrial fibrillation) and other cardiovascular disease, metabolic disease, adult type II diabetes and other life-threatening diseases. In particular, published research shows that, if sleep apnea is untreated: (1) the risk of stroke or death from sudden cardiac arrest doubles; (2) the risk of death from CVD is five times greater; and (3) the risk of recurrence of atrial fibrillation following ablation increases by 42%. In addition, a 2010 study published in Anesthesiology Clinics and a 2018 study published by the Journal of the American Heart Association illustrate the following co-morbidities associated with sleep apnea: drug resistant hypertension (63-83% of the studied patients with drug resistant hypertension were diagnosed with OSA); congestive heart failure (76%); diabetes type 2 (36%); stroke (71-90%); arrhythmias (58%); ischemic heart disease (38%); and atrial fibrillation (49%).

There are several treatment options for sleep apnea, including: (1) CPAP machines that are used with a variety of breathing masks — the mask, worn snugly over the nose or mouth during sleep, uses the CPAP machine to supply pressurized air that flows continuously or intermittently into the throat to prevent the airway from collapsing; (2) MADs also known as sleep apnea oral or dental appliances — that are used to position the lower jaw slightly forward of its usual rest position, which may be enough to keep the airway open during sleep for patients with mild to moderate OSA; and (3) other treatment options, such as positional pillows, upper airway neurostimulation devices, tongue ablation and even surgery.

Linkage between Sleep Apnea and Cardiovascular Disease

There is increasing awareness among cardiologists and the general population of the importance of sleep apnea in the causation or promotion of hypertension, coronary artery disease, heart failure, atrial arrhythmias, and stroke, and, consequently, as a predictor of premature cardiovascular death.

A 2013 study published in American Journal of Epidemiology estimated that sleep apnea is evident in 26% of adults in the general population, but in certain cardiovascular diseases its prevalence can be 40-60%. Similarly, according to research published in the Journal of the American College of Cardiology in 2017, sleep apnea is highly prevalent in patients with cardiovascular disease and evidence supports a causal association of sleep apnea with the incidence and morbidity of hypertension, coronary heart disease, arrhythmia, heart failure and stroke. In many cases, sleep apnea was demonstrated to increase the risk for cardiovascular disease or its recurrence post treatment — such as in atrial fibrillation, high blood pressures and myocardial infarction. The 2017 research also indicates that patients undergoing surgery or other invasive procedures who suffer from sleep apnea are at a greater risk to develop post-operative complications and recurrence of the disease.

Other studies also support the linkage between sleep apnea and cardiovascular disease. For example, a 2017 study published in Circulation: Arrhythmia and Electrophysiology concluded, among other things, that OSA is associated with structural and functional atrial remodeling, and that in the sleep apnea cohort, post pulmonary vein, or PV, isolation, additional non-PV triggers elimination improves ablation outcome, compared with the cohort with no sleep apnea where PV isolation only was sufficient. In addition, this 2017 study calls for conducting sleep studies before ablation, which lead us to believe that the presence of sleep apnea may help define the ablation strategy.

Current Alternatives for Sleep Apnea Diagnosis and their Limitations

According to the 2017 clinical practice guidelines published by the AASM, a definitive diagnosis of sleep apnea can be made with either (1) a PSG study or test, conducted during an overnight visit to a sleep laboratory or sleep center, or (2) through the aid of a technically adequate HSAT:

- *In-lab PSG Tests*. PSG tests have been the standard method of diagnosing sleep apnea. They are performed in a sleep lab while the patient is constantly monitored by medical professionals, usually sleep technicians. Patients are hooked up to a web of sensors, electrodes and wires attached to various body parts, as well as chest and abdomen belts and air tubes in the nostrils. PSG tests typically record 12 or more channels of measurements, including brain waves, eye and chin movements that signal the different stages of sleep; heart rate and rhythm; respiration, such as nasal air flow; abdominal and chest belts; and oxygen levels in the blood.

- *Home Sleep Apnea Test*. HSATs are low-cost, portable devices that allow patients to be tested in the comfort of their homes. They vary in terms of the number of channels or parameters that they measure, the simplicity in setting up and using the technology, and the level of comfort afforded to the patient. Most HSATs are self-administered and the data collected is downloaded and interpreted by a board-certified sleep physician after the equipment is returned.

We believe that there are several shortcomings to in-lab PSG testing, including:

- *Inconvenience*. Patients must travel to a sleep lab and stay overnight;

- *Cost*. Third-party reimbursement for PSG is higher than for HSAT devices. We estimate that PSG testing in the United States is reimbursed by Medicare at an approximate range of between $600 and $1,100, compared to HSAT tests described by codes 95800 and 95806, that are reimbursed by Medicare at an approximate range between $120 and $170. As a result, patient deductibles or copayments for HSATs can be considerably lower;

- *Access to Care*. Due to a limited number of sleep centers and higher denial rates by medical insurance companies (requiring an HSAT prior to approving an in-lab PSG test), patients often have to wait longer for their scheduled appointment; and

- *Patient Discomfort and Quality of Sleep During a PSG Test*. Patients are less likely to have a typical night's sleep in a sleep lab, compared to sleeping in their own homes. This is primarily because they are in an unfamiliar setting, hooked up to a web of sensors and wires, while being watched by strangers, potentially exposed to allergens which do not exist in their home environment (such as pollens and animal particles).

We believe that HSATs address many of the shortcomings of PSG, as HSATs provide easy access to care, are more convenient for the patient, are less expensive and provide a more typical night sleep recorded in the comfort of the patient's home.

The importance of HSATs has been recognized by various medical organizations and associations. The AASM approved the usage of home sleep testing to aid in the diagnosis of sleep apnea with a portable sleep device in 2009. In addition, in 2008, CMS approved HSATs as a new covered technology alternative and, by 2011, CMS recognized new "Current Procedural Terminology", or CPT codes, and "Healthcare Common Procedure Coding System", or HCPCS codes, for HSAT reimbursement. As such, various commercial payors have been implementing prior authorization programs stipulating that reimbursement requests for in-lab PSG testing would be rejected, unless an HSAT was first conducted. These all contribute to increased use of HSATs and we believe that it will become the predominant form of sleep testing in the future, at least in the United States.

Despite the advantages of HSATs over PSG tests, we believe there are several deficiencies in cardio-pulmonary HSAT devices, to which we sometimes refer herein as traditional HSAT devices. These deficiencies include:

- *Possible Misdiagnosis*. Most HSATs use Total Recording Time, or TRT, as their denominator to calculate the most critical criteria of the Apnea Hypopnea Index, or AHI, the index used by physicians to analyze sleep apnea, compared with PSG tests that use Total Sleep Time, or TST. TST is similar to TRT but deducts the total time that the patient was awake, such as the time it takes the patient to fall asleep, insomniac episodes and trips to the restroom. The use of TRT without manual scoring of the data by a sleep technician has been proven in recent studies to result in a net misdiagnosis of up to 20% of patients; and

- *Completion Rates*. The rates of completion of traditional HSATs are relatively low in the first night due to technical challenges, such as disconnection of sensors, mainly due to finger oximetry and nasal probes, and patient self-setup errors. For example, according to a 2014 study published by Frost & Sullivan, approximately 20% of HSATs fail in the first night.

Direct to Consumer Market Overview

In 2019, we started focusing on the DTC market, and we plan to launch our DTC activity during the first half of 2020. We believe the raising awareness of sleep apnea and its adverse health effects, combined with consumer demand for cost effective, accessible solutions, overcome inefficiencies in traditional healthcare provider systems, may represent an opportunity for us to enhance the sales of our technology platform directly to consumers.

In this market segment we plan to offer through channel partners, who have an off-line and on line consumer market presence, a full digital health sleep apnea solution for the patient, at the comfort of their home. We plan to address this market with our prescription WatchPAT 300 device as well as the WatchPAT ONE fully disposable prescription device, combined with our CloudPAT and SleePath digital care continuum management assets.

With the support of our operational capabilities, we have developed in the implantation of our WatchPAT Direct program, we plan to provide best in class digital health patient pathway management services through these partners.

To facilitate the clinical oversight of the patients in this journey, we plan to facilitate remote on-line consultation through our CloudPAT system in order to create an on-line market place that allows demand for clinical services to be met with qualified and certified physicians. That way, we will facilitate patient access to real time consultations, advice and therapy prescriptions throughout the care pathway. In addition, we have partnered with high quality sleep practices and DMEs that have demonstrated effective ability to set up CPAP therapeutic solution remotely, as well as monitor and drive compliance.

We believe that our digital health platform can facilitate the journey of patients from diagnosis to therapy and compliance in an easy, efficient and innovative manner which we believe will make our offering successful in this new market segment and will position the company for new growth opportunities. Our DTC partner, SoClean, has launched this DTC activity during March 2020.

Our Products and Services

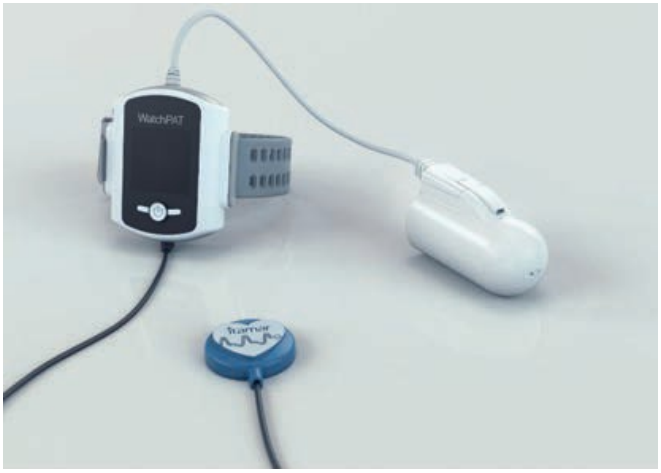
The WatchPAT Family of Products

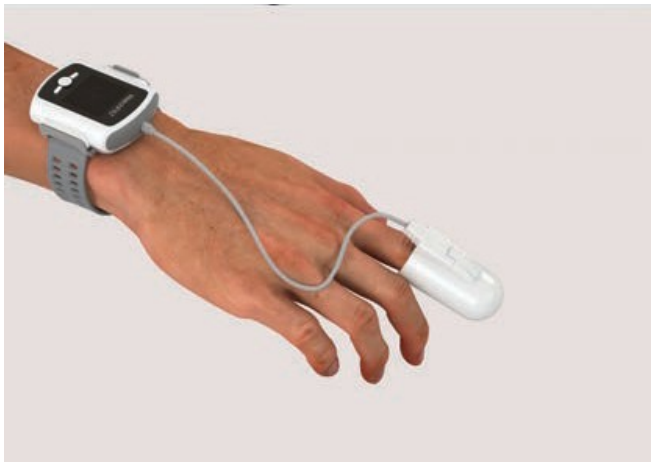
Overview. Our prescription WatchPAT sleep apnea test line of products, the first generation of which received its initial United States Food and Drug Administration, or FDA, clearance in 2001, is a watch-like wrist-mounted device with one or two (depending on the model of the WatchPAT product) single-use disposable bio-sensors connected to the patient’s fingers, designed to non-invasively record, measure and analyze digital pulse volume change, or changes in arterial blood volume.

The product is based on our proprietary, clinically validated, technology using the PAT signal, which is capable of monitoring the PAT signal to analyze it for diagnostic purposes. The PAT signal measures changes in the patient’s peripheral arterial pulse volumes as well as various parameters of arterial activity. These arterial activity parameters accurately reflect the patient’s sympathetic nervous system (autonomous (involuntary) nervous system) activity. The WatchPAT continuously records and interprets the autonomic or involuntary nervous system activation during sleep, as measured through the PAT signal. The PAT probe uses optical sensors to non-invasively measure the changes in arterial blood volume while applying sub-diastolic pressure on the distal two thirds of the finger, including the tip. The pressure fields reduce the arterial wall tension and generate a greater dynamic range of the measured PAT signal and improved sensitivity to changes in the signal amplitude.

With the original models of the WatchPAT, the patient had an additional oximetry sensor attached to another finger measuring blood oxygen saturation. In 2014, we introduced WatchPAT 200 Unified, which allows our proprietary sleep apnea test to be performed using only a single finger to collect both oximetry and PAT data in a unified probe. In the year ended December 31, 2018, the WatchPAT 200 Unified was our main product offering. In March 2019, we introduced the WatchPAT 300, a new generation of the WatchPAT line of products, which, among other things, is designed to expedite data transfer and allow the use of a lighter and smaller watch. In June 2019, we received FDA clearance for our WatchPAT ONE, which, to our knowledge, is the first and only disposable HSAT diagnostic aid on the market. The WatchPAT ONE collects the same data as the WatchPAT 200 Unified and WatchPAT.

The following pictures depict the WatchPAT 300 device:





The following pictures depict the WatchPAT ONE device:

Key Features

The key features of WatchPAT are as follows:

· *Single-use disposable bio-sensor*. WatchPAT 300 and WatchPAT 200 Unified employs a single-use disposable finger bio-sensor to measure the PAT signal. The bio-sensor is built of external hard shell and sensitive internal membrane that create blood pooling in the finger circulation as well as sensitive optical sensors designed to accurately measure changes in blood volumes and oxygen levels.

- *Reusable WatchPAT 200 Unified and WatchPAT 300 devices*. Except for the bio-sensor, the WatchPAT 200 Unified and WatchPAT 300 devices are reusable and returned to the physician or clinic after patient use.

- *Data processing*. The data acquired by the various sensors is automatically processed by our proprietary algorithm and a final report is automatically generated to the physicians through local or cloud-based software.

- *Seven channels*. WatchPAT is designed to measure seven unique parameters, also known as channels:

    - *PAT* — which is a physiological signal that mirrors changes in the autonomic nervous system caused by respiratory disturbances during sleep.

    - *Oximetry* — the measurement of oxygen levels in the blood.

    - *Actigraphy* — the measurement of body movement while sleeping. WatchPAT actigraphy is equipped with adaptive algorithms that prevent detection of severe apneic events, such as wakefulness.

    - *Heart Rate* — the number of heart beats per minute while sleeping.

    - *Body Position* — notes whether the patient is asleep on back (supine), front (prone) or side, all of which influence sleep apnea.

    - *Snoring Intensity* — loud snoring is a major indicator of sleep apnea.

    - *Chest Motion* — three axial movement of a point on the chest, just under the sternum notch, during the breathing cycle.

- *Rich Data Output*. WatchPAT uses the seven channels of patient data and our proprietary algorithms to process and provide the physicians various data outputs to aid their diagnosis, including:

    - *Total Sleep Time* — WatchPAT reports both TST and basic Hypnogram (also known as sleep architecture), even though it does not employ the traditional airflow and chest and abdominal effort belts channels nor the electroencephalograph, or EEG, and eye movement detectors used in some other HSAT devices.

    - *Apnea/Hypopnea Index, or AHI, and RDI* — WatchPAT provides information on AHI and RDI, the clinically accepted indices that determine the severity of sleep apnea.

    - *Central Sleep Apnea, or CSA*. — With our Central Plus module, WatchPAT can also provide quantification of AHI, which is the portion of events per hour that are identified as CSA and percent of sleep time with Cheyne- Stokes Respiration.

    - *Oxygen Desaturation Index, or ODI* — WatchPAT provides information on ODI, which is the total number of blood oxygen saturation drops per hour of sleep, as well as statistics about the blood oxygen saturation statistics throughout the night.

    - *Sleep Stages and Architecture* — WatchPAT provides information on the cyclical pattern of sleep stages, summarized in a chart called a hypnogram, which differentiates between the non-REM stages of light sleep, deep sleep and REM (rapid eye movement) sleep. REM related sleep disorders are associated with significant higher risk for hypertension.

    - *Sleep Fragmentation* — WatchPAT detects repeated short interruptions of sleep throughout the night.

- *Other* — WatchPAT provides data on outputs of various other channels, including heart rate, body position and snoring intensity.

Key Benefits of WatchPAT

We believe that WatchPAT has several key advantages over in-lab PSG testing and competing HSAT products by providing the following key benefits:

- *Ease of Use and Patient Comfort*. Composed of a simple wrist worn watch-like device with one finger probe (in the WatchPAT 200 Unified, WatchPAT 300 and WatchPAT ONE models), the prescription WatchPAT was specifically designed for home sleep apnea testing for appropriate patients with minimal patient education. As such, we believe it is easy and intuitive to operate for patients, equipped with validated automated scoring algorithms that reduces time of processing and analyzing the raw data collected to few minutes, compared with manual scoring that we estimate takes on average between 30 to 40 minutes. We estimate that these advantages also translate to a test completion rate of 98%, compared with other HSAT devices that have estimated completion rates of 80%.

- *Accuracy*. Based upon, among other things, several studies, including a meta-analysis study, we believe that the WatchPAT offers accuracy that, while not equivalent, presents a viable alternative to in-lab PSG for confirmation of clinically suspected sleep apnea. In addition, our WatchPAT devices have several features that are provided by in-lab PSG but we believe are lacking in most traditional HSATs, including:

    - The ability to accurately report TST, not just TRT like in traditional HSATs. The TST detection is important for patients who tend to wake up frequently during the night or suffer from insomnia; and

    - The ability to detect sleep stages, with a focus on REM sleep. The diagnosis of REM related sleep patients can be missed because their overall AHI is low, whereas their REM-related AHI is high. According to one study from 2014, if REM related sleep apnea is left untreated, it is associated with up to a 24% increase in risk for hypertension.

- *Cost*. The total cost of a WatchPAT test is less expensive for third-party payors than an overnight sleep center test. We estimate that PSG testing is reimbursed by Medicare in the United States at an approximate range of between $600 and $1,100, compared to HSAT tests described by codes 95800 and 95806 that are reimbursed by Medicare at an approximate range of between $120 and $170 and, consequently, the deductible to the patient for HSATs is lower. We believe this cost advantage to payors and patients will help drive market penetration.

- *Provides Immediate and Easy-to-Read Results*. Most in-lab PSG and HSATs require a sleep technician to review and interpret the raw data recording and identify areas of poor signals, wakefulness and other technical issues related to nasal cannula motion. The WatchPAT is designed to provide validated automated reports, without the need for the additional step of a sleep technician's review.

WatchPAT 300. In April 2018, we publicly announced that we submitted our application to the FDA for clearance of the prescription WatchPAT 300, a new generation of the WatchPAT line of products that is designed to expedite data transfer, allow the use of a lighter and smaller watch and reduce manufacturing costs. The WatchPAT 300 also lays the foundation for possible additional future capabilities, such as wireless communication embedded in the device. In August 2018, we obtained the FDA clearance of the WatchPAT 300 for use with patients suspected to have sleep related breathing disorders as a diagnostic aid for the detection of sleep related breathing disorders, sleep staging, snoring level and body position, and, in March 2019, we announced the commercial launch of the WatchPAT 300.

WatchPAT ONE. In January 2019, we publicly announced that we submitted our application to the FDA for clearance of WatchPAT ONE, the first and only disposable HSAT that does not require the patient to return the WatchPAT to the physician or clinic. In June 2019, we received FDA clearance for the prescription WatchPAT ONE for use with patients suspected to have sleep related breathing disorders as a diagnostic aid for the detection of sleep related breathing disorders, sleep staging, snoring level and body position, and commenced with a limited commercial introduction. The WatchPAT ONE uses an app on a smartphone to guide the patient through the set-up, initiation and completion of the sleep study. Through Bluetooth connection, data is transferred from the WatchPAT ONE to the smartphone app and then transferred to a secure server through a WiFi or cellular connection.

WatchPAT Related Services and Accessories

Total Sleep Solution. Our TSS program aims to provide a complete sleep apnea management solution to cardiology customers, either at the cardiology center or through third-party service providers. The key components of our TSS program, which is currently offered only in the United States, include:

- *Screening* — We provide information and best practices that help cardiology clinics to properly implement patients' systematic screening to identify patients with high pre-test probability into their practice workflow routine by using validated questionnaires, such as STOP-Bang (Snoring, Tired Observed stop breathing, high blood Pressure, BMI, Age, Neck size and Gender). This initial screening is a required documentation step by most insurance companies to qualify for HSAT reimbursement;

- *Diagnostics* — Following initial screening, we aid the diagnostic stage by offering (1) home sleep testing using our WatchPAT family of products; use of our CloudPAT solution, as described below, to transfer the test results to a board-certified sleep physician for customers who prefer outsourcing the logistics; or (2) for those customers who prefer to prescribe for the test only, access to a network of IDTF for patient diagnostic services using the WatchPAT or other HSAT devices;

- *Treatment* — Through arrangements between the clinics and DMEs, providers, patients diagnosed with sleep apnea can be provided with sleep apnea therapy devices, such as CPAP, or, by the clinic referring to dentists specializing in sleep medicine, with prescriptions for MADs. Those providers may use third-party therapy devices, if the certified sleep physician assigned to interpret the test results prescribes such devices; and

- *Reporting* — Using our CloudPAT and SleePath solutions, as described below, we facilitate the cardiology customers' receipt of status reports and to otherwise monitor the patients' sleep apnea management status and compliance, if their DME providers use devices compatible with our SleePath solutions.

WatchPAT Direct. WatchPAT Direct is a set of logistic support services that we offer from our service center in Atlanta, Georgia. These services follow the prescription orders and include the coordination and delivery of the WatchPAT to the patient and the shipment back to our service center in Atlanta. Once the device is returned the data from the device is downloaded and delivered to an assigned physician for interpretation, WatchPAT Direct is currently offered only in the mainland United States.

CloudPAT. CloudPAT is a cloud-based information technology, or IT, platform, designed to allow customers to transfer the WatchPAT test results primarily to board-certified sleep physicians, IDTF and DMEs. The board-certified sleep physicians receive and interpret the test results, make a diagnosis and potentially prescribe therapy. In the United States, the signing off on the diagnostic report by a board-certified sleep physician is required by the reimbursement guidelines of AASM and CMS. The CloudPAT, together with the SleePath will also be used to deploy our direct to consumer digital health model and provide digital health patient pathway management services directly to consumers, including through channel partners. We plan to facilitate, via our CloudPAT, remote on-line consultations in order to create an on-line market place that will allow demand for clinical services to be met with qualified and certified physicians. The CloudPAT will facilitate patient access to real time consultation, advice and prescriptions throughout the care pathway.

zzzPAT. zzzPAT is an analysis software used in conjunction with our WatchPAT family of products. This software stores the recorded raw signals and provides a set of both automated as well as manual scoring and analytical functions for interpretation and reporting purposes used in the diagnosis of sleep apnea.

SleePath. SleePath is an integrated e-health sleep apnea care pathway monitoring module, included as part of our CloudPAT system, that is designed to allow cardiologists to monitor a patient's sleep apnea management status and compliance with CPAP therapeutic devices on demand. Key features of SleePath include (1) utilizing data from both the CloudPAT and the cloud-based data transmitted and stored by leading CPAP devices manufacturers, including Philips United States and ResMed, to provide a "cardio sleep dashboard", which is designed to allow physicians to track the sleep care pathway status of both the physician practice and the individual patient; and (2) the system monitors and reports CPAP device compliance (the number of days and hours on CPAP and residual sleep apnea), with the data being presented in a user-friendly visual format that is designed to show progress or deviation toward specific treatment goals and changes in metrics over time.

The EndoPAT

The EndoPAT device, the first generation of which received FDA clearance in 2003, is designed to diagnose endothelial function by measuring the ability of blood vessels to dilate as a response to shear stress, or other stimuli, in order to accommodate increased blood flow. The endothelium is the inner lining of all blood vessels regulating their function and ability to dilate or constrict. The EndoPAT device uses our PAT-based technology to measure the ability of blood vessels to dilate after an artificially created CVD. In the United States, EndoPAT has no reimbursement and is sold primarily for research purposes. We anticipate that, in 2020, we will begin selling our newly developed EndoPATX for which we recently received authorization to affix a CE mark.

Clinical Results and Studies

We have invested in and developed a significant body of clinical studies and data that demonstrates the effectiveness and safety of our WatchPAT family of products by validating it against "gold-standard" PSG tests. The effectiveness and safety of our WatchPAT family of products have been consistent across both company-funded and independent clinical studies that have evaluated, in the aggregate, more than nine hundred patients, all of which have been published in peer-reviewed publications.

The following is a summary that highlights key findings from some of these studies. We believe that (except to the extent indicated under "*Impact of Arterial Stiffness on WatchPAT Variables in Patients With Obstructive Sleep Apnea*" below) (1) these studies are the most material, reliable (primarily in the sense that the study uses commonly adhered procedures for such type of studies) and comprehensive studies conducted that are relevant to our main product, the WatchPAT, (2) these studies address (whether in a favorable or negative manner) material elements underlying our statements regarding the key features of the WatchPAT and its comparison to PSG tests, and (3) disclosing such studies is meaningful to investors.

In our discussion of the results of the studies described below, we have indicated the relevant p-values, or P, which demonstrate the statistical significance, all of which are less than 0.05, which is the commonly accepted threshold for statistical significance and follows the convention used by the authors of the relevant studies as well as what we believe is standard clinical practice.

Where we have not indicated the p-value in the results of the studies described below, it is either because the relevant result is not a statistical parameter or the study itself did not publish the p-value for the specific result. We believe such findings, despite the lack of p-value, are still meaningful and useful to investors primarily because they were part of the findings highlighted or conclusions provided by the authors and are otherwise relevant to an understanding of our WatchPAT family of products and, with respect to the Health Provider System Study described below, also illustrate how one health provider has evaluated the transition from PSG tests to HSATs.

Diagnosis of Obstructive Sleep Apnea by Peripheral Arterial Tonometry

This meta-analysis study, which was published in JAMA Otolaryngology — Head & Neck Surgery in December 2013, aimed to assess the correlation between sleep indexes (namely, RDI, AHI and ODI, which indexes are described under "*Marketing Overview and Our Solutions*" above) measured by a PAT-based portable sleep testing device (using our WatchPAT family of products) and those measured by PSG tests, by conducting a review of multiple studies that, overall, examined 909 patients.

The key results of this study were that (1) studies comparing the RDI between the PAT-based tests and PSG tests had a correlation of r = 0.879 (P<0.001), where r = 1.00 would indicate the highest correlation; (2) studies comparing the AHI between the PAT-based tests and PSG tests had a correlation of r = 0.893 (P<0.001); and (3) studies comparing the ODI between the PAT-based tests and PSG tests had a correlation of r = 0.942 (P<0.001).

Based on the results, we believe PAT-based portable devices, such as our WatchPAT family of products, present a viable alternative to PSG for confirmation of clinically suspected sleep apnea.

Impact of Arterial Stiffness on WatchPAT Variables in Patients with Obstructive Sleep Apnea

This study, which was published in Journal of Sleep Medicine in March 2018, aimed to assess the effects of arterial stiffness on WatchPAT results, by examining a total of 61 patients with suspected OSA, where each patient initially underwent a home sleep study with WatchPAT, followed, after an average of 39 days, by both an in-lab full PSG sleep study and an arterial stiffness evaluation using a Brachial-Ankle Pulse Wave Velocity, or baPWV, test.

The key results of this study were that (1) overall, WatchPAT's apnea-hypopnea index, or AHI, was moderately correlated (r=0.69) to those AHI of PSG (P<0.0001); (2) for patients with lower baPWV, there was a significant correlation between the WatchPAT and PSG's AHI (for example, for patients with baPWV< 1500, r = 0.782 (P≤0.0001)); and (3) for the high baPWV group, there was low or non-significant correlation between the WatchPAT and PSG's AHI (for example, for patients with baPWV>1500, r=0.397 (P=0.04)). The study concluded, on a cautionary note, that high arterial stiffness may affect the respiratory variables measured by WatchPAT.

We note that, while this study addresses (in a positive as well as negative manner) various features of the WatchPAT and its comparison to PSG tests, we believe its results are limited for the following primary reasons: (1) the WatchPAT validation comparison with the PSG test was conducted after a delay of 39 days on average, instead of being performed simultaneously as in most WatchPAT validation studies. Based on the literature on the consequences of delays of such length between repeated studies, we believe the delay may have introduced a substantial degree of variability between respective tests; and (2) the study used an AHI threshold of 30 to diagnose OSA instead of using other, lower and more commonly used conventional diagnostic AHI thresholds, such as an AHI threshold of 15.

Sleep Staging Based on Autonomic Signals: A Multi-Center Validation Study

This multi-center study, which was published in the *Journal of Clinical Sleep Medicine* in June 2011, aimed to assess the WatchPAT-based algorithm for determining wake, light sleep, deep sleep, and REM sleep based on epoch-by-epoch comparisons to PSG tests, by monitoring a total of 237 patients (of which 38 were normal and 189 were diagnosed with OSA) that underwent simultaneous, synchronized overnight recordings with PSG and the WatchPAT. As described under "*Our Products and Services — The WatchPAT Family of Products — Sleep Stages and Architecture*," the ability to detect the various sleep stages provides important information on the cyclical pattern of sleep stages, which differentiates between light sleep, deep sleep and REM sleep. It should be noted that this study, which was authored by, among others, certain of our current or former employees and consultants, was partially sponsored by us and, to our knowledge, also used certain data from previous studies that we supported.

The key results of this study were that (1) the overall agreement between PSG tests and WatchPAT in detecting light/deep sleep was 88.6% ± 5.9% (P<0.05); (2) the overall agreement between PSG tests and WatchPAT in detecting REM sleep was 88.7% ± 5.5% (P<0.05); (3) detecting REM latency provided similar results in PSG tests and WatchPAT (237 ± 148 and 225 ± 159 epochs in PSG and WatchPAT, respectively) (P<0.05); (4) quantifying REM percentage in PSG tests and WatchPAT was 14.4% ± 6.5% and 19.3% ± 8.7%, respectively (P<0.05); and (5) detecting sleep efficiency in PSG tests and WatchPAT provided similar results (78.4% ± 9.9% and 78.8% ± 13.4% in PSG and WatchPAT, respectively (P<0.05)). In addition, according to this study, OSA severity did not affect the sensitivity and specificity of the WatchPAT algorithm.

Based on the results, we believe this study showed that WatchPAT is capable of detecting sleep stages with moderate agreement to PSG tests in normal subjects and OSA patients and that sleep staging based on actigraphy and signals recorded by the WatchPAT is of reasonable accuracy.

A Novel Adaptive Wrist Actigraphy Algorithm for Sleep-Wake Assessment in Sleep Apnea Patients

This study, which was published in *Sleep* in December 2004, aimed to validate an automatic algorithm, developed for actigraphic studies in normal subjects and patients with OSA, by comparing it on an epoch-by-epoch basis to PSG tests, by monitoring a total of 228 subjects from three different sleep centers that underwent simultaneous, synchronized recordings with PSG and the WatchPAT (a model with a built-in actigraph). It should be noted that, to our knowledge, this study used certain data from other previous studies that we have supported.

The key results of this study were that (1) the overall agreement between PSG and WatchPAT ranged from 86% in normal subjects to 86%, 84%, and 80% in the patients with mild, moderate, and severe OSA, respectively ($P<0.05$); (2) the overall sensitivity (i.e., the probability that WatchPAT detected sleep when the PSG detected sleep at that epoch) and specificity (i.e., the probability that WatchPAT detected wake when the PSG detected wake at that epoch) to identify sleep was 89% and 69%, respectively; and (3) there was a very small statistical difference between WatchPAT and PSG in determining sleep efficiency (i.e., the total sleep time as percentage of the amount of time spent in bed from first attempting to go to sleep until final waking up) (78.4% +/- 9.9% and 78.8% +/- 13.4%, respectively) and TST (690 +/- 152 epochs and 690 +/- 154 epochs, respectively) but there was a significant difference in determining sleep latency (i.e., the time it takes for the patient to fall asleep) (56.8 +/- 31.4 epochs and 43.3 +/- 45.4 epochs, respectively). For most individuals, the difference between the PSG and actigraphy was relatively small, although for some there was a substantial disagreement up to a maximum of 37% in sleep efficiency.

Based on the results, we believe this study showed that the WatchPAT actigraphy algorithm provides a reasonably accurate estimation of sleep and wakefulness in normal subjects as well as in OSA patients.

Health Provider System Study

This study, which was published under the title *The Effect of the Transition to Home Monitoring for the Diagnosis of OSAs on Test Availability, Waiting time, Patients' Satisfaction, and Outcome in a Large Health Provider System* in Sleep Disorders in April 2014, to which we refer as the Health Provider System Study, aimed to assess the effects of the transition of one of the leading health insurance providers in Israel from PSG tests to HSATs in terms of accessibility, waiting time, patient satisfaction, costs and CPAP device purchases by patients, by comparing data that was retrieved from the insurance provider's database of 650,000 patients between the period of 2007-2008 and 2010-2011 (2009 was excluded during the transition from PSG to HSAT).

The key results of this study were that (1) 1,471 sleep studies were conducted during 2007-2008 (or, on average, 735.5 studies per year), compared with 2,794 sleep studies (or, on average, 1,397 studies per year) during 2010-2011 ($P<0.05$), reflecting a 90% increase of the number of sleep study tests performed following the transition to HSAT (while the increase in total insured people during same period was less than 5%); (2) despite an increase in the number of tests, the shift to HSAT was accompanied by a decrease of over 20% in overall expense of OSA diagnosis; (3) the average waiting time decreased from 9.9 weeks during 2007-2008 to 1.1 week during 2010-2011 ($P<0.05$); (4) CPAP device purchases increased by 39%, from 597 devices in 2007-2008 to 831 devices in 2010-2011; (5) there were similar outcomes for both HSAT and PSG tests of compliance to CPAP treatment, daily CPAP usage, improvement in daytime sleepiness and quality of life, and patient satisfaction; and (6) in retrospect, 56% of patients who underwent PSG tests indicated that they preferred HSAT and 72% of patients who underwent HSATs indicated that they preferred HSAT ($P<0.05$).

Based on the results, we believe this study showed that a transition from in-lab testing to unattended home sleep testing improved OSA diagnosis test accessibility reduced waiting time and reduced overall OSA diagnosis costs, while maintaining patient satisfaction.

Sales and Marketing

General. Our WatchPAT family of products and related services are sold and marketed through both direct and indirect channels, including distributors. Our primary customers are hospitals, medical centers (including sleep centers), health management organizations (HMOs), physicians (including sleep specialists), research institutions and cardiology practices and departments. The targeted customers for our WatchPAT technology are primarily cardiologists and electrophysiologists who are interested in integrating sleep medicine into their practice, as well as physicians who specialize in sleep medicine. Sleep specialists represent a variety of medical backgrounds, including pulmonologists (lung specialists), otolaryngologists (ears, nose, and throat), neurologists, primary care physicians and dentists. Our physician customers typically practice in office settings, clinics, or hospitals. Our EndoPAT products and related services are sold primarily through indirect channels to research institutions and directly to pharmaceutical companies to support their clinical research.

We offer our WatchPAT family of products to customers in two main business models:

- TaaS whereby our customers pay a fixed fee per each home sleep test conducted with our product. The fee per test includes all the components associated with the test, including the disposable bio-sensor (one disposable is used once with each WatchPAT test), the hardware (the WatchPAT device itself) and access to our CloudPAT platform; and

- Capital purchase, whereby our customers purchase and own the hardware (the WatchPAT device itself), the disposables bio-sensor (one disposable is used once with each WatchPAT test) and other related accessories. We also offer our customers capital purchase through a lease model, whereby the customer leases the product for monthly lease payments, typically over a period of between 18 to 24 months, and becomes the owner of the product at the end of the lease period in consideration for a nominal amount.

While sleep physicians and traditional sleep business represent the majority of our United States customers today, consistent with our strategy, our plan is that cardiologists will represent the majority of our growth and will become an increasingly larger component of our United States sleep business over time.

In the years ended December 31, 2019, 2018 and 2017, a substantial majority of our revenues were derived from our WatchPAT family of products and related services (92.7% in the year ended December 31, 2019, 92.5% in the year ended December 31, 2018 and 87.5% in the year ended December 31, 2017). In terms of geographic markets in the years ended December 31, 2019, 2018 and 2017, a substantial majority of our revenues were from sales in the United States (73.5% in the year ended December 31, 2019, 72.7% in the year ended December 31, 2018 and 71.3% in the year ended December 31, 2017). For additional details regarding the breakdown of our revenues by geographical distribution and by activity, see Item 5.A. "*Operating and Financial Review and Prospects — Operating Results*".

For the year ended December 31, 2019, (1) Kaiser, one of the largest medical insurers and hospital system in the United States, accounted for approximately 22.4% of our total revenues (compared with 18.9% in the year ended December 31, 2018 and 17.5% in the year ended December 31, 2017); (2) Philips Japan, a leading global provider of solutions to the sleep and respiratory market, accounted for approximately 11.0% of our total revenues (compared with 13.3% in the year ended December 31, 2018 and 12.7% in the year ended December 31, 2017); and (3) VA, one of the largest United States hospital and clinics chains, accounted for approximately 6.6% of our total revenues (compared with 11.9% in the year ended December 31, 2018 and 12.1% in the year ended December 31, 2017).

Direct Sales. We continue to develop our sales and marketing organization that consists of a dedicated sales team that is complemented by a marketing team as well as sales and marketing support personnel. Our sales force (including marketing, sales and sales and marketing support personnel) as of December 31, 2019, was comprised of a total of 72 persons, of which 63 persons were located in the United States (in the United States, we had 27 distinct geographic territories (including three verticals) as of December 31, 2019) and 9 persons were located in other locations. *Indirect Sales and Strategic Collaborations*. Over the course of the past several years, we have focused on developing long- term strategic partnerships with distributors and other business partners, including leading global partners such as Medtronic and Philips Respironics:

- *Co-Marketing Agreement with Medtronic, Inc.* In April 2015, we entered into a co-marketing agreement with Medtronic, Inc., an indirect wholly owned subsidiary of Medtronic plc. Medtronic currently markets and sells its cardiac ablation products for the treatment of cardiac arrhythmias, including atrial fibrillation condition. Under the co-marketing agreement, Medtronic was granted exclusive rights to co-market, with us, our WatchPAT family of products within our Total Sleep Solution framework to electrophysiologists (physicians who specialize in cardiology arrhythmias) in the United States.

- *Distribution Agreement with Philips Respironics GK*. In February 2014, we entered into a distribution agreement with Philips Respironics GK, a subsidiary of Koninklijke Philips NV (also known as Royal Philips), or Philips Japan, which was renewed in December 2018 for an additional three years' period until December 2021. Under the distribution agreement, Philips Japan was granted exclusive rights to distribute our WatchPAT family of products and ancillary accessories in Japan. According to this agreement, we may terminate the agreement if Philips Japan does not meet certain minimum purchase requirements of our products.

- *Co-Marketing Agreement with BioTel Heart, a division of BioTelemetry, Inc*. In June 2019, we expanded our pilot program to make our Total Sleep Solution available to select BioTel Heart cardiology customers in the United States. We conducted a successful pilot program with several BioTel Heart customers and are making the service available in additional targeted regions and we continue to evaluate the expansion of such collaboration. The collaboration is designed to respond to the growing demand for home sleep apnea testing among cardiologists, who recognize effective sleep apnea management as a critical strategy for improving health in patients with cardiac disease. Such collaboration provides the framework for cardiologists to prescribe home sleep apnea tests without worrying about pre-authorization and billing. This next step in our strategy is intended to simplify the integration of our Total Sleep Solution offering into routine cardiac care pathways.

- *Direct to Consumer Services Agreement with SoClean*. In December 2019, we entered into an agreement with SoClean to provide SoClean exclusive rights to market WatchPAT ONE directly to consumers in the United States with additional on line services to be facilitated by our CloudPAT digital health platform. The collaboration is designed to overcome the barriers to sleep apnea testing by enabling consumers to obtain online sleep consultations and, if prescribed, purchase home based sleep test using the WatchPAT ONE. Under the collaboration, SoClean has committed to a minimum purchase of $4.5 million worth of WatchPAT ONE devices through 2020 with annual growth commitments through 2024 to maintain exclusivity to the DTC segment. SoClean will have exclusive DTC rights in the United States through any and all marketing and sales channels, excluding healthcare providers and facilities.

In order to promote our Total Sleep Solution program, we are also developing partnerships with various business partners whose products or services are complimentary to ours. For example, we have entered into agreements with Philips United States, an affiliate of Philips Japan and ResMED, under which (1) we were granted non-exclusive rights to distribute Philips United States sleep apnea treatment devices, such as CPAP devices, to DMEs that participate in our Total Sleep Solution program to cardiovascular centers in the United States, and (2) Philips United States allowed us to use its cloud-based CPAP data as part of our SleePath platform.

While we view our partnerships with Medtronic, Philips Respironics and other business partners as strategic, our direct sales to healthcare providers represented more than 80% of our total revenues in the year ended December 31, 2019.

Marketing. Our marketing efforts are focused on developing a strong reputation with physicians and hospitals that we have identified as key opinion leaders in cardiology, sleep, and internal medicine based on their knowledge of our technology, clinical expertise and reputation. We do so by various marketing channels, including hosting clinical education programs and symposium and participating in professional conferences to promote our products and increase awareness amongst physicians, primarily cardiologists, to the linkage between sleep apnea and CVD and to the advantages of shifting the point of care for sleep apnea from sleep centers to the cardiology care point.

Third-Party Coverage and Reimbursement

General. In the United States and elsewhere, demand for our products is dependent to a large extent on the availability of coverage and reimbursement from third-party payors, including governmental payors, such as Medicare and Medicaid, and private payors, such as medical insurance providers. The manner in which reimbursement is sought and obtained varies based upon the type of payor involved and the setting in which the product is furnished and utilized. In general, third-party payors will provide coverage and reimbursement for medically reasonable and necessary procedures and tests that utilize medical devices and may provide separate payments for HSATs, such as our WatchPAT family of products and related professional and technical services. However, our EndoPAT product has not obtained, and we do not expect it will obtain, coverage or reimbursement from third-party payors. In determining payment rates, third-party payors are continuously scrutinizing the costs of medical products and services.

United States. In the United States and markets in other countries, patients who are prescribed medical devices for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. WatchPAT devices are typically reimbursed by the patient's health insurance plan, which include governmental health programs in the United States such a Medicare and Medicaid, commercial health insurers and managed care organizations. To obtain approval for reimbursement, payors require a physician's written order, a history of the patient's medical condition and past treatment, and demonstration of medical necessity. In 2009, CMS issued a National Coverage Determination, or NCD, to extend coverage to a number of sleep tests, including the WatchPAT and other sleep testing devices measuring three or more channels that include actigraphy, oximetry, and peripheral arterial tone when used to aid the diagnosis of OSA in Medicare beneficiaries who have signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility or attended in a sleep lab facility.

In November 2010, the American Medical Association, or AMA, which is responsible for maintaining and updating billing codes for medical services and procedures, known as CPT codes, created a new a Category I CPT code for sleep studies using home sleep testing devices such as the WatchPAT: CPT code 95800 ("Sleep study, unattended, simultaneous recording; heart rate, oxygen saturation, respiratory analysis (e.g., by airflow or peripheral arterial tone), and sleep time"), effective January 1, 2011. After CMS issued the NCD and the AMA created the new CPT code, certain commercial third-party payors, including Aetna, Cigna, UnitedHealthcare and others, updated their coverage policies to include coverage for these tests, including the WatchPAT, as described by CPT code 95800. In March 2017, AASM published guidelines establishing updated clinical practice recommendations to aid in the diagnosis of OSA in adults, pursuant to which devices that measure a minimum of the following sensors are technically adequate to diagnose OSA in uncomplicated adult patients presenting with signs and symptoms that indicate an increased risk of moderate to severe OSA: (1) nasal pressure, chest and abdominal respiratory inductance plethysmography, and oximetry, or (2) PAT with oximetry and actigraphy, such as our WatchPAT device, are technically adequate to diagnose OSA in uncomplicated adult patients presenting with signs and symptoms that indicate an increased risk of moderate to severe OSA. In November 2017, AIM Specialty Health, or AIM, a specialty benefits management company who advises many United States health insurance plans on coverage policies, determined that devices utilizing the combination of PAT, actigraphy, EKG/heart rate and oxygen saturation are considered medically necessary when certain clinical criteria are met.

We believe that AIM Specialty Health's, or AIM's, updated clinical guidelines, as well as the July 2019 publication of an updated policy by the Blue Cross Blue Shield Association's, or BCBSA's, Evidence Street organization supporting coverage for HSATs utilizing PAT technology, resulted in expanded coverage of HSATs by several Blue Cross Blue Shield, or BCBS, payors across the country. Since BCBSA's Evidence Street publication, seven BCBS plans covering approximately 15 million lives, most notably Blue Shield of California with 3.7 million covered lives and BCBS Federal Employee Plan with 5.3 million covered lives, have adopted policies providing coverage for HSATs utilizing PAT-based technology, including the WatchPAT device. We believe that the Evidence Street report provides important validation of the clinical value of the PAT technology, which we anticipate additional plans will reference to expand coverage of WatchPAT.

Nevertheless, certain commercial payors and most Medicaid programs currently do not cover HSATs, such as our WatchPAT. In addition, while private healthcare insurers often follow reimbursement policies adopted by Medicare, this is not always the case and the reimbursement terms of different private insurers vary. We invest, and plan to continue to invest, resources in our efforts to expand coverage to include sleep tests using our WatchPAT device.

In addition to uncertainties surrounding coverage policies, there are periodic changes to reimbursement. Third-party payors regularly update reimbursement amounts and also from time to time revise the methodologies used to determine reimbursement amounts. This includes annual updates to payments to physicians for tests using our products. Because the cost of our products generally is recovered by our customers as part of the payment for performing the test and not separately reimbursed, these updates could directly impact the demand for our products. An example of payment updates is the Medicare program's updates to physician payments under the MPFS, which are done on an annual basis using a prescribed statutory formula. In November 2019, CMS issued final revisions to its payment policies under the MPFS, effective January 1, 2020, reducing the work relative value units associated with certain HSAT codes, including 95800. CMS's 2020 MPFS update represents the second year of a 3-year plan communicated by CMS to reevaluate reimbursement in home sleep apnea diagnostic codes. It is unclear the impact, if any, these payment reductions will have on our customers' willingness to adopt the broad use of our WatchPAT and other devices. Any changes in coverage and reimbursement that further restrict coverage of our products or lower reimbursement for tests using our devices could materially affect our business.

International. In other markets outside the United States, HSAT has been endorsed to different degrees. For example, in Sweden, which is characterized with scattered population, HSATs have been promoted as the only means of diagnosis, and, in Germany, an HSAT is the first-line diagnosis tool and PSG is only allowed if multiple HSAT attempts failed to deliver conclusive diagnosis. On the other hand, in Japan, local authorities (namely, the Ministry of Health Labour and Welfare of Japan, or MHLW) have limited HSAT clearance to diagnose OSA for the purpose of prescribing therapy to those patients who are categorized as suffering from severe OSA (the MHLW set an AHI threshold of 40), and, to our knowledge, PSG remains the dominant means of sleep apnea diagnosis. In addition, in many foreign markets, including the countries in the European Union, pricing of medical devices is subject to governmental control. To our knowledge, WatchPAT is covered by medical insurance to different degrees in Japan, the UK, The Netherlands, Sweden, Germany, Switzerland, Italy, Israel and few smaller countries.

Outlook. In the United States, there have been, and we expect that there will continue to be, a number of federal and state proposals to limit payments by governmental payors for medical devices, and the procedures in which medical devices are used. For example, in March 2010, comprehensive healthcare reform legislation was enacted through the passage of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education and Reconciliation Act, or ACA, which, among other things, imposed, among other things, a new federal excise tax on the sale of certain medical devices, provided incentives to programs that increase the federal government's comparative effectiveness research, and implemented payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models. Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, included reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013, and will stay in effect through 2029 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012, was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals. We cannot predict whether future healthcare initiatives will be implemented at the federal or state level or internationally, or the effect any future legislation or regulation will have on us. Such legislation and regulation of healthcare costs may, however, result in decreased lower reimbursements by governmental and private payors for our products, which may adversely affect our business, financial condition and results of operations.

Competition

Our industry is subject to rapid change from the introduction of new products and technologies and other activities of industry participants. In particular, the sleep test marketplace is highly competitive and has relatively few barriers to entry. We believe that the primary competitive factors affecting sales of our products and related services are:

- market acceptance by physicians and key opinion leaders, especially within the cardiology market;
- obtaining required local regulatory approvals or licenses for the sale of our products in the pertinent territories;

- obtaining insurance reimbursement status from the relevant third-party payors, especially within the United States;
- company, product and brand recognition;
- product efficacy, safety, reliability and durability;
- product ease of use and patient comfort; and
- technological innovation, product enhancements and speed of innovation.

We compete primarily with international and local vendors of sleep tests, including in the following main categories:

- *PSG tests*: PSG systems are provided by several companies, including Philips United States (part of Philips Medical), Embla, Nihon Kohden, Viasys Healthcare, Puritan Bennett, Cadwell Laboratories, Clevemed, Stellate Healthcare, Grass Technologies (a subsidiary of Astro-Med Inc.). As more fully described under "*Business Overview—Our Products and Services—The WatchPAT Family of Products—Key Benefits of WatchPAT*" above, we believe that HSATs in general, and our WatchPAT family of products in particular, are competitive in price and features and have certain advantages as compared to PSG tests;
- *HSATs (PSG)*: Suppliers of home sleep testing for diagnostic purposes that offer devices that perform full PSG tests at home, such as Embla and Aura-Grass, which, consequently, typically do not provide a significant cost benefit relative to in-lab PSG tests;
- *HSATs*: Suppliers of home sleep testing as diagnostic aids or for diagnostic purposes that offer ambulatory systems, such as Embletta MPR (provided by Embla Systems), Apnea Link Air (provided by ResMed Corp.), ARES (provided by SleepMed Inc.), Alice NightOne (provided by Philips United States) and Nox T3 (provided by Nox Medical), which devices typically measure four to five parameters (compared to the seven parameters measured by WatchPAT), and lack measurement of TST when not used with EEG (which, to our knowledge, is used only by ARES, which provides total sleep time by a device placed on the forehead with built-in EEG electrodes) and all of which also require nasal cannula. As more fully described under *Key Benefits of WatchPAT* above, we believe that, while our WatchPAT family of products may be more expensive than such HSATs, they offer various features and advantages as compared to such HSATs; and
- *Pulse oximetry devices*: Suppliers of pulse oximetry devices, such as Nonin and Masimo. In contrast to diagnostic devices, pulse oximetry devices that only measure one or two physiological parameters (oxygen saturation and motion) participate in the sleep space mostly as a screening tool.

Many of these competitors and potential competitors have significantly greater financial, human and other resources than we do, and have established relationships with healthcare professionals, customers and third-party payors. In addition, many of our competitors are more established globally and better positioned with sales and distribution networks, greater resources for product development, additional lines of products and the ability to offer financial incentives that we cannot provide. Our products and services could also be rendered obsolete or uneconomical by technological advances developed by one or more of our competitors.

Intellectual Property

General. Our intellectual property and proprietary technology are important to the development, manufacturing and sale of our current and future pipeline products. We seek to protect our intellectual property, core technologies and other know-how through a combination of patents, copyrights, trademarks, trade secret laws, non-disclosure and confidentiality agreements and other contractual arrangements with our employees, consultants, partners, suppliers, customers and others. We primarily rely on our own research and development efforts to enhance and develop our technology and products although, in some instances that do not involve our core competencies, such as with CloudPAT, we choose to license customized platforms from third parties.

Patents. As of December 31, 2019, we have been granted a total of 62 patents and have 11 pending national phase applications directly relating to our current products. A further 25 granted patents are potentially applicable, pending ongoing research and development. The families of patents that specifically cover WatchPAT consist of 45 granted patents worldwide and 10 pending patent applications, while EndoPAT is covered by 12 granted patents worldwide and one pending patent application as well as a further 15 granted patents that are potentially applicable pending ongoing research and development. In addition, we have 5 granted patents that relate to features which are common to both WatchPAT and EndoPAT, as well as a further 10 patents that are potentially applicable pending ongoing research and development.

We submit applications under the Patent Cooperation Treaty, or PCT, an international patent law treaty that provides a unified procedure for filing a single initial patent application to reserve the option to seek patent protection for an invention in each of the member states and regions. Although a PCT application cannot be issued as a patent, it allows for the applicant to seek protection at a later date in any of the member states and regions through national or regional phase applications. National and regional phase applications are examined by the allocable authorities in each member state or region in which we elect to file an application. We can elect to file a regional application in Europe, in which case we will not be required to file a separate state specific application for each member state in Europe, until such time as the European application is granted a patent, whereupon state specific validations may subsequently be selected.

Patents and patent applications covering our WatchPAT and EndoPAT technology have been issued or are currently pending in the United States, Japan, Europe and other international markets. Many of our patents and patent applications cover our technology around methods of and related devices for measuring the PAT signal and the application thereof.

Absent patent-term extensions and excluding granted patents that are potentially applicable pending ongoing research and development, several patents for (1) the WatchPAT are set to expire between 2021 and 2029 in Europe, Japan, and other foreign jurisdictions and between 2024 and 2030 in the United States and (2) the EndoPAT are set to expire between 2021 and 2032 in Japan, in 2021 in Europe and other foreign jurisdictions and in 2022 in the United States. While the original patents covering the PAT signal and certain embodiments thereof expired in July 2017, we believe that since our products have undergone substantial development and changes since our original products were first introduced, our current products should be protected in the United States, Japan, and many other countries by newer patents that we obtained and which are scheduled to expire as detailed above. The EndoPAT could also potentially be protected by additional granted patents, which may be applicable pending ongoing research and development, and are set to expire between 2027 and 2030 in the United States, and between 2023 and 2025 in Europe, Japan and other foreign jurisdictions. Currently pending patent applications, should they issue without terminal disclaimers or other term shortening restrictions, for the WatchPAT could expire as late as 2037 in the United States, Europe, Japan and other foreign jurisdictions. However, we cannot be sure that any of our patents will be commercially useful in protecting our technology. Moreover, while our policy is to obtain patents by application, license or otherwise, to maintain trade secrets and to seek to operate without infringing on the intellectual property rights of third parties, technologies related to our business have been rapidly developing in recent years. Additionally, patent applications that we have filed, may file or may license from third parties may not result in the issuance of patents, and our issued patents and any issued patents that we may receive in the future may be challenged, invalidated or circumvented. If third parties have prepared and filed patent applications or prepare and file patent applications in the future that also claim technology to which we have rights, we may have to partake in proceedings to determine priority of invention or in derivation proceedings, which could result in substantial costs to us, even if the eventual outcome is favorable to us. Moreover, because of the extensive time required for clinical development and regulatory review of a product we may develop, it is possible that, before our products can be fully commercialized or commercialized in additional jurisdictions, related patents will have expired or will expire a short period following commercialization, thereby reducing the advantage of such patent rights.

Other. In addition to patent protection, we also rely on trade secrets, including unpatented know-how, technology innovation, technical specifications and other proprietary information, as well as trade names, trademarks and service marks and non-disclosure and confidentiality agreements and other contractual arrangements with our employees, consultants, partners, suppliers, customers and others in attempting to develop and maintain our competitive position. We have obtained trademark registrations in the United States for PAT, EndoPAT, WatchPAT, EndoScore, ITAMAR, CloudPAT and SleePath and some of them are also registered in additional jurisdictions, including Europe, Japan, Canada, China, India, Russia, Mexico, Korea and Singapore.

However, our trade secrets may become known or be independently discovered by competitors, our confidentiality agreements may be breached, and our tradenames may not achieve the brand recognition that we pursue.

Research and Development

We devote a significant amount of our resources towards research and development in order to introduce new products and continuously enhance existing products and to support our growth strategy. We have assembled a core team of experienced research and development professionals as well as an advisory board comprised of experts in their respective fields. These professionals are involved in advancing our core technologies, as well as in applying these core technologies to our product development activities.

In order to carry our research and development activities, which take place primarily in Israel, we maintain teams in the following areas: physiology, hardware development, software, algorithms, data processing, clinical application development and clinical trials. As of December 31, 2019, we had 20 full-time employees engaged in research and development.

Since our incorporation, we have been engaged in the research of the PAT signal, as well as in the continuous research and development of our PAT-based technology and additional products and applications based on this technology, including in conjunction with additional technologies.

As part of our research and development activities, we also initiate or monitor, from time to time, clinical and research collaborations, such as with academic centers, in order to, among other things, achieve scientific backing of our products; promote recognition of our products within the medical community; support, where necessary, regulatory authorizations required to market and sell our products in applicable territories; and examine the applicability of our products in various clinical markets, particular population groups and various comorbidities.

Manufacturing and Supply

Our products consist of off-the-shelf and custom-made components. Our manufacturing, quality assurance testing, final integration, packaging and shipping operations as well as our final assembly activities are primarily performed at our facility in Caesarea, Israel, where we employed, as of December 31, 2019, 56 full-time employees and engaged 28 temporary contractor workers.

We engage various suppliers and subcontractors who deliver us materials and components used in our products, including plastic and electronic components, as well as development services and database management services. We also engage subcontractors, on an as needed basis, to manufacture finished products, based on our product specifications and requirements. We are not bound by any minimum purchase volume undertakings with such subcontractor. Engaging subcontractors to manufacture our finished products on an as needed basis, in addition to our own manufacturing work force, allows us flexibility to manage and meet our manufacturing goals and we believe that our manufacturing capacity, comprised of our own manufacturing work force and of our suppliers and subcontractors, is suitable and adequate for our operations as currently conducted and as currently foreseen.

We typically engage our subcontractors by means of a renewable framework agreement or by a particular purchase order. We aim to engage different subcontractors in various locations, to reduce any potential dependency in any particular subcontractor. In addition, we believe that there are sufficient alternative subcontractors in the market, which would allow us to replace any subcontractor, if necessary, though such replacement may be a lengthy process. In addition, if needed, we may transfer some to the final assembly stages, to our own manufacturing facility.

As of the date of this Annual Report, several of our subcontractors are single source subcontractors. Depending on the type of such subcontractors and the alternative we choose (such as using alternative subcontractors and manufacturing the component ourselves), we estimate that replacement of such single source subcontractors may range between six and twelve months. In addition, while we were not able to identify an alternative supplier for a component incorporated in one of our older models of the WatchPAT, which model we only sell in China, we plan to obtain regulatory approval to sell our more advanced WatchPAT product model in China. Nevertheless, there is no assurance if and when we will obtain such approval. Due to their nature, certain components must be ordered from such single source subcontractors a few months in advance, resulting in substantial lead time. In the event that such limited source suppliers are unable to meet our requirements in a timely manner, we may experience a limited interruption in production until we can obtain an alternate source of supply and, if we do not accurately forecast such demand, our operating results could be adversely affected. However, as explained above, we take various steps in order to mitigate this risk, including by (1) providing our relevant suppliers with a purchasing forecast and estimate of future orders, (2) requiring such single source subcontractors to provide us long prior notice should the subcontractor wish to terminate our agreement, and (3) we constantly hold safety inventory stock sufficient to meet our estimated manufacturing forecasts, aligned with the lead time of each component. In this respect, see also the discussion under Item 3.D. "*Risk Factors—Risks Related to Our Business and Operations—We are dependent upon third-party manufacturers and suppliers, which makes us vulnerable to supply disruptions*". We believe that our manufacturing processes and our subcontractors' manufacturing processes are in material compliance with pertinent United States and international quality and safety standards, such as ISO 9001:2000 and the FDA's quality system regulations.

Seasonality

We have not identified seasonal effects in relation to a specific quarter or quarters in our business. However, in the past several years, the results of our first quarter were typically weaker than other quarters, which may be due to some of our customers capital expenditures cycles, which are not in our control. In the first quarter, our results can be impacted by the resetting of annual United States patient healthcare insurance plans deductibles, which may cause delays in patients seeking our solutions.

Government Regulations

Overview

We must comply with the laws, regulations and standards applicable to our activities in the countries in which we operate. In particular, we are subject to laws, regulations and standards applicable to our manufacturing activities as well as to laws and regulatory requirements in each country in which we market and sell our products, including the United States, Europe, Japan and Israel. In each country where we seek to market and sell our products, we typically need to first obtain a local approval or clearance allowing us to market and sell our products in the pertinent territory. The requirements, length of time and costs associated with obtaining such local approvals differ from country to country. Depending on the pertinent territory, we either hold such approvals independently or through a local subsidiary or through a local partner with whom we maintain a contractual arrangement securing our rights in such marketing and sales approvals, such as in Japan where our partner, Philips Japan, is the one holding the marketing approval. Except as described below, the WatchPAT related services and accessories that we currently offer, do not require any separate regulatory approval or clearance beyond the ones we obtained for the WatchPAT as described below.

We are also subject to announced and unannounced inspections and audits by such regulatory bodies, primarily of our manufacturing facility in Israel. Our products and operations are also often subject to the rules or norms of industrial standards bodies, such as the International Standards Organization, or ISO, or the rules of associations of healthcare professionals. For example, in the United States we maintain certifications of a Nationally Recognized Testing Laboratory, or NRTL, which is a third-party organization that certifies products for the North American market. NRTLs are recognized by the Occupational Safety and Health Administration, or OSHA, under United States deferral regulations to provide product safety testing and certification for products to be used in the United States workplace. Future products, or components thereof, may also be subject to regulation by the Federal Communications Commission, or the FCC**,** due to inclusion of digital or communication components.

In addition, we are subject to certain foreign medical device reporting regulations in the countries in which we market and sell our products. While the specifics of the reporting regulations in each country in which we market and sell our products may vary, we are generally required to report adverse events or incidents about which we received or become aware of information that reasonably suggests that one of our marketed devices or a malfunction of such device has caused or may have caused or contributed to a death or serious injury, or of a recurring malfunction likely to contribute to death or a serious injury. The decision of whether an adverse event or incident is reportable under the applicable regulations requires our management's judgment. Any adverse event or incident involving our products could result in regulatory actions, such as inspection and mandatory product recalls, as well as voluntary corrective actions that we may initiate for various reasons, such as product recalls or customer notifications.

In Israel, the United States, Europe and other territories we are also subject to environmental regulations governing the use of certain hazardous materials, such as RoHS and RoHS II, EU directives that require products sold in Europe to meet certain design specifications, which exclude the use of hazardous substances; REACH, an EU regulation covering the registration, evaluation, authorizations and restriction of chemicals; and EU Directive 2002/96/EC on Waste Electrical and Electronic Equipment (known as the "WEEE" Directive), which requires producers of electrical and electronic equipment to register in different European countries and to provide collection and recycling facilities for used products.

We invest resources in order to maintain our regulatory compliance, successfully pass audits and maintain our certifications and marketing and sales approvals.

The United States Market

Our products and our operations are subject to extensive regulation by the FDA, and other federal and state authorities in the United States. Our products are subject to regulation as medical devices in the United States under the Federal Food, Drug, and Cosmetic Act, or FDCA, as implemented and enforced by the FDA.

The FDA regulates the development, design, non-clinical and clinical research, manufacturing, safety, efficacy, labeling, packaging, storage, installation, servicing, recordkeeping, premarket clearance or approval, adverse event reporting, advertising, promotion, marketing and distribution, and import and export of medical devices to ensure that medical devices distributed domestically are safe and effective for their intended uses and otherwise meet the requirements of the FDCA.

FDA Premarket Clearance and Approval Requirements

Unless an exemption applies, each medical device commercially distributed in the United States requires either FDA clearance of a 510(k) premarket notification, or approval of a premarket approval, or PMA, application. Under the FDCA, medical devices are classified into one of three classes — Class I, Class II or Class III — depending on the degree of risk associated with each medical device and the extent of manufacturer and regulatory control needed to ensure its safety and effectiveness. Class I includes devices with the lowest risk to the patient and are those for which safety and effectiveness can be assured by adherence to the FDA's General Controls for medical devices, which include compliance with the applicable portions of the Quality System Regulation, or QSR, facility registration and product listing, reporting of adverse medical events, and truthful and non-misleading labeling, advertising, and promotional materials. Class II devices are subject to the FDA's General Controls, and special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. These special controls can include performance standards, post-market surveillance, patient registries and FDA guidance documents.

While most Class I devices are exempt from the 510(k) premarket notification requirement, manufacturers of most Class II devices are required to submit to the FDA a premarket notification under Section 510(k) of the FDCA requesting permission to commercially distribute the device. The FDA's permission to commercially distribute a device subject to a 510(k) premarket notification is generally known as 510(k) clearance. Devices deemed by the FDA to pose the greatest risks, such as life sustaining, life supporting or some implantable devices, or devices that have a new intended use, or use advanced technology that is not substantially equivalent to that of a legally marketed device, are placed in Class III, requiring approval of a PMA. Some pre-amendment devices are unclassified, but are subject to FDA's premarket notification and clearance process in order to be commercially distributed. Our currently marketed products are Class II devices subject to 510(k) clearance.

510(k) Clearance Marketing Pathway

All of our current products (excluding one 510(k)-exempt product) are subject to premarket notification and clearance under section 510(k) of the FDCA. To obtain 510(k) clearance, we must submit to the FDA a premarket notification submission demonstrating that the proposed device is "substantially equivalent" to a predicate device already on the market. A predicate device is a legally marketed device that is not subject to premarket approval, i.e., a device that was legally marketed prior to May 28, 1976 (pre-amendments device) and for which a PMA is not required, a device that has been reclassified from Class III to Class II or I, or a device that was found substantially equivalent through the 510(k) process. The FDA's 510(k) clearance process usually takes from three to twelve months, but often takes longer. The FDA may require additional information, including clinical data, to make a determination regarding substantial equivalence. In addition, FDA collects user fees for certain medical device submissions and annual fees and for medical device establishments. For fiscal year 2020, the standard user fee for a 510(k) premarket notification application is $11,594.

If the FDA agrees that the device is substantially equivalent to a predicate device currently on the market, it will grant 510(k) clearance to commercially market the device. If the FDA determines that the device is "not substantially equivalent" to a previously cleared device, the device is automatically designated as a Class III device. The device sponsor must then fulfill more rigorous PMA requirements, or can request a risk-based classification determination for the device in accordance with the "de novo" process, which is a route to market for novel medical devices that are low to moderate risk and are not substantially equivalent to a predicate device.

After a device receives 510(k) marketing clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change or modification in its intended use, will require a new 510(k) clearance or, depending on the modification, PMA approval or de novo reclassification. The FDA requires each manufacturer to determine whether the proposed change requires submission of a 510(k), de novo request or a PMA in the first instance, but the FDA can review any such decision and disagree with a manufacturer's determination. If the FDA disagrees with a manufacturer's determination, the FDA can require the manufacturer to cease marketing and/or request the recall of the modified device until 510(k) marketing clearance or until PMA approval is obtained or a de novo request is granted. Also, in these circumstances, the manufacturer may be subject to significant regulatory fines or penalties.

Over the last several years, the FDA has proposed reforms to its 510(k) clearance process, and such proposals could include increased requirements for clinical data and a longer review period, or could make it more difficult for manufacturers to utilize the 510(k) clearance process for their products. For example, in November 2018, FDA officials announced forthcoming steps that the FDA intends to take to modernize the premarket notification pathway under Section 510(k) of the FDCA. Among other things, the FDA announced that it planned to develop proposals to drive manufacturers utilizing the 510(k) pathway toward the use of newer predicates. These proposals included plans to potentially sunset certain older devices that were used as predicates under the 510(k) clearance pathway, and to potentially publish a list of devices that have been cleared on the basis of demonstrated substantial equivalence to predicate devices that are more than 10 years old. In May 2019, the FDA solicited public feedback on these proposals. These proposals have not yet been finalized or adopted, and the FDA may work with Congress to implement such proposals through legislation.

More recently, in September 2019, the FDA finalized guidance describing an optional "safety and performance based" premarket review pathway for manufacturers of "certain, well-understood device types" to demonstrate substantial equivalence under the 510(k) clearance pathway by showing that such device meets objective safety and performance criteria established by the FDA, thereby obviating the need for manufacturers to compare the safety and performance of their medical devices to specific predicate devices in the clearance process. The FDA intends to develop and maintain a list device types appropriate for the "safety and performance based" pathway and will continue to develop product-specific guidance documents that identify the performance criteria for each such device type, as well as the testing methods recommended in the guidance documents, where feasible.

PMA Approval Pathway

Class III devices require PMA approval before they can be marketed, although some pre-amendment Class III devices for which FDA has not yet required a PMA are cleared through the 510(k) process. The PMA process is more demanding than the 510(k) premarket notification process. In a PMA, the manufacturer must demonstrate that the device is safe and effective, and the PMA must be supported by extensive data, including data from preclinical studies and human clinical trials. The PMA must also contain a full description of the device and its components, a full description of the methods, facilities, and controls used for manufacturing, and proposed labeling. Following receipt of a PMA, the FDA determines whether the application is sufficiently complete to permit a substantive review. If FDA accepts the application for review, it has 180 days under the FDCA to complete its review of a PMA, although in practice, the FDA's review often takes significantly longer, and can take up to several years. An advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. The FDA may or may not accept the panel's recommendation. In addition, the FDA will generally conduct a pre-approval inspection of the applicant or its third-party manufacturers' or suppliers' manufacturing facility or facilities to ensure compliance with the QSR. PMA devices are also subject to the payment of user fees, which for fiscal year 2020 includes a standard application fee of $340,995 and an annual establishment registration fee of $5,236.

The FDA will approve the new device for commercial distribution if it determines that the data and information in the PMA constitute valid scientific evidence and that there is reasonable assurance that the device is safe and effective for its intended use(s). The FDA may approve a PMA with post-approval conditions intended to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution, and collection of long-term follow-up data from patients in the clinical study that supported PMA approval or requirements to conduct additional clinical studies post-approval. The FDA may condition PMA approval on some form of post-market surveillance when deemed necessary to protect the public health or to provide additional safety and efficacy data for the device in a larger population or for a longer period of use. In such cases, the manufacturer might be required to follow certain patient groups for a number of years and to make periodic reports to the FDA on the clinical status of those patients. Failure to comply with the conditions of approval can result in material adverse enforcement action, including withdrawal of the approval.

Certain changes to an approved device, such as changes in manufacturing facilities, methods, or quality control procedures, or changes in the design performance specifications, which affect the safety or effectiveness of the device, require submission of a PMA supplement. PMA supplements often require submission of the same type of information as a PMA, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA and may not require as extensive clinical data or the convening of an advisory panel. Certain other changes to an approved device require the submission of a new PMA, such as when the design change causes a different intended use, mode of operation, and technical basis of operation, or when the design change is so significant that a new generation of the device will be developed, and the data that were submitted with the original PMA are not applicable for the change in demonstrating a reasonable assurance of safety and effectiveness. None of our products are currently marketed pursuant to a PMA.

Clinical Trials

Clinical trials are almost always required to support a PMA and are sometimes required to support a 510(k) submission. All clinical investigations of devices to determine safety and effectiveness must be conducted in accordance with the FDA's investigational device exemption, or IDE, regulations which govern investigational device labeling, prohibit promotion of the investigational device, and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. If the device presents a "significant risk," to human health, as defined by the FDA, the FDA requires the device sponsor to submit an IDE application to the FDA, which must become effective prior to commencing human clinical trials. If the device under evaluation does not present a significant risk to human health, then the device sponsor is not required to submit an IDE application to the FDA before initiating human clinical trials, but must still comply with abbreviated IDE requirements when conducting such trials. A significant risk device is one that presents a potential for serious risk to the health, safety or welfare of a patient and either is implanted, used in supporting or sustaining human life, substantially important in diagnosing, curing, mitigating or treating disease or otherwise preventing impairment of human health, or otherwise presents a potential for serious risk to a subject. An IDE application must be supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE will automatically become effective 30 days after receipt by the FDA unless the FDA notifies the company that the investigation may not begin. If the FDA determines that there are deficiencies or other concerns with an IDE for which it requires modification, the FDA may permit a clinical trial to proceed under a conditional approval.

Regardless of the degree of risk presented by the medical device, clinical studies must be approved by, and conducted under the oversight of, an Institutional Review Board, or IRB, for each clinical site. The IRB is responsible for the initial and continuing review of the IDE, and may pose additional requirements for the conduct of the study. If an IDE application is approved by the FDA and one or more IRBs, human clinical trials may begin at a specific number of investigational sites with a specific number of patients, as approved by the FDA. If the device presents a non-significant risk to the patient, a sponsor may begin the clinical trial after obtaining approval for the trial by one or more IRBs without separate approval from the FDA, but must still follow abbreviated IDE requirements, such as monitoring the investigation, ensuring that the investigators obtain informed consent, and labeling and record-keeping requirements. Acceptance of an IDE application for review does not guarantee that the FDA will allow the IDE to become effective and, if it does become effective, the FDA may or may not determine that the data derived from the trials support the safety and effectiveness of the device or warrant the continuation of clinical trials. An IDE supplement must be submitted to, and approved by, the FDA before a sponsor or investigator may make a change to the investigational plan that may affect its scientific soundness, study plan or the rights, safety or welfare of human subjects.

During a study, the sponsor is required to comply with the applicable FDA requirements, including, for example, trial monitoring, selecting clinical investigators and providing them with the investigational plan, ensuring IRB review, adverse event reporting, record keeping and prohibitions on the promotion of investigational devices or on making safety or effectiveness claims for them. The clinical investigators in the clinical study are also subject to FDA's regulations and must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of the investigational device, and comply with all reporting and recordkeeping requirements. Additionally, after a trial begins, we, the FDA or the IRB could suspend or terminate a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits.

Post-market Regulation

After a device is cleared or approved for marketing, numerous and pervasive regulatory requirements continue to apply. These include:

- establishment registration and device listing with the FDA;
- QSR requirements, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the design and manufacturing process;
- labeling regulations and FDA prohibitions against the promotion of investigational products, or the promotion or advertising of "off-label" uses of cleared or approved products;
- requirements related to promotional activities;
- clearance or approval of product modifications to 510(k)-cleared devices that could significantly affect safety or effectiveness or that would constitute a major change in intended use of one of our cleared devices, or approval of certain modifications to PMA-approved devices;
- medical device reporting regulations, which require that a manufacturer report to the FDA if a device it markets may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur;
- correction, removal and recall reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health;

- the FDA's recall authority, whereby the agency can order device manufacturers to recall from the market a product that is in violation of governing laws and regulations; and

- post-market surveillance activities and regulations, which apply when deemed by the FDA to be necessary to protect the public health or to provide additional safety and effectiveness data for the device.

Our manufacturing processes are required to comply with the applicable portions of the QSR, which cover the methods and the facilities and controls for the design, manufacture, testing, production, processes, controls, quality assurance, labeling, packaging, distribution, installation and servicing of finished devices intended for human use. The QSR also requires, among other things, maintenance of a device master file, device history file, and complaint files. As a manufacturer, we are subject to periodic scheduled or unscheduled inspections by the FDA. Our failure to maintain compliance with the QSR requirements could result in the shut-down of, or restrictions on, our manufacturing operations and the recall or seizure of our products, which would have a material adverse effect on our business. The discovery of previously unknown problems with any of our products, including unanticipated adverse events or adverse events of increasing severity or frequency, whether resulting from the use of the device within the scope of its clearance or off-label by a physician in the practice of medicine, could result in restrictions on the device, including the removal of the product from the market or voluntary or mandatory device recalls.

The FDA has broad regulatory compliance and enforcement powers. If the FDA determines that we failed to comply with applicable regulatory requirements, it can take a variety of compliance or enforcement actions, which may result in any of the following sanctions:

- warning letters, untitled letters, fines, injunctions, consent decrees and civil penalties;

- recalls, withdrawals, or administrative detention or seizure of our products;

- operating restrictions or partial suspension or total shutdown of production;

- refusing or delaying requests for 510(k) marketing clearance or PMA approvals of new products or modified products;

- withdrawing 510(k) clearances or PMA approvals that have already been granted;

- refusal to grant export approvals for our products; or

- criminal prosecution.

Healthcare Regulatory Laws

Within the United States, our products and our customers are subject to extensive regulation by a wide range of federal and state agencies that govern business practices in the medical device industry. These laws include federal and state anti-kickback, fraud and abuse, false claims and physician payment transparency laws and regulations.

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, to induce or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any good, facility, item or service reimbursable, in whole or part by Medicare, Medicaid or other federal healthcare programs. The term "remuneration" has been broadly interpreted to include anything of value, including cash, improper discounts, and free or reduced price items and services. Among other things, the Anti-Kickback Statute has been interpreted to apply to arrangements between medical device manufacturers on the one hand and prescribers and purchasers on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor.

Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the Anti-Kickback Statute has been violated. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate, in order to have committed a violation. Further, a claim including items or services resulting from a violation of the federal

Anti-Kickback Statute also constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Many states have adopted laws similar to the Anti-Kickback Statute. Some of these state prohibitions apply to referral of patients for healthcare items or services reimbursed by any payor, not only the Medicare and Medicaid programs. Commercial payors may also bring a private cause of action for treble damages against a manufacturer for a pattern of causing false claims to be filed under the federal Racketeer Influenced and Corrupt Organizations Act, or RICO.

The federal civil False Claims Act prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment to or approval by the federal government or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. A claim includes "any request or demand" for money or property presented to the U.S. government. The qui tam provisions of the False Claims Act allow a private individual to bring actions on behalf of the federal government alleging that the defendant has submitted a false claim to the federal government, and to share in any monetary recovery. In recent years, the number of suits brought against healthcare providers by private individuals has increased dramatically. The government has obtained multi-million and multi-billion dollar settlements under the False Claims Act in addition to individual criminal convictions under applicable criminal statutes. In addition, the federal civil monetary penalties statute imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent. Given the significant size of actual and potential settlements, it is expected that the government will continue to devote substantial resources to investigating healthcare providers' and manufacturers' compliance with applicable fraud and abuse laws. Various states have also enacted false claim laws analogous to the federal civil False Claims Act, although many of these state laws apply where a claim is submitted to any third-party payor and not merely a federal healthcare program.

The federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, or HIPAA, among other things, created two new federal crimes: healthcare fraud and false statements relating to healthcare matters. The HIPAA healthcare fraud statute prohibits, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private payors. A violation of this statute is a felony and may result in fines, imprisonment and/or exclusion from government sponsored programs. The HIPAA false statements statute prohibits, among other things, knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation in connection with the delivery of or payment for healthcare benefits, items or services. A violation of this statute is a felony and may result in fines and/or imprisonment. Similar to the Anti-Kickback Statute, a person or entity does not need to have actual knowledge of these statutes or specific intent to violate them in order to have committed a violation.

Additionally, there has been a recent trend of increased federal and state regulation of payments made to physicians and other healthcare providers. The ACA, imposed, among other things, new annual reporting requirements for covered manufacturers for certain payments and "transfers of value" provided to physicians and certain other healthcare providers and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. In addition, certain states require implementation of compliance programs and compliance with the device industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, impose restrictions on marketing practices, and/or tracking and reporting of gifts, compensation and other remuneration or items of value provided to physicians and other healthcare professionals and entities.

Data Privacy and Security

Medical device companies may be subject to U.S. federal and state and foreign health information privacy, security and data breach notification laws, which may govern the collection, use, disclosure and protection of health-related and other personal information. In the U.S., HIPAA imposes privacy, security and breach reporting obligations with respect to individually identifiable health information upon "covered entities" (health plans, health care clearinghouses and certain health care providers), and their respective business associates, individuals or entities that create, received, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HIPAA mandates the reporting of certain breaches of health information to HHS, affected individuals and if the breach is large enough, the media. Entities that are found to be in violation of HIPAA as the result of a breach of unsecured protected health information, a complaint about privacy practices or an audit by HHS, may be subject to significant civil, criminal and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance. Even when HIPAA does not apply, according to the Federal Trade Commission or the FTC, failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act, or the FTCA, 15 U.S.C § 45(a). The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards. The FTC's guidance for appropriately securing consumers' personal information is similar to what is required by the HIPAA security regulations.

In addition, certain state and non-U.S. laws, such as the European Union General Data Protection Regulation 2016/679, or GDPR, govern the privacy and security of health information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. For example, California recently enacted legislation, the California Consumer Privacy Act, or CCPA, which went into effect January 1, 2020. The CCPA, among other things, creates new data privacy obligations for covered companies and provides new privacy rights to California residents, including the right to opt out of certain disclosures of their information. The CCPA also creates a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. Although the law includes limited exceptions, including for "protected health information" maintained by a covered entity or business associate, it may regulate or impact our processing of personal information depending on the context. In Europe, the GDPR went into effect in May 2018 and introduces strict requirements for processing the personal data of European Union data subjects. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. Additionally, following the United Kingdom's withdrawal from the European Union, we will have to comply with the GDPR and the United Kingdom GDPR, each regime having the ability to fine up to the greater of €20 million/ £17.5 million or 4% of global turnover. The relationship between the United Kingdom and the European Union in relation to certain aspects of data protection law remains unclear, for example around how data can lawfully be transferred between each jurisdiction, which exposes us to further compliance risk. The State of Israel has also implemented data protection laws and regulations, including the Israeli Protection of Privacy Law, 1981.

Health Care Reform

The United States has enacted or proposed legislative and regulatory changes affecting the healthcare system that could affect our ability to profitably sell our products. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

In the United States, there have been and continue to be a number of legislative initiatives and judicial challenges to contain healthcare costs. For example, in March 2010, the ACA was passed, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the United States medical device industry to which we sell our products. Among other things, the Affordable Care Act:

- established a 2.3% excise tax on sales of medical devices with respect to any entity that manufactures or imports specified medical devices offered for sale in the United States, which, through a series of legislative amendments, was suspended, effective January 1, 2016, and subsequently repealed altogether on December 20, 2019;

- established a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research;

- implemented payment system reforms, including a national pilot program to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain health care services through bundled payment models; and

- created an independent payment advisory board that will submit recommendations to reduce Medicare spending if projected Medicare spending exceeds a specified growth rate.

There have been a number of significant changes to the ACA and its implementation. By way of example, the Tax Cuts and Jobs Act of 2017, or Tax Act, effective January 1, 2019, included a provision repealing the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, or the Texas District Court Judge, ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. On December 18, 2019, the Fifth Circuit Court of Appeals also struck down the individual mandate and remanded to the Northern District of Texas the decision as to whether the remainder of the ACA is valid. It is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA and our business. Litigation and legislation over the ACA are likely to continue with unpredictable and uncertain results. We will continue to evaluate the effect that the ACA and its possible repeal and replacement has on our business.

The European Market

In order to sell our products in member countries of the European Economic Area, or the EEA, our products must comply with the essential requirements of the European Union, or 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 our products, without which they cannot be sold or marketed in the EEA. To demonstrate compliance with the essential requirements we 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 non sterile, non-measuring devices), 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 of the EU Medical Devices Directive, a conformity assessment procedure requires the intervention of an organization accredited by a member state of the EEA to conduct conformity assessments, or a Notified Body. Depending on the relevant conformity assessment procedure, the Notified Body would typically 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 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 general 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, 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 are supported by suitable evidence. If we fail to remain in compliance with applicable European laws and directives, we would be unable to continue to affix the CE mark to our products, which would prevent us from selling them within the EEA.

On April 5, 2017, the European Parliament passed the Medical Devices Regulation (Regulation 2017/745), which repeals and replaces the MDD and the Active Implantable 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 ensure a high level of safety and health while supporting innovation. The Medical Devices Regulation will, however, only become applicable three years after publication (in May 2020). 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 the 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.

Starting May 2020, no new applications under the previous directives will be permitted. By that date, we will need to update our technical documentation and other quality management system processes to meet the new MDR requirements.

During 2017, we decided to transition to a new Notified Body. As part of the transition, a quality audit was performed and the technical dossier of one product was reviewed. In January 2018, we received a new CE certificate from our new Notified Body, BSI Group, bearing an expiration date of October 10, 2019, the same expiration date as the previous certificate issued by our former Notified Body, for our WatchPAT 200 Unified (including one of its probes) and EndoPAT 2000, to which we refer as the main certificate. The main certificate was renewed by the BSI Group in October 2019 with an expiration date of May 26, 2024, and was broadened to also cover EndoPATX. In addition, we have obtained a CE certificate for our accessories, such as probes and sensors that we sell for use with such products, to which we refer as the accessory certificate, which certificate does not bear any expiration date (and is not required to be issued by a Notified Body like the main certificate). It should be noted that under the MDR requirements, CE certificates issued under the previous directives prior to May 2020 shall remain valid in accordance with their term, beyond the expiration of the transition period, however certain limitations set forth in the MDR, such as the need to use classifications that are different from the previous directives, would apply. We do not expect such limitations to have any material impact on our ability to maintain our accessory certificate (or obtain a new one if such new classifications shall apply) beyond May 2020.

We currently have a CE mark for our WatchPAT 200 Unified, EndoPAT 2000 and WatchPAT 300 (which, for the WatchPAT 300, was granted in February 2019).

The Japanese Market

In Japan, the Pharmaceutical Medical Devices Authority, or PMDA, is the regulatory body supervising and regulating the marketing and sale of medical devices such as our products, similarly to the FDA in the United States. In order to market and sell medical devices, such as ours, in Japan, we must comply with Japan's Pharmaceuticals and Medical Devices Act, or the PMD Act. Among other requirements, as part of the approval process, medical device manufacturers must comply with the MHLW Ordinance No. 169 related to quality management systems, register design and manufacturing facilities, and appoint an in-country representative, also known as MAH/D-MAH.

We currently hold PMDA authorizations to market and sell our WatchPAT 200 Unified and EndoPAT 2000 in Japan. Such authorizations are held by the local MAH/D-MAH with whom we maintain a contractual engagement.

The Canadian Market

Health Canada is the Canadian authority supervising and regulating the marketing and sale of medical devices such as our products, similarly to the FDA in the United States.

We previously had authorizations of Health Canada to market and sell our WatchPAT 200 Unified and EndoPAT 2000. However, in August 2018, we announced that we will not renew such authorizations and therefore, in January 2019, we ceased offering our products for sale in Canada.

The Israeli Market

General. All of our products are approved for sale and distribution in Israel by the Israeli Ministry of Health. Our manufacturing activities in Israel are also subject to regulation by the Israeli Ministry of Health. In addition to marketing and selling our products, we or our partners also must obtain pertinent approvals or permits to perform our clinical trials in the countries in which we perform such trials, such as in compliance with an international guideline for the ethical conduct of clinical research known as the Declaration of Helsinki. In Israel, our clinical trials require a permit for a research plan (protocol) by the Helsinki Committee, operating under the Israeli Public Health Regulations (Clinical Trials in Human Subject Research), 1980.

Israeli Innovation Authority

From time to time, eligible participants may receive grants under programs of the Israeli Innovation Authority, or IIA. Grants received are generally repaid through mandatory royalties based on revenues from the sale of products (and ancillary services) incorporating know-how developed, in whole or in part, with the grants. This governmental support is conditioned upon the participant's ability to comply with certain applicable requirements and conditions specified in the IIA's programs and the R&D Law.

Under the R&D Law, research and development programs that meet specified criteria and are approved by the Research Committee of the IIA are eligible for grants of certain approved expenditures of such programs, as determined by said committee. In exchange, the recipient of such grants is required to pay the IIA royalties from the revenues derived from products incorporating know-how developed within the framework of each such program or derived therefrom (including ancillary services in connection therewith), up to an aggregate of 100% of the U.S. dollar-linked value of the total grants received in respect of such program, plus interest.

The R&D Law also provides that know-how developed under an approved research and development program or rights associated with such know-how (1) may not be transferred to third parties in Israel without the approval of the IIA; and (2) may not be transferred to any third parties outside Israel, except in certain special circumstances and subject to the IIA's prior approval, which approval, if any, may generally be obtained in the following cases: (a) the grant recipient pays to the IIA a portion of the sale price paid in consideration for such IIA-funded know-how (according to certain formulas, which may result in repayment of up to 600% of the grant amounts plus interest), or (b) the grant recipient receives know-how from a third-party in exchange for its IIA-funded know-how. Such approval is not required for the export of any products resulting from such research or development.

The R&D Law provides that products developed under an approved research and development program should, as a general matter, be manufactured in Israel. Manufacturing products developed under an approved research and development program outside of the State of Israel is prohibited without receiving prior approval from the Innovation Authority (except for the transfer of less than 10% of the manufacturing capacity in the aggregate which requires only a notice). If a company receives approval to manufacture products developed with government grants outside of Israel, it will be required to pay increased royalties to the IIA, up to 300% of the grant amount plus interest, depending on the manufacturing volume that is performed outside of Israel. The company may also be subject to accelerated royalty repayment rates. A company also has the option of declaring in its IIA grant application its intention to exercise a portion of the manufacturing capacity abroad, thus avoiding the need to obtain additional approval following the receipt of the grant.

The abovementioned restrictions continue to apply even after a grant recipient has repaid the full amount of the grants received in connection with an approved research and development program.

The R&D Law imposes reporting requirements with respect to certain changes in the ownership of a grant recipient. The law generally requires the grant recipient and its controlling shareholders and foreign interested parties to notify the IIA of a change in control of the recipient or a change in the holdings of the "means of control" of the recipient that would make a non-Israeli an "interested party" and that non-Israeli "interested parties" provide an undertaking to the IIA to comply with the R&D Law. In addition, the rules of the IIA may require additional information or representations in respect of certain of such events. For these purposes, "control" is defined as the ability to direct the activities of a company other than any ability arising solely from serving as an officer or director of the company. A person is presumed to have control if such person holds 50% or more of any of the means of control of a company. "Means of control" refers to voting rights or the right to appoint directors or the chief executive officer. An "interested party" of a company includes a holder of 5% or more of its outstanding share capital or voting rights, its chief executive officer and directors, someone who has the right to appoint its chief executive officer or at least one director, and a company with respect to which any of the foregoing owns 25% or more of the outstanding share capital or voting rights or has the right to appoint 25% or more of the directors. Accordingly, a change of control in us and the acquisition of 5% or more of our ordinary shares by a non-Israeli may require notification to the IIA and the provision of an undertaking to comply with the R&D Law.

The Israeli authorities have indicated in the past that the government may reduce or abolish the IIA grants in the future. Even if these grants are maintained, we cannot presently predict what would be the amounts of future grants, if any, that we might receive.

Our research and development efforts for the development of EndoPAT 3000, a new generation of our EndoPAT product (the development of which was discontinued before its completion with no sales to date), during the period between 2003 and 2005, were financed in part through royalty-bearing grants from the IIA, in a total amount of approximately $0.9 million. The amount of the grants including interest accrued as of December 31, 2019 was approximately $1.06 million. In 2009, the IIA notified us that we are required to pay royalties on the sale of all of our products commencing as of 2012. Although we believe that we are not required to repay these grants to the IIA from the sale our past and currently marketed products, we may be required to pay royalties with respect to sales of future products that incorporate the know-how developed under these grant programs. There is no assurance that we will prevail in our efforts opposing the IIA's position. Since we made a full accrual in our financial statements for such possible liability, in the event that our efforts with the IIA are not successful, the primary effect will be on our cash flows and financial condition. We anticipate that in 2021 we will begin selling our newly developed EndoPATX, for which we recently received authorization to affix a CE mark. We developed EndoPATX while using some of the knowledge and developments of the EndoPAT 3000, and therefore anticipate paying royalties on all sales of EndoPATX, against the grants received for the EndoPAT 3000.

C. Organizational Structure

Our wholly owned subsidiaries act primarily as sales, marketing and customer service organizations in the countries where they are incorporated and in most instances for neighboring countries. The following table sets forth the legal name, location and country of incorporation and percentage ownership of each of our current principal operating subsidiaries:

Subsidiary Name	Country of Incorporation	Ownership Percentage
Itamar Medical, Inc.	Delaware, United States	100%
Itamar Medical Japan Co. Ltd.*	Japan	100%
I.M.E. 2016 B.V.	The Netherlands	100%

* Currently in the process of dissolution.

D. Property, Plants and Equipment

Our headquarters, manufacturing and research and development facilities as well as our sales offices are located in the Northern Caesarea Business Park, Caesarea, Israel, where we lease approximately 14,000 square feet of office and manufacturing space pursuant to a lease that is currently scheduled to expire in July 2021. Our current monthly rent is NIS 96,000 (equivalent to approximately $26,244) and we have provided the lessor with a bank guarantee of NIS 637,000 (equivalent to approximately $174,139) to secure our obligations thereunder.

During 2019, we entered into a lease agreement for new manufacturing facilities located in the Southern Caesarea Business Park, Caesarea, Israel, where we lease approximately 14,000 square feet This lease is currently scheduled to expire in February 2023, but provides for two optional extensions until February 2030. Our current monthly rent is NIS 45,000 (equivalent to approximately $12,302) and we have provided the lessor with a bank guarantee of NIS 217,000 (equivalent to approximately $59,322) to secure our obligations thereunder. We are currently in the process of construction and adjustment of these new manufacturing facilities to our manufacturing requirements and expect the construction to be completed and the new manufacturing facilities to be operative during the third quarter of 2020. We estimate our total expenditures related to these construction works to amount to approximately $1 million and estimate that our production capacity capabilities after completion of construction will increase by approximately 350%, compared to 2019 capacity.

In addition, we lease storage facilities in the Northern Caesarea Business Park, Caesarea, Israel, where we lease approximately 1,900 square feet of storage space pursuant to a lease that is scheduled to expire in June 2021. Our current monthly rent is NIS 9,000 (equivalent to approximately $2,460) and we have provided the lessor with a deposit of NIS 55,000 (equivalent to approximately $15,036) to secure our obligations thereunder.

In addition to the above, we lease approximately 10,900 square feet of office space in Atlanta, Georgia, pursuant to a lease that expires in March 2022, with an optional extension until March 2025. Our current monthly rent is $17,000 and we have provided the lessor with a bank guarantee of $15,000 to secure our obligations thereunder.

Item 4A. Unresolved Staff Comments

None.

Item 5. Operating and Financial Review and Prospects

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with the section entitled Item 3.A. "Selected Financial Data" and our consolidated financial statements and the related notes included elsewhere in this Annual Report. This discussion contains forward-looking statements and involves numerous risks and uncertainties, including, but not limited to, those described in Item 3.D. "Risk Factors". Actual results could differ materially from those contained in any forward-looking statements.

Overview

We are a medical technology company focused on the development and commercialization of non-invasive medical devices and solutions to aid in the diagnosis of respiratory sleep disorders. We use a digital healthcare platform to facilitate the continuum of care for effective sleep apnea management with a focus on the core sleep, cardiology and direct to consumer, or DTC, markets. We offer TSS to help physicians provide comprehensive sleep apnea management in a variety of clinical environments to optimize patient care and reduce healthcare costs. In addition, we have recently begun offering our WatchPAT family of products and certain components of TSS to the DTC market.

Since our incorporation in 1997, we have incurred operating and net losses in most of our years of operation and, as of December 31, 2019, we had an accumulated deficit of $109.6 million. We expect to continue to incur operating and net losses for the foreseeable future, as we continue to invest in research and development and marketing and sales operations aimed at growing our business.

In the years ended December 31, 2019, 2018 and 2017, we have generated revenues of $31.3 million, $24.2 million and $20.7 million, respectively. We have grown our WatchPAT family of products revenue from approximately $18.1 million for the year ended December 31, 2017 to $22.4 million for the year ended December 31, 2018, reflecting a growth rate of 23.6%, and from $22.4 million for the year ended December 31, 2018 to $29.0 million for the year ended December 31, 2019, reflecting a growth rate of 29.5%.

Trend Information

The following is a description of the significant trends and uncertainties that we believe will continue to materially influence our market, financial condition and the demand for our products.

We expect to continue to generate revenues mainly from the sales of our WatchPAT family of products in the United States, Japan, Europe, Asia Pacific and China, which is consistent with our strategy to expand our sales of the WatchPAT in general and in those markets in particular. The level of our future revenues, however, is hard to predict and depends on many factors which are outside of our control.

We expect that the sales of our EndoPAT product will continue to fluctuate. There are few factors that may cause a decrease in our sales of the EndoPAT product, including (i) our strategic decision to reduce our sales and marketing efforts for such product, (ii) the reduction of research funds available to research institutions, which represent the vast majority of customers who purchase this product from us and (iii) the ongoing difficulties associated with obtaining coverage or reimbursement from third-party payors for the use of such product for clinical use in the United States. However, we expect to continue to sell EndoPAT to pharmaceutical companies' large studies and may, from time to time, yield relatively material revenue from EndoPAT sales, as we did in the year ended December 31, 2019.

We market our products, directly or through distributers and other sales channels, primarily to health facilities, physicians and research institutions, many of whom rely on coverage or reimbursement for the healthcare services they receive or provide to their patients, from third-party payors, such as private insurance plans offered by medical insurance companies. Currently, many medical insurers cover or allow only partial reimbursement of expenses associated with medical tests that use our products. However, we believe that the changes in the guidelines issued by the American Academy of Sleep Medicine, or AASM and coverage policies of third-party payors in the past two years may lead to the inclusion by more medical insurers of the WatchPAT test in the basket of medical examinations and procedures covered. In addition, we believe that continuing changes to Medicare reimbursement amounts for HSAT services will continue to support and expand the use of our WatchPAT technology. In particular, in November 2019, CMS published its annual update to the MPFS, which included changes to the Medicare reimbursement levels for CPT codes describing HSATs. The 2020 MPFS continued with the second year of a four-year schedule that has reduced and is expected to further reduce the Medicare payment associated with CPT code 95806, which describes HSAT services that do not utilize PAT technology. Medicare payment for CPT code 95800, which can describe PAT-based HSAT services like our WatchPAT, remained relatively stable from 2019 to 2020, with an approximate 2% reduction.

Based upon, among other things, CMS publications regarding the number of home sleep tests conducted in the United States during 2017 and 2018, we estimate that tests conducted with WatchPAT represent approximately 19.0%, and 18.0% of the total home sleep tests conducted in the United States in 2018 (approximately 1.5 million tests) and 2017 (approximately 1.4 million tests), respectively.

We estimate that the costs for our selling and marketing expenses will increase in future years, as we continue to build our business, including by expanding our footprint and the territories in which we operate. We also estimate that the costs for developing our products will increase in future years, as we execute our plan to develop new products and services, including new applications that are based on our PAT-based technology, to accelerate adoption by sleep physicians and cardiologists. We estimate that our general and administrative expenses will increase, primarily due to the continued expansion of our management team as well as compliance costs associated with being subject to reporting and other requirements under applicable United States securities laws and Nasdaq rules.

We intend to continue to invest in selling and marketing, in developing new products and services and otherwise implementing our strategy. We believe that this strategy will enable us to support continued sales growth and enhance market acceptance for our offerings. However, we expect to continue to incur operating losses in the near future as we increase our sales and marketing activities associated with implementing our strategy, mainly in the United States, Japan, Europe, Asia Pacific and China, and otherwise continue to invest capital in the development and expansion of our products and our business generally, including the commitment of substantial resources toward reimbursements and clinical studies.

In December 2019, a novel strain of coronavirus was reported in Wuhan, China. While, initially, the coronavirus outbreak was largely concentrated in China, it has now spread globally, including to the U.S., Europe, Japan and Israel. Many countries around the world, including in the U.S., Europe, Japan and Israel, have since implemented significant measures in an attempt to control the spread of the virus, such as temporary limitations on international and domestic travel, restrictions with respect to public gatherings, including the number of employees who may be present at a work place at any given time, limitations on access and entrance to various facilities, such as healthcare institutes, and other material limitations.

These measures have resulted in work stoppages, particularly in China, which disrupted our supply chain. While, prior to the coronavirus outbreak, we maintained a safety inventory which was designed to allow us to meet demand for our products during at least the first quarter of 2020, and while our supplies in China are resuming operations with first deliveries recently arriving to Israel, there is no assurance that we will not suffer additional supply chain interruptions or limitations on access to our facilities as a result of the various measures taken or that will be implemented to contain the coronavirus outbreak.

Limitations on access to healthcare facilities, including those who typically service our products, as well as a potential shift of respiratory personnel and resources toward a focus on addressing the coronavirus outbreak, could adversely impact demand for our multi-use reusable products. At the same time, in the U.S., the AASM has recently issued guidance encouraging sleep clinicians to use disposable single use home sleep tests, instead of traditional in-lab PSG tests or multi-use reusable home sleep tests, to reduce risk of infections, especially during the coronavirus outbreak. While demand for our multi use reusable home sleep test devices may be adversely impacted by the coronavirus outbreak, we believe that we are well positioned in the U.S. to benefit from this AASM guidance, with our single-use WatchPAT ONE home sleep test, combined with our CloudPAT digital health platform. We are also accelerating our efforts in Europe and in other parts of the world, in order to obtain regulatory approvals for our WatchPAT ONE disposable device. In response to these anticipated changes in the market, we are changing our manufacturing mix to prioritize WatchPAT ONE production. To that end, we are also currently investing considerable resources, including hiring of additional production and production related employees, to increase our WatchPAT ONE production capacity, while, given the rapidly changing market environment, there is no certainty as to when such investments and regulatory approvals will materialize into additional WatchPAT ONE sales.

The extent to which the coronavirus impacts our manufacturing, operations, demand for our products and business results, will depend on future developments, which are rapid and highly uncertain and cannot be predicted with confidence, including the duration and severity of the outbreak, and the actions that may be implemented in an attempt to contain the coronavirus or treat its impact. As such, the continued spread of the coronavirus globally and uncertainty about current global economic conditions, could adversely impact our operations and workforce, including our manufacturing and sales and marketing activities, which in turn, could have a material adverse impact on our business, financial condition and results of operation.

Our ability to continue our growth and achieve profitability depends, in part, on the global economy, including the potential effects of the coronavirus outbreak as described above and elsewhere in this Annual Report, the growth rates and changes in trends in industries in which we operate, including the availability of reimbursement for the use of our products by medical insurance companies as described elsewhere in this Annual Report, and the level of market acceptance of our products and services. As such, our results may be adversely affected if, among other things, there is an economic slowdown, a failure of our products to achieve market recognition or demand or interruption to our supply chains.

Financial Overview

Revenues

Our revenues consist primarily of sales of our WatchPAT family of products and, to a lesser extent, our EndoPAT product and related services to hospitals, clinics and physicians' practices, including health management organizations (HMOs), directly as well as through distribution channels. These products are offered mainly as a combination of TaaS (as part of our TSS program in the cardiology field in the United States), capital equipment (which can be used for several years) and one-time disposable probes. For additional details regarding the manner in which we recognize revenues, see the discussion under the caption "*Critical Accounting Policies and Significant Judgments and Estimates — Revenue Recognition*" below.

Cost of Revenues

Our cost of revenues consists of costs of raw materials and subcontractors, as well as labor, utility and maintenance costs associated with the operation of our manufacturing facility, depreciation and shipping and handling.

Operating Expenses

Our current operating expenses consist of three components:

- *Selling and Marketing.* Our selling and marketing expenses consist primarily of salaries, including share-based compensation and related personnel expenses to selling, marketing and business development personnel, sales commission and related personnel expenses, sales offices maintenance, administrative costs conferences and trade shows, advertising and marketing, cost of third-party consultants (including in respect of our efforts to increase the number of insurers entitled to reimbursement for use of our products) and travel expenses.

- Research and Development. Our research and development expenses consist primarily of salaries, including share-based compensation and related personnel expenses, cost of third-party consultants, advisory board, raw materials, costs related to conducting clinical studies, patent costs, regulatory costs and travel expenses. Some development costs that relate to development of products or processes that are technically and commercially feasible and for which we have sufficient resources to complete development and intent to use or sell them are capitalized and subsequently amortized.

- General and Administrative. General and administrative expenses consist primarily of salaries, including share-based compensation and related personnel expenses, professional service fees for accounting, legal, bookkeeping, directors' fees and associate costs, and doubtful debts.

Financial Expenses and Income

Financial expenses and income consist primarily of interest expenses and exchange rate differences on loans and lease liabilities, interest income and exchange rate differences on bank deposits and marketable securities and changes in the fair value of warrants which expired in May 2019, and embedded warrants of our convertible notes that were fully repaid in February 2018, interest expenses and exchange rate differences on such convertible notes, change in the fair value of marketable securities and foreign currencies gains or losses. The warrants, including the embedded warrants in our convertible notes, were measured on each reporting date and the results from the changes in their fair value which was being impacted, among other things, by the changes in our share price were included in financial expenses or income, net. Typically, when the share price increased, the fair value of the warrants and the embedded warrants increased, which resulted in higher net financial expenses, and when share price decreased, the fair value of the embedded warrants decreased, which resulted in lower net financial expenses or in net financial income.

Taxes on Income

We are subject to income taxes in Israel, the United States, the Netherlands and Japan. Our Japanese subsidiary is in the process of being dissolved.

Critical Accounting Policies and Significant Judgments and Estimates

The preparation of financial statements in conformity with IFRS requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent liabilities at the date of the financial statements and the reported amounts of assets, liabilities, revenues and expenses during the reporting period.

The accounting estimates used in the preparation of our financial statements require management to make assumptions regarding circumstances and events that involve considerable uncertainty. Management prepares the estimates based on past experience, various facts, external circumstances, and reasonable assumptions according to the pertinent circumstances of each estimate. Actual results may differ from these estimates under different assumptions or conditions. Estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognized in the period in which the estimates are revised and in any affected future periods.

While our significant accounting policies are more fully described in Note 2 to our audited consolidated financial statements included elsewhere in this Annual Report, we believe the following accounting policies are most critical to understanding and evaluating our reported financial results.

Revenue Recognition

As of January 1, 2018, we apply the following accounting policies under IFRS 15, *Revenues from Contracts with Customers.*

We recognize revenues when the customer obtains control over the products or services that have been secured, net of provision for returns and discounts. The revenue is measured according to the amount of consideration that we expect to be entitled to in return for the transfer of products or services promised to the customer, other than amounts collected in favor of third parties.

We recognize estimated sales discounts as a reduction of sales in the same period at which revenue is recognized. We adjust reserves to reflect differences between estimated and actual. We estimate our sales returns reserve based on historical return rates and analysis of specific accounts.

When we sell our products through distributors, revenue is being recognized upon delivery of the product to the distributor, as the distributor does not have the right to return and the control over the products is transferred at this point in time.

We account for a contract with a customer only when the following conditions are met: (i) the parties to the contract have approved the contract (in writing, orally or according to other customary business practices) and they are committed to satisfying the obligations attributable to them; (ii) we can identify the rights of each party in relation to the products or services that will be transferred; (iii) we can identify the payment terms for the products or services that will be transferred; (iv) the contract has a commercial substance (i.e., the risk, timing and amount of the entity's future cash flows are expected to change as a result of the contract); and (v) it is probable that the consideration, to which we are entitled to in exchange for the products or services transferred to the customer, will be collected.

If a contract with a customer does not meet all of the above criteria, consideration received from the customer is recognized as a liability until the criteria are met or when one of the following events occurs: (i) we have no remaining obligations to transfer products or services to the customer and any consideration promised by the customer has been received and cannot be returned; or (ii) the contract has been terminated and the consideration received from the customer cannot be refunded.

We identify products or services promised to the customer as being distinct performance obligations when the customer can benefit from the products or services on their own or in conjunction with other readily available resources and our promise to transfer the products or services to the customer is separately identifiable from other promises in the contract. In order to examine whether a promise to transfer products or services is separately identifiable, we examine whether we are providing a significant service of integrating the products or services with other products or services promised in the contract into one integrated outcome that is the purpose of the contract.

Products or services that are not considered as being distinct are grouped together as a single performance obligation. The revenue from each such performance obligation is recognized upon transfer of control over the promised products or services to customer. In general, we allocate the transaction price to the identified performance obligations in the contract, based on the relative stand-alone selling prices when the products or services are sold separately. In cases where the products or services are not sold separately, for example, in the case of installations or training, we establish the stand-alone selling price assigned to that performance obligation, based on estimated costs plus a reasonable margin. Significant financing component in installment sales is separated in determining the transaction price.

As applicable to us, revenues from sales agreements consisting of multiple products or services, such as devices, consumables, access to our CloudPAT application, WatchPAT Direct logistic services and support, extended warranty and other service agreements, are separated into different performance obligations, based on its relative fair values, and revenue is separately recognized for each performance obligation.

We recognize revenue from renting our products over the rent term, in conformity with the agreement with the customer.

Since 2015, we have focused on offering TSS to our customers focusing on the cardiology market through various business models; however, TaaS, is the primary model we utilized to date. In the TaaS model, the medical practice or physician ordering the TaaS pays a fixed fee per HSAT that includes all the components associated with the test, including the disposable biosensor, hardware rental fees and access to our CloudPAT platform. Under the TaaS model, some rent agreements of the WatchPAT family of products are made for a period of one to two years. The rental fees are separated under the relative fair value approach.

In some cases, we handle sale transactions of these devices as a finance lease and recognize revenue in respect of the products supplied at the commencement date of the lease. When these transactions include multiple performance obligations, revenue is recognized based on the relative stand-alone selling prices of each performance obligation in the transaction when they are sold separately.

Revenue is recognized when we satisfy a performance obligation by transferring control over the promised products or services to the customer. Sale of devices and disposables are generally recognized upon shipment. Services (including extended warranty) are recognized ratably over the service period.

A contract asset is recognized when we have a right to consideration for products or services, we transferred to the customer that is conditional on other than the passing of time, such as our future performance. Contract assets are classified as receivables when the rights in their respect become unconditional.

A contract liability is recognized when we have an obligation to transfer products or services to the customer for which we received consideration (or the consideration is payable) from the customer. An asset and liability relating to the same contract are presented on a net basis in the statement of financial position. On the other hand, a contract asset and contract liability deriving from different contracts are presented on a gross basis in the statement of financial position.

As to the accounting policy applied in periods prior to January 1, 2018, see Note 2r to our audited consolidated financial statements included elsewhere in this Annual Report.

Discount Rate for Lease liabilities

Lease contracts that give us control over the use of the leased asset over a period of time for consideration, are treated as leases. At the initial recognition, we recognize a liability at the present value of the lease payments (these payments do not include certain variable lease payments) discounted using the interest rate implicit in the lease or, if that rate cannot be readily determinable, our incremental borrowing rate, and at the same time we recognize a right-of use asset at the same amount of the lease liability, adjusted for prepaid or accrued lease payments, plus any direct costs incurred in respect of the lease.

An increase or decrease in the incremental borrowing rate will be reflected in a decrease or increase in the lease liability or in the right-of use asset and in the depreciation and financial expenses that will be recognized in the statement of operations.

Derivatives

We recognize all derivative instruments as assets or liabilities in the statements of financial position at their estimated fair values, and the changes in such fair values are recognized in the statements of operations within "financial income (expenses), net" for the period in which they occur. During the reported periods, we did not have derivatives designated as hedges. We review our contracts to identify the existence of embedded derivatives. Identified embedded derivatives are analyzed to determine if they need to be separated from the host contract and recognized in the statements of financial position as assets or liabilities, applying the same valuation rules used for other derivative instruments.

Derivatives with either a conversion price or an exercise price that are denominated in NIS, a currency different than our functional currency, are accounted for as a derivative financial instrument measured at fair value through the statements of operations on each reporting date and constitute a liability.

The fair value of derivatives which are embedded in our formerly outstanding convertible notes is measured based on direct or indirect observed market data, using the binomial model, based on relevant parameters of the conditions of the convertible notes which have been identified for determining the fair value of the warrant component.

The Warrants (Series 4), which were traded on the TASE, and the Viola Warrants were essentially identical in their conditions (both expired in May 2019). We believed that there was no active market for the traded Warrants (Series 4), primarily due to an ongoing gradual decline in the frequency and volume of trading in such warrants with significant variance in the transactions prices of the warrants without a corresponding material change in the share price, and often with a negative correlation between the change in the share price and the change in the warrants price. Consequently, we estimated the fair value of the Warrants (Series 4) and the Viola Warrants based on observable market data, directly or indirectly, based on the binomial model and based on relevant parameters of the terms of the Warrants (Series 4) and the Viola Warrants.

The following parameters were used in the calculation of the fair value of the above derivatives, using the binomial model: discount rate for notes (yield to maturity of the notes), the discount rate of the Viola Warrants and Warrants (Series 4) (risk free interest), the share price and standard deviation of the share price.

Recently Issued Accounting Pronouncements

For information with respect to recent accounting pronouncements, see Note 2g to our audited consolidated financial statements included elsewhere in this Annual Report.

A. Operating Results

For a discussion of our results of operations for the year ended December 31, 2017, including a year-to-year comparison between 2018 and 2017, and a discussion of our liquidity and capital resources for the year ended December 31, 2017, refer to "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our final prospectus filed with the SEC pursuant to Rule 424(b)(4) on January 31, 2020.

The following discussion of our results of operations for the years ended December 31, 2019 and December 31, 2018, including the following tables, which present selected financial information data in U.S. dollars and as a percentage of total revenues, is based upon our consolidated statements of operations contained in our consolidated financial statements and the related notes included elsewhere in this Annual Report.

	Year Ended December 31,	
	2019	2018
	(in thousands, except per share and share data)	
Consolidated Statements of Operations Data:		
Revenues	$ 31,258	$ 24,189
Cost of revenues	6,984	5,726
Gross profit	24,274	18,463
Operating expenses:		
Selling and marketing	18,294	12,699
Research and development	4,520	3,638
General and administrative	6,354	5,247
Total operating expenses	29,168	21,584
Operating loss	(4,894)	(3,121)
Financial income from cash, deposits and investments	454	244
Financial expenses from leases, notes, loans and other	(1,233)	(1,161)
Gain from derivative instruments, net	442	2,433
Financial income (expenses), net	(337)	1,516
Loss before income taxes	(5,231)	(1,605)
Taxes on income	(37)	(124)
Net loss	$ (5,268)	$ (1,729)
Loss per share:		
Basic	$ (0.02)	$ (0.01)
Diluted	$ (0.02)	$ (0.01)

	Year Ended December 31,	
	2019	2018
Revenues	100.0%	100.0%
Cost of revenues	22.3	23.7
Gross profit	77.7	76.3
Operating expenses:		
Selling and marketing	58.5	52.5
Research and development	14.5	15.0
General and administrative	20.3	21.7
Total operating expenses	93.3	89.2
Operating loss	(15.6)	(12.9)
Financial income from cash, deposits and investments	1.5	1.0
Financial expenses from leases, notes, loans and other	(3.9)	(4.8)
Gain from derivative instruments, net	1.4	10.1
Financial income (expenses), net	(1.1)	6.3
Loss before income taxes	(16.7)	(6.6)
Taxes on income	(0.1)	(0.5)
Net loss	(16.8)%	(7.1)%

Comparison of the Year Ended December 31, 2019 to the Year Ended December 31, 2018

Revenues

The following tables provide a breakdown of our revenues, by line of product and by geographic area, during the years ended December 31, 2019 and 2018, as well as the percentage change between such years:

	Year Ended December 31,		Increase
	2019	2018	
	(in thousands)		%
WatchPAT and other related services	$ 28,988	$ 22,384	29.5
Endo PAT and other related services	2,270	1,805	25.8
Total	$ 31,258	$ 24,189	29.2

	Year Ended December 31,		Increase
	2019	2018	
	(in thousands)		%
United States and Canada	$ 22,960	$ 17,582	30.6
Japan	3,489	3,374	3.4
Europe	3,383	1,885	79.5
Asia Pacific (excluding Japan)	912	849	7.4
Other	514	499	3.0
Total	$ 31,258	$ 24,189	29.2

Our revenues in 2019 increased by 29.2% to $31.3 million, compared with $24.2 million in 2018. The increase is mainly attributable to an increase of 29.5% in revenues from sales of our WatchPAT family of product and an increase of 25.8%, in the revenues from sales of our EndoPAT product in 2019, compared with 2018.

The increase in revenues from sale of our WatchPAT family of products in 2019, is mainly associated with the following: (i) an increase of 30.0% in sales of disposables in the United States which is attributable to an increase in the volume of disposables being used with each WatchPAT test sold in the United States and an increase of 53.2% in revenues from a significant customer as a result of an order of $2.3 million for WatchPAT 300, mostly for an upgrade and expansion of such customer's current WatchPAT fleet; (ii) an increase of 58.1% in WatchPAT sales in Europe, which is attributable to an increase in the volume of sales in such territory; and (iii) an increase of 13.8% sales of WatchPAT in Japan, which is attributable to an increase in the volume of sales of WatchPAT in such territory.

The increase in revenues from sales of our EndoPAT product in 2019, is primarily associated with a purchase order of approximately $1.1 million for EndoPAT, from an existing customer in the pharmaceutical industry, pursuant to an existing framework agreement with such customer, out of which revenues of $1.0 million were recognized in 2019.

The portion of revenues from the sale of disposables out of our total revenues in 2019 increased to 56.5%, from 54.9% in 2018 (such portion in the United States increased from 62.4% 2018 to 64.2% in 2019 (or, if we exclude the $2.3 million order from the significant customer mentioned above, to 70.9%)), while the ratio of revenues from the sale of devices out of our total revenues in 2019 decreased to 31.5%, from 33.9% in 2018. The change in the ratio between revenues from sale of disposables and sale of devices in the comparison years was mainly attributed to an increase in the number of WatchPAT tests (and hence, use of disposables) conducted during such years, primarily in the United States.

Revenues from each of the other services, such as access to our CloudPAT platform, WatchPAT Direct logistic services and support and other service agreements were also immaterial in each of 2019 and 2018 and represented less than 5% of our total revenues during such years.

Cost of Revenues and Gross Profit

Our cost of revenues for 2019 increased by 22.0% to $7.0 million, compared with $5.7 million in 2018, whereas our gross profit for 2019 increased by 31.5% to $24.3 million, compared with $18.5 million in 2018. The increase in absolute gross profit is primarily due to our increased volume of sales. The increase in our gross profit margin to 77.7% in 2019, from 76.3% in 2018 is primarily attributable to: (i) increased efficiency and cost reduction in the production process; and (ii) allocation of fixed costs and overhead expenses on a higher volume of sales.

Operating Expenses

The following table sets forth a breakdown of our operating expenses (excluding cost of revenues) for the years ended December 31, 2019 and 2018 as well as the percentage change between such years:

	Year Ended December 31,		Increase
	2019	2018	%
	(in thousands)		
Selling and marketing	$ 18,294	$ 12,699	44.1
Research and development	4,520	3,638	24.2
General and administrative	6,354	5,247	21.1
Total	$ 29,168	$ 21,584	35.1

Selling and Marketing

Selling and marketing expenses for 2019 increased by 44.1% to $18.3 million, compared with $12.7 million in 2018. This increase is primarily due to an increase in employee related costs (including payroll, share-based compensation, sales commissions and travel expenses) associated with the expansion of our U.S. sales team into new geographical territories and verticals (27 territories and verticals as of December 31, 2019, compared to 19 territories and verticals as of December 31, 2018).

Research and Development

Research and development, or R&D, expenses increased by 24.2% to $4.5 million in 2019, compared with $3.6 million in 2018. This increase is primarily due to an increase in employee related costs related to recruitment of new R&D personnel, offset by a decrease in expenses associated with clinical studies.

General and Administrative Expenses

General and administrative, or G&A, expenses increased by 21.1% to $6.4 million in 2019, compared with $5.2 million in 2018. This increase is primarily due to due to additional legal, audit and other expenses relating to the listing of the ADSs, on Nasdaq in February 2019, to an increase in employee related costs and to an increase of $0.2 million in allowance for doubtful debts.

Operating Loss

Based on the foregoing, our operating loss increased from $3.1 million in 2018 to $4.9 million in 2019.

Financial Income, Net

Financial expenses, net for 2019 were $0.3 million, compared to financial income, net of $1.5 million in 2018. The change is primarily because in 2018, we incurred net gain from changes in the fair value of derivative instruments, which amounted to $2.4 million, compared with $0.4 million in 2019. This was offset by an increase of $0.2 million in financial income from cash, bank deposits and investments, as a result of an increase in cash balances resulting from the cash raised in a private placement in the first quarter of 2019.

The decrease in gain with respect to derivative instruments in 2019 is due to the decrease in the fair value of the Warrants (Series 4) and the Viola Warrants as a result of their expiration in May 2019. According to IFRS, a valuation at each reporting date of such derivative instruments is required since they are denominated in NIS. The fair value is primary impacted by our share price and the reduction of the maturity period.

Net Loss

Net loss for 2019 increased by $3.5 million, or 204.7%, to $5.3 million, compared with a net loss of $1.7 million in 2018. This increase is primarily attributable to the transition from net financial income to net financial expenses and an increase in our operating loss, as described above.

Impact of Currency Fluctuations and of Inflation

Our financial results may be impacted by foreign currency fluctuations and inflation although, except as set forth below, foreign currency fluctuations and the rate of inflation did not have a material impact on our financial results in the past three years.

Since the majority of our revenues are paid in or linked to the U.S. dollar, we believe that inflation and fluctuations in the NIS and U.S. dollar exchange rate have no material effect on our revenues. However, a significant portion of the cost of our Israeli operations, mainly personnel and facility-related, is incurred in NIS and, consequently, inflation in Israel and fluctuations in the U.S. dollar/NIS exchange rate may have an impact on our expenses and, as a result, on our net income or loss. Our NIS costs, as expressed in U.S. dollars, are influenced by the extent to which any increase in the rate of inflation in Israel is not offset (or is offset on a lagging basis) by a devaluation of the NIS in relation to the U.S. dollar. To protect against the changes in value of forecasted foreign currency cash flows resulting from payments in NIS, we maintain liquid means on hand in NIS and U.S. dollar and we execute, from time to time, hedging transactions in accordance with our needs. As of December 31, 2019, we did not enter into any hedging transactions. Even if we enter into such hedging transactions, these measures may not adequately protect us from material adverse effects due to the impact of currency fluctuations or inflation.

For additional details, see Item 11. "*Quantitative and Qualitative Disclosures about Market Risk*."

B. Liquidity and Capital Resources

Since our incorporation in 1997, we have incurred operating and net losses in most of our years of operation. As of December 31, 2019, we had an accumulated deficit of approximately $109.6 million. We expect to continue to incur operating and net losses for the foreseeable future, as we continue to invest in research and development and marketing and sales operations aimed at growing our business.

In the past several years, we financed our operations primarily through issuance of equity and debt to the public, private placements of our ordinary shares and ADSs to institutional and other investors and loans from our major shareholders and commercial banks.

Our funding and treasury activities are conducted within corporate practices to maximize investment returns while maintaining appropriate liquidity for both our short and long-term needs. Cash and cash equivalents are held primarily in U.S. dollars and NIS.

Principal Financing Activities

Since January 1, 2018, we have engaged in the following principal financing activities:

Credit Line. On March 29, 2017, we entered into a credit line agreement with an Israeli commercial bank, to which we refer, as amended on January 30, 2018 and May 28, 2018, as the Credit Agreement. Under the Credit Agreement, we secured a credit line in a total amount of up to $10 million comprised of (i) up to $6 million in long-term loan, or Loan; and (ii) up to $4 million of revolving credit line against our trade accounts receivable, or Revolving Credit Line. The Credit Agreement was replaced by new credit line agreements entered into on March 12, 2019, or the 2019 Credit Agreement, and on February 9, 2020, as detailed below:

- In connection with the Credit Agreement, we issued the bank warrants exercisable into up to 798,088 ordinary shares at an exercise price of NIS 1.36 per share (equivalent to approximately $0.37 per share), subject to adjustments. The warrants were initially exercisable until May 14, 2022 (see extensions below).

- In order to secure our obligations to the bank, we pledged and granted to the bank a first priority floating charge on all of our assets and a first priority fixed charge on (i) our intellectual property, goodwill, holdings in our subsidiaries and certain other, immaterial, assets and (ii) all of the assets of the U.S. Subsidiary. We refer to the agreements relating to such charges and other security interests (as amended or replaced, as described below) as the Security Agreements. The Security Agreements contain a number of customary restrictive terms and covenants that limit our operating flexibility, such as (i) limitations on the creation of additional liens, on the incurrence of indebtedness, on the provision of loans and guarantees and on distribution of dividends; and (ii) the ability of the bank to accelerate repayment in certain events, such as breach of covenants, liquidation, and a change of control of our Company. Such provisions may hinder our future operations or the manner in which we operate our business, which could have a material adverse effect on our business, financial condition or results of operations.

- On March 12, 2019, we and the bank entered into the 2019 Credit Agreement under which the total credit line to be available under the credit facility was increased from $10 million under the Credit Agreement to $15 million under the 2019 Credit Agreement, comprised of: (i) up to $9 million in long-term or short-term loan; and (ii) and up to $6 million of credit facility against trade accounts receivable. As part of the 2019 Credit Agreement, we (i) issued to the bank additional warrants exercisable into 399,044 ordinary shares at an exercise price of NIS 1.30 per share (equivalent to approximately $0.36 per share), which were initialy exercisable until March 28, 2023 (see extension below), and (ii) extended the exercise period of the original warrants issued in connection with the Credit Agreement until March 28, 2023 (see extension below). In addition, we have amended certain of the Security Agreements and replaced certain of them in order to secure our obligations under the 2019 Credit Agreement.

- On February 9, 2020, we and the bank entered into the Credit Facility under which the total credit line to be available under the credit facility was increased from $15 million under the 2019 Credit Agreement to $17 million under the Credit Facility, comprised of: (i) up to $10 million in long-term or short-term loan, or the Loan; and (ii) and up to $7 million of credit facility against trade accounts receivable, or the Revolving Credit Line. The amount of $10 million may increase in July 2020 by an additional $3 million, to a total of $13 million (and, consequently, the total amount of the credit line will increase from up to $17 million to up to $20 million), if we will achieve certain revenue targets in the first half of 2020.

    - The Loan may be drawn until October 25, 2020 and bears interest at the annual interest rate of the quarterly dollar LIBOR rate plus 5.5%, except that the additional $3 million of long-term or short-term loan, if available and drawn, will bear annual interest of the quarterly dollar LIBOR rate plus 7.0%.

    - The Revolving Credit Line may be drawn until October 25, 2020 and bears interest at the annual interest rate of the monthly dollar LIBOR rate plus 4.25%.

    - The right to make any draws, whether under the Loan or the Revolving Credit Line, is conditioned upon us having cash balances in our account with the lending bank of not less than 30% of the total amount drawn for draws of up to $10 million in the aggregate and 40% of the aggregate amount exceeding $10 million.

    - As part of the Credit Facility, we (i) issued to the bank additional warrants exercisable into 359,140 ordinary shares at an exercise price of NIS 1.04 per share (equivalent to $0.29 per share), which will be exercisable until November 30, 2023, and (ii) extended the exercise period of the original warrants issued in connection with the Credit Agreement and the 2019 Credit Agreement until November 30, 2023. In addition, we have amended certain of the Security Agreements in order to secure our obligations under the Credit Facility.

- As of December 31, 2019, we had a total outstanding principal amount of $5.0 million under the 2019 Credit Agreement, of which (i) $1.6 million were drawn on November 20, 2019 as a short-term loan; and (ii) $3.4 million were drawn under the Revolving Credit Line. On February 20, 2020, as part of the new Credit Facility, we renewed the term of the $5.0 million loan and changed the mix of the amount, such that $1.2 million were drawn as a short-term loan for three months, until May 20, 2020; and $3.8 million were drawn under the Revolving Credit Line for three months, until May 20, 2020.

2018 Repayment of Series L Convertible Notes. In February 2018, we repaid all of the outstanding principal amount and accrued interest of our then outstanding Series L Convertible Notes, or the convertible notes, which were issued as part of a public offering we conducted in 2013 and had a conversion price of NIS 1.92 per share (equivalent to approximately $0.54, based on the exchange rate on the last exercise date, i.e., on February 12, 2018). The full repayment, which totaled in a sum of NIS 32.1 million (equivalent to approximately $9.2 million, based on the exchange rate as of the repayment date), did not include (i) repayment to Dr. Giora Yaron (through a company wholly owned by him), our Chairman of the Board of Directors and a major shareholder, and Medtronic, our former shareholder, both of whom held convertible notes and agreed to waive such repayment and used the funds otherwise owed to them to make the investment described under "*2018 Private Placement*" below; and (ii) repayment of NIS 1.6 million (equivalent to approximately $0.5 million, based on the exchange rate as February 28, 2018) to Mr. Martin Gerstel, a member of our Board of Directors and a major shareholder, who held convertible notes and agreed to postpone such repayment from February 2018 to June 2018.

2018 Shareholders' Loan. As described under "*2018 Repayment of Series L Convertible Notes*" above, the repayment of the convertible notes did not include (i) the repayment to Dr. Giora Yaron (through a company wholly owned by him) and Medtronic, who agreed to waive such repayment and used the funds otherwise owed to them to make the investment described under "*2018 Private Placement*" below; and (ii) repayment of NIS 1.6 million (equivalent to approximately $0.5 million, based on the exchange rate as February 28, 2018) to Mr. Martin Gerstel who held convertible notes and agreed to postpone such repayment from February 2018 to June 2018. Such amounts were treated as shareholders' loan until repaid or converted to investment in shares as part of the 2018 private placement described in the next paragraph.

2018 Private Placement. On March 22, 2018, we entered into separate securities purchase agreements with Dr. Giora Yaron (through a company wholly owned by him), our Chairman of the Board of Directors and a major shareholder; Viola, our largest shareholder; and Medtronic, a former shareholder, and various funds affiliated with three Israeli institutional investors, Yelin Lapidot, Meitav Dash and The Phoenix Holdings Ltd., or Phoenix:

- On May 27, 2018, following approval by our shareholders of the private placement contemplated by these securities purchase agreements, we completed the transaction and issued to the investors a total of 22,013,893 ordinary shares (representing as of such date approximately 7.7% of our issued and outstanding shares on a post-issuance basis) at a purchase price of NIS 0.947 per share (equivalent to approximately $0.27, based on the exchange rate as of that date), resulting in aggregate proceeds (before expenses) of NIS 20.8 million (equivalent to approximately $6.0 million, based on the exchange rate as of that date). Out of the total NIS 20.8 million investment, Dr. Yaron, Viola and Medtronic invested NIS 2.1 million, NIS 5.2 million and NIS 2.4 million, respectively.

- The ordinary shares issued to the investors were subject to resale restrictions under Israeli law as applicable to private placements, including an initial six-month full lockup resale restriction that expired in late November 2018.

- The securities purchase agreements contained customary terms and conditions, including limited representations and warranties of the parties which survived the completion of the transaction and, in general, expire on May 27, 2019.

2019 Private Placement. On January 16, 2019 and January 28, 2019, we entered into separate securities purchase agreements with several U.S. and Israeli accredited investors: a fund managed by Deerfield Special Situations Fund, L.P., or Deerfield; Triple Gate Capital, L.P., or Triple Gate; West Elk Partners, L.P., or West Elk; Alpha Capital Anstalt, or Alpha; More Trust Fund Management (2013) Ltd., or More Trust; More Alternative Investments, L.P., or More Alternative; Hatzavim, L.P. (in the process of being acquired by Meitav Dash, one of our former major shareholders), or Hatzavim; Tachlit Complex Instruments Ltd. (wholly owned by Meitav Dash, one of our former major shareholders) , or Tachlit; Noked Long L.P.; and Noked Bonds, L.P.:

- Under the securities purchase agreements, we undertook to issue to the investors, upon and subject to the closing, (i) a total of 1,170,707 ADSs, at a price per ADS of $9.55, to the investors (other than More Investment House), or U.S. Tranche; and (ii) a total of 10,944,185 ordinary shares to More Trust, at a price per ordinary share of NIS 1.1693 (equivalent to approximately $0.32, based on the exchange rate as of the date of the agreement), or Israeli Tranche, or, in the aggregate, we will issue to the investors a total of 46,115,395 ordinary shares (including ordinary shares underlying the ADSs) representing, as of January 28, 2019, approximately 13.8% of our issued and outstanding shares on a post-issuance basis, resulting in aggregate proceeds (before expenses) of approximately $14.7 million. Out of the total $14.7 million investment, Deerfield, Triple Gate, West Elk, Alpha, More Trust, More Alternative, Hatzavim, Tachlit, Noked Long, and Noked Bond undertook to invest approximately $3.0 million, $2.0 million, $2.0 million, $1.0 million, $3.5 million, $0.5 million, $0.5 million, $0.5 million, $1.4 million and $0.3 million, respectively.

- On February 3, 2019, we completed the private placement with More Trust and issued to More Trust, 10,994,185 ordinary shares, and on March 6, 2018, we completed the private placement with the U.S. Tranche and issued to the investors under the U.S, Tranche 1,170,707 ADSs.

- Pursuant to the securities purchase agreements, we agreed, subject to customary exceptions, not to raise additional funds or issue equity securities until the earlier of 180 days following the closing or an initial public offering of our ADSs. In addition, our directors and executive offices have entered into customary lockup agreements, whereby each of them agreed not to sell their ordinary shares from January 16, 2019 until the earlier of (i) 180 days following the closing of the U.S. Tranche, (ii) the termination of the securities purchase agreement, or ten (10) months following the signing (November 15, 2019).

- The ordinary shares and ADSs issued to the investors are subject to resale restrictions under applicable U.S. and Israeli securities laws. None of the investors were granted registration rights under the securities purchase agreements.

- The securities purchase agreements contain other customary terms and conditions, including customary representations and warranties of the parties which survive the completion of the transaction until the date on which the investors no longer hold any of the ADSs or shares, as applicable.

2020 Public Offering. In February 2020, we completed a registered public offering of 2,927,267 ADSs, each representing 30 ordinary shares of the Company, at a price of $13.75 per ADS, for total gross proceeds of approximately $40.25 million, or total net proceeds of approximately $35.5 million after deducting underwriting discounts and commissions of approximately $2.8 million and offering expenses of approximately $2.0 million. In connection with the public offering, we and certain of our shareholders and ADS holders, directors and officers have agreed not to sell any of our ordinary shares or ADSs without the prior written consent of the representatives of the underwriters until July 29, 2020. The representatives of the underwriters may, however, in their sole discretion and without notice, release all or any portion of these securities from the restrictions in the lock-up agreements. After these agreements expire, these securities will be eligible for sale in the public market.

Working Capital

As of December 31, 2019, we had $15.1 million in cash and cash equivalents, compared with $6.5 million as of December 31, 2018. The increase in the year ended December 31, 2019, compared to the year ended December 31, 2018 derives primarily from the $14.0 million net proceeds from the private placement we completed in January and February 2019, partially offset by the cash flows used in operating activities in an amount of $4.2 million (which includes interest payments for our credit line).

As of December 31, 2019 and 2018, we did not have any debt to a third party, other than the short-term loans from a bank under the Credit Agreement or the 2019 Credit Agreement.

As of December 31, 2019, our working capital amounted to $15.0 million, compared with $6.2 million as of December 31, 2018. The increase in the year ended December 31, 2019, compared to the year ended December 31, 2018 was derived primarily from the private placement we completed in January and February 2019, partially offset by the decrease in cash and cash equivalents resulting from the financing of our operating activities.

Cash Flows

The following table presents the major components of net cash flows used in and provided by operating, investing and financing activities for the periods presented

	Year Ended December 31,	
	2019	**2018**
	(in thousands)	
Net cash used in operating activities*	$ (4,232)	$ (3,883)
Net Cash provided by (used in) investing activities	(615)	2,799
Net Cash provided by (used in) financing activities	13,292	(85)
Increase (decrease) in cash and cash equivalents	$ 8,445	$ (1,169)

* Including interest on our convertible notes and bank loans.

Operating Activities

Cash flows from operating activities consist primarily of loss adjusted for various non-cash items, including depreciation and amortization, share-based compensation expenses and gain or loss from reevaluation of derivatives. In addition, cash flows from operating activities are impacted by changes in operating assets and liabilities, which include inventories, accounts receivable and other assets and accounts payable.

Net cash used in operating activities for the year ended December 31, 2019 was $4.2 million. This net cash used in operating activities primarily reflects a net loss of $5.3 million, net of non-cash expenses, net of $3.1 million, as well as an increase of $2.1 million in trade receivables due to an increase in revenues in 2019, an increase of $1.6 million in inventories due to the aforesaid increase in revenues and the launch of the WatchPAT 300 and WatchPAT ONE product, an increase of $0.4 million in other accounts receivable, and interest of $0.4 million paid on our bank loan and leases, offset by an increase of $2.2 million in accounts payable and an increase of $0.2 million in employee benefits. Net non-cash expenses of $3.1 million consisted primarily of depreciation and amortization of $1.4 million, net financial cost of $0.5 million, share-based compensation of $1.3 million, and an increase of $0.3 million in provision for doubtful and bad debt, offset by a net gain from changes in fair value of derivative instruments of $0.4 million relating to warrants, mainly attributable to share price decrease.

Net cash used in operating for the year ended December 31, 2018 was $3.9 million. This net cash used in operating activities primarily reflects a net loss of $1.7 million, net of non-cash expenses, net of $0.1 million, an increase of $1.0 million in trade receivables due to an increase in revenues in 2018, an increase of $0.3 million in other accounts receivable, and an increase of $0.3 million in inventories due to the aforesaid increase in revenues and the desire to hold inventory levels for one additional quarter, offset by an increase of $0.3 million in accounts payable and interest of $0.8 million paid on our convertible notes and bank credit line. Net non-cash expenses of $0.1 million consisted primarily of depreciation and amortization of $0.5 million, net financial cost of $0.9 million, share-based compensation of $1.0 million, and an increase of $0.1 million in provision for doubtful and bad debt, offset by a net gain from changes in fair value of derivative instruments of $2.4 million relating to warrants, including warrants embedded in our convertible notes, mainly attributable to share price decrease.

Investing Activities

Net cash used in investing activities for the year ended December 31, 2019 was $0.6 million. This net cash used in investing activities is primarily attributable to capital expenditure and capitalized development costs of $0.5 million.

Net cash provided by investing activities for the year ended December 31, 2018 was $2.8 million. This net cash provided by investing activities is primarily attributable to realization of marketable securities in the amount of $3.1 million, offset by capital expenditures and capitalized development costs of $0.3 million.

Financing Activities

Net cash provided by financing activities for the year ended December 31, 2019 was $13.3 million. This net cash provided by financing activities is primarily due to net proceeds from issuance of shares in a private placement in the net amount of $14.0 million, offset by principle element of lease payments in the amount of $0.8 million.

Net cash used in financing activities for the year ended December 31, 2018 was $0.1 million. This net cash used in financing activities is primarily due to the second and final repayment of our convertible notes in the amount of $9.9 million and repayment of shareholders' loan in the amount of $0.4 million, offset by the proceeds of $5.2 million from the private placement in May 2018 and a draw of $5.0 million out of our bank credit line.

Principal Capital Expenditure and Divestitures

During the year ended December 31, 2019, our capital expenditures and capitalized development costs totaled $0.5 million, compared to $0.3 million during the year ended December 31, 2018, most of which were used for the purchase of production and research and development equipment, office furniture and equipment and computers and self-manufactured equipment (WatchPAT devices that are used by our customers). Except as described in this Annual Report, we have no significant capital expenditures in progress. For more information regarding the process of constructions and adjustment of our new manufacturing facilities, see under Item 4.D. "*Information on the Company — Property, Plants and Equipment*".

We did not affect any principal divestitures in the past three years.

Outlook

Currently, our principal commitments consist mainly of our lease obligations and bank credit line. In light of our cash balances and other factors, including our ability to use our bank credit line, we believe that our existing capital resources will be adequate to satisfy our working capital and capital expenditure requirements for a period of no less than 12 months from the date of this Annual Report. However, from time to time, we may seek additional financing sources to maintain and grow our business.

C. Research and Development, Patents and Licenses, etc.

We view sleep medicine in general and in particular, sleep in cardiology, as our main business. Therefore, our research and development efforts in recent years were focused on (i) enhancing and improving the technology underlying our main platform, the WatchPAT 200, primarily in order to address market needs (such as by adding the ability to identify central sleep apnea and Cheyne-Stokes respiration that is typical to cardiac patients); (ii) evolution of our product lines by introducing a new generation of products (such as the WatchPAT 300, for which we obtained FDA clearance In August 2018 and the WatchPATONE for which we obtained FDA clearance in June 2019); and (iii) improving our solutions in collaboration with other companies in the sleep arena, with the goal of introducing a superior solution to our customers.

We also invest in clinical research to support the expansion of our sleep apnea solutions in the cardiology market and in the sleep medicine market in general, as well as in order to substantiate and support the data which is at the basis of the products we are developing or enhancing. We also use such research to gain recognition in the medical community and for scientific publications.

Our research and development activities for all our products principally take place in Israel with the exception of clinical trials that are also conducted outside of Israel. As of December 31, 2019, we employed 20 persons in research and development, compared to 17 persons as of December 31, 2018 and 14 persons as of December 31, 2017.

We have committed substantial financial resources to our research and development efforts. During the years ended December 31, 2019, 2018 and 2017, our research and development expenditures were $4.7 million, $3.7 million and $4.2 million, respectively (including development costs of $0.1 million in each of those years, which were capitalized).

As described in Item 4.B "*Information on the Company — Business Overview — Government Regulations*," we participated in the past in programs sponsored by the IIA.

D. Trend Information

Other than as disclosed elsewhere in this Annual Report, including in 5.B "*Operating and Financial Review and Prospects — Trend Information*, we are not aware of any trends, uncertainties, demands, commitments or events since December 31, 2019 that are reasonably likely to have a material adverse effect on our revenues, income, profitability, liquidity or capital resources, or that would cause the disclosed financial information to be not necessarily indicative of future operating results or financial conditions.

E. Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements, as such term is defined under Item 5.E of the instructions to Form 20-F, that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to investors.

F. Tabular Disclosure of Contractual Obligations

The following table summarizes our significant contractual obligations and commercial commitments, as of December 31, 2019:

	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
			(in thousands)		
Operating leases [(1)]	$ 3,424	$ 1,081	$ 1,073	$ 344	$ 926

(1) Includes lease payments for our facilities, offices and motor vehicles.

Severance payments of $1.9 million are payable only upon termination, retirement or death of the respective employee. Of this amount, $0.2 million is unfunded. Since we are unable to reasonably estimate the timing of settlement, the timing of such payments is not specified in the table. See also Note 11 to our audited consolidated financial statements included elsewhere in this Annual Report.

As required by IFRS, our obligation to pay royalties to the IIA is presented in our consolidated financial statements as part of our long-term liabilities and accrued expenses in respect of future sales of our products. However, since these obligations are contingent upon the volume and timing of sales of our products, we are unable to reasonably estimate the timing and scope of such payments and they are not specified in the table. See also Item 4.B. "*Business Overview—Government Regulations—The Israeli Market - Israeli Innovation Authority*" above and Note 13 to our audited consolidated financial statements included elsewhere in this Annual Report.

G. Safe Harbor

See the section entitled "*Cautionary Statement Regarding Forward-Looking Statements*" at the beginning of this Annual Report.

Item 6. Directors, Senior Management and Employees

A. Directors and Senior Management

Executive Officers and Directors

The following table presents information about our current executive officers and members of our Board of Directors, including their ages as of March 24, 2020:

Name	Age	Position
Executive Officers		
Gilad Glick	47	President and Chief Executive Officer, Acting Vice President Marketing and Sales, Acting President of our U.S. subsidiary
Shy Basson	48	Chief Financial Officer and U.S. Chief Operating Officer
Itay Kariv	61	Vice President of Research and Development
Dan Shlezak	55	Vice President of Engineering and Operations
Efrat Litman	46	Vice President of Advanced Research and Development
Eilon Livne	49	Vice President of Sales and Channels Development EMEA
Shiri Shneorson, PhD	45	Vice President and General Manager of Digital Health Business Unit
Non-Employee Board Members		
Giora Yaron, PhD	71	Director
Martin Gerstel(1)(3)	78	Director
Ilan Biran(2)	73	Director
Jonathan Kolber	58	Director
Sami Totah	62	Director
Christopher M. Cleary	59	Director
Yaffa Krindel Sieradzki(2)(3)	65	External Director
Zipora (Tzipi) Ozer-Armon(2)(3)	55	External Director

(1) Mr. Gerstel intends to retire at the end of his term, which is scheduled to expire at the annual general meeting of shareholders to be held in 2020, and not seek reelection at such meeting.
(2) Member of the audit committee of the Board of Directors, or the Audit Committee.
(3) Member of the compensation committee of the Board of Directors, or the Compensation Committee.

The current business addresses for our executive officers and directors is c/o Itamar Medical Ltd., 9 Halamish Street, Caesarea 3088900, Israel.

Executive Officers

Gilad Glick has served as our Chief Executive Officer and President since July 2013. Mr. Glick also serves as a director and as acting president of our U.S. subsidiary, Itamar Medical, Inc. Prior to joining the Company, Mr. Glick served in various positions in the medical devices industry, spanning across multiple countries in Europe and the U.S. in a variety of functional areas including sales, marketing, service and research & development. Between June 2008 and July 2013, Mr. Glick held the position of worldwide vice president of sales and marketing of Biosense Webster, a Johnson & Johnson company, overseeing all strategic and commercial activities. Mr. Glick earned an M.B.A from the Maastricht School of Management, majoring in general and strategic management. He is also a graduate of the Strategic Marketing Management Executive Program at the Stanford Graduate School of Business.

Shy Basson has served as our Chief Financial Officer since May 2017 and U.S. Chief Operating Officer since May 2019. Mr. Basson also serves as a director of our U.S. subsidiary, Itamar Medical, Inc. Prior to joining the Company, between January 2008 and October 2016, Mr. Basson served as Chief Financial Officer, Business and Strategy of WeFi, Inc., a provider of mobile data collection and Wi-Fi connectivity solutions. Prior thereto Mr. Basson served as Director of Business Development at AOL (a Time Warner Company). Prior thereto, Mr. Basson served as the CFO of ICQ. Mr. Basson holds a B.A. degree in business administration and accounting from the College of Management in Rishon Lezion and an M.B.A. from the Kellogg-Recanati Business School of the Tel Aviv University and is a Certified Public Accountant in Israel.

Itay Kariv has served as our Vice President of Research and Development since October 2018. Between January 2015 and October 2018, Mr. Kariv served as our Vice President of Advanced Research and Development. Mr. Kariv has more than 25 years of experience in research and development managerial roles. Prior to joining the Company, Mr. Kariv held several managerial positions, including as a Program Director at St. Jude Medical between 2008 and 2014 and as Research and Development Director and subsequently as Program Director at Biosense Webster, a Johnson & Johnson company, between 2001 and 2008. Prior to that, between 1999 and 2001, Mr. Kariv served as Vice President of Research and Development at MeetU.com, Ltd., and as Vice President of Research and Development at Lognet Systems Ltd. between 1997 and 1999. Mr. Kariv holds a Landscape Architect degree and a B.Sc. and M.Sc. in Computer Science, all from the Technion — Israel Institute of Technology.

Dan Shlezak has served as our Vice President of Operations and Engineering since 2020. Prior to joining the Company, between 2006 and 2019, Mr. Shlezak served as General Manager at Carestream Health Ltd., a worldwide provider of dental and medical imaging systems and healthcare IT solutions. Between 2003 and 2006 Mr. Shlezak served as Vice President Operations at Advanced Dicing Technologies Ltd., a company specialized in the development and manufacturing of dicing systems and blades for the semiconductor industry. Between 2000 and 2003, Mr. Shlezak served as Operations General Manager at Kulicke and Sofa (Israel) Ltd. and prior to that, he served between 1992 and 2000 in additional operational roles in Israeli based companies. Mr. Shlezak holds a B.Sc. degree in Mechanical Engineering, from the Technion — Israel Institute of Technology (graduated with honors); a M.Sc. degree in Mechanical Engineering, from the Technion; an MBA from the Technion, and an M.A. in Law from Haifa University.

Efrat Litman has served as our Vice President of Advanced Research and Development since October 2018. Between April 2017 and October 2018, Ms. Litman served as our Vice President of Research, Development and Technology and from March 2011 to April 2017 as Vice President of Research and Development. Ms. Litman has 25 years of experience in research and development work. Prior to joining the Company, Ms. Litman held several positions as a project and product manager and algorithm team leader in high-tech and bio-tech industries and the Israel Defense Forces, including over eight years at Orbotech Ltd. Ms. Litman holds a B.Sc. degree in Physics and Mathematics from the Talpiot program of the Hebrew University of Jerusalem.

Eilon Livne has served as our Vice President of Sales and Channels Development, EMEA Region since 2015. Between 2014 and 2015, Mr. Livne served as our Head of Wellness Activity, USA. Between 2013 and 2014, Mr. Livne served as the VP Sales and Marketing of Adhestick Ltd., leading the international sales and marketing of its consumer goods products line. Between 2002 and 2013, Mr. Livne served as the CEO of Silverline Jewelry Ltd. Between 2001 and 2002, Mr. Livne served as Product Manager of Giteko Technologies, and prior to that, he served as Senior Consultant at the Governmental Incentives Department at Ernst & Young Israel. Mr. Livne holds a B.A. degree in Economy and Accountancy from the Rupin Academic Institute and is a Certified Public Accountant in Israel.

Shiri Shneorson, PhD, has served as our Vice President and General Manager of the Digital Health Business Unit since June 2019. Between October 2005 and May 2019, Dr. Shneorson served in multiple management roles at Intel Corporation in Israel and California, as Vice President of Strategic Planning, key customers and strategic initiatives, Vice President and General Manager, Laptop Products and Director of Product — Mobile Clients Platforms. Dr. Shneorson holds a B.S. degree in Industrial Engineering and Management from the Technion — Israel Institute of Technology, an M.S. in statistics from the Stanford University School of Humanities and Science and a PhD in Operations Information and Technology from the Stanford University Graduate School of Business.

Non-Employee Directors

Giora Yaron, PhD, is one of the co-founders of our Company and has served as Chairman of our Board of Directors since 2016. Between 1997 and 2016, Dr. Yaron served as Co-Chairman of our Board of Directors. Dr. Yaron also serves as a member of the Board of Directors of Amdocs Limited (Nasdaq: DOX), on the Board of Directors of Excelero (ExpressIO), a provider of ultra-fast block storage solutions and as the Chairman of the Board of Directors of Equalum, a provider of a real-time Data Beaming for Big Data Analytics. Dr. Yaron co-founded several privately-held technology companies, sold to multinational corporations, including, P-cube, Pentacom, Qumranet, Exanet, Comsys and Hyperwise Security. Dr. Yaron continues to invest in technology companies and most recently invested in Vulcan Security, Salto and Apolicy. From 2010 until December 2018, Dr. Yaron served as Chairman of the Executive Council of the Tel Aviv University. He also served as Chairman of Ramot, the Tel Aviv University technology transfer company from 2010 until 2015. In 2009, Dr. Yaron also co-founded Qwilt, Inc., a privately-held video technology provider and serves on its Board of Directors. Between 1996 and 2006, Dr. Yaron served as a member of the Board of Directors of Mercury Interactive, a publicly-traded IT optimization software provider, acquired by Hewlett-Packard, including as its Chairman of the Board of Directors between 2004 and 2006. Between 1992 and 1995, Dr. Yaron served as President of Indigo NV. Prior to joining Indigo, Dr. Yaron served as Corporate Vice President of National Semiconductor. Dr. Yaron has previously served on the advisory board of Rafael Advanced Defense Systems, Ltd., a developer of high-tech defense systems, and on the advisory board of the Israeli Ministry of Defense. Dr. Yaron holds a PhD in device physics, and a Bachelor’s degree in physics and mathematics from the Hebrew University of Jerusalem.

Martin S. Gerstel is one of the co-founders of Itamar Medical and has served as a director on our Board of Directors since 1997. Between 1997 and 2016, Mr. Gerstel also served as the Co-Chairman of our Board of Directors. Mr. Gerstel also serves as the Chairman of the Board of Directors of Evogene Ltd. (Nasdaq and TASE: EVGN), a developer of novel products for life science markets since 2004. In addition, between 1997 and 2017, Mr. Gerstel served as the Chairman of the Board of Directors of Compugen Ltd., (Nasdaq and TASE: CGEN), a predictive drug discovery and development company. Mr. Gerstel currently serves as a director of YEDA Research and Development Company Ltd., the technology transfer company for the Weizmann Institute of Science and served as a director of Yissum Ltd., the technology transfer company of the Hebrew University of Jerusalem, between 2003 and 2015. Mr. Gerstel is also a member of the Board of Governors and the executive committee of the Weizmann Institute of Science and the Board of Governors of the Hebrew University of Jerusalem. Prior to relocating to Israel in 1994, Mr. Gerstel was the Co-Chairman and CEO of ALZA Corporation, a U.S. pharmaceutical company specializing in advanced drug delivery (sold to Johnson & Johnson). Mr. Gerstel holds an M.B.A. degree from Stanford Graduate School of Business and a B.Sc. from Yale University.

Ilan Biran has served as a director on our Board of Directors since 2013. Mr. Biran has previously served as Bezeq's Chief Executive Officer. Mr. Biran serves as a director of Kinneret College on the Sea of Galilee (R.A). Mr. Biran has previously served as the Chairman of the Board of Directors of Rafael — Advanced Defense Systems Ltd. between 2007 and 2013 and as a member of the Board of Directors of Israel Discount Bank Ltd. between 2008 and 2017. Mr. Biran served in the Israel Defense Forces for 32 years, most notably as the former General Director of the Ministry of Defense, and in various staff and command positions, including commanding general, central command, head of the technology and logistics branch, and head of the operations division at the general staff. Mr. Biran has received an honorary degree of PHD from the Technion Israel Institute of Technology in 2013. Mr. Biran holds an Associate Diploma in Strategy and Political Economic Research from Georgetown University and the United States Marine Corps Command and Staff College. Mr. Biran also holds a B.A. in Economics and Business Administration from the Bar Ilan University.

Jonathan Kolber has served as a director on our Board of Directors since 2015. Mr. Kolber is a Partner and Senior Advisor at Viola Growth, a technology buyout and growth capital fund that is an affiliate of the Viola Group. In addition, he is an investor in numerous Israeli technology companies, including Fiverr, Eyeclick, ViTrainer, REAL and MoonActive. Mr. Kolber also serves as Chairman of the Board of Directors of ION Asset Management Ltd., an Israeli hedge fund and Chairman of the Board of Directors of Panaxia Pharmaceutical Industries Ltd. Mr. Kolber founded and managed Claridge Israel, together with the Canadian Bronfman family, from 1986 to 1997. Between 1998 and 2006, Mr. Kolber served as the Chief Executive Officer of Koor Industries, one of Israel's then largest conglomerates, with investments in the agrochemical, telecommunications and defense industries, which was sold in 2006 to the IDB Group. Between 1997 and 2007, he also served on the Board of Directors of ECI Telecom Ltd., and as Chairman thereof between 1999 and 2002. Mr. Kolber currently serves as a member of the board of directors of several companies, including Fiverr International Ltd., Optimax Ltd. and Kidbox Ltd. and during his career has served as chairman of the board of directors, chief executive officer or director in over 60 public and private companies in Israel and North America. He holds a Bachelor's degree in Near Eastern Language and Literature from Harvard University and a Certificate of Advanced Arabic Language from the American University of Cairo.

Sami Totah has served as a director on our Board of Directors since 2015. Mr. Totah is a partner of Viola Growth, a technology buyout and growth capital fund that is an affiliate of the Viola Group. Mr. Totah has served as chairman of the board of directors of several Israeli start-up companies since 2003, including Pilat Media, Sheer Networks, Red Bend, and Flash Networks. Between 1984 and 2002, Mr. Totah served in various positions at Amdocs, including the position of Chief Operating Officer. Mr. Totah is a practical software engineer and participated in professional courses over the years, including courses of the Executive M.B.A. program of the Hebrew University of Jerusalem Business School.

Christopher M. Cleary has served as a director on our Board of Directors since 2017. Since 2014, Mr. Cleary has served as the Vice President of Corporate Development for Medtronic plc. Prior to 2014, Mr. Cleary was the CEO for Alesia Capital Services LLC, providing advisory and financial analysis services to Fortune 500 companies, including Medtronic. Prior to that Mr. Cleary served in a multitude of managerial roles at GE Capital. Mr. Cleary holds a B.A. from Colorado College.

Yaffa Krindel Sieradzki has served as an external director on our Board of Directors since 2016. Ms. Krindel also serves as a director of Sol-Gel Technologies Ltd. (Nasdaq: SLGL), a pharmaceutical company, BGN Technologies Ltd., the technology transfer company of Ben Gurion University, and two medical device start-up companies and has served on the boards of directors of numerous companies publicly traded on Nasdaq. Between 1997 and 2007, Ms. Krindel served as Partner and Managing Partner of Star Ventures, a private venture capital fund headquartered in Munich, Germany. Between 1993 and 1997, Ms. Krindel served as CFO and later as director of BreezeCOM Ltd., an Israeli telecommunications company, which was traded on Nasdaq and the TASE. Between 1992 and 1996, Ms. Krindel served as CFO and VP Finance of Lannet Data Communications Ltd., an Israeli telecommunications company, publicly traded on Nasdaq which is now part of Avaya Inc. Ms. Krindel also served on the board of directors of Fundtech Ltd., which was traded on Nasdaq until its acquisition by GTCR, Voltaire Ltd. until its acquisition by Mellanox Technologies Ltd. and Syneron Medical until its acquisition by Apax. Ms. Krindel holds an M.B.A. degree from the Tel Aviv University and a B.A. in Economics and Japanese Studies from the Hebrew University of Jerusalem.

Zipora (Tzipi) Ozer-Armon has served as an external director on our Board of Directors since 2016. She is the Chief Executive Officer of Lumenis Ltd. since 2012. Before joining Lumenis, Ms. Ozer-Armon headed the Japanese market activities of Teva Pharmaceutical Industries Ltd. and served as Senior Vice President of Sales and Marketing at SanDisk. Previously, she also served as VP & General Manager at MSystems. Ms. Ozer-Armon is a director at ICI Ltd., Rambam MedTech, Israel's National Technological Innovation Authority's Commission and Tel Aviv University. Ms. Ozer-Armon holds a BA in Economics and an MBA majoring in Finance and Marketing from Tel Aviv University and she is an AMP graduate of the Harvard Business School.

Additional Information

There are no family relationships between any of the directors or members of senior management named above.

Our articles of association provide for a Board of Directors of not less than five and not more than nine members, including two external directors as required by the Companies Law. Our Board of Directors is currently composed of eight directors (including the two external directors). Officers serve at the pleasure of the Board of Directors, subject to the terms of any agreement between the officer and us.

Dr. Yaron and Messrs. Biran, Kolber, Cleary and Totah will serve as directors until our annual general meeting of shareholders to be held in 2020. Ms. Krindel Sieradzki and Ms. Ozer-Armon were reelected as external directors in May 2019 for a three-year term. Mr. Gerstel intends to retire at the end of this term and not seek reelection at our annual general meeting of shareholders to be held in 2020.

We are not aware of any arrangements or understandings with major shareholders, customers, suppliers or others, pursuant to which any person referred to above was selected as a director or member of senior management.

B. Compensation

Aggregate Executive Compensation

Our objective is to attract, motivate and retain highly skilled personnel who will assist the Company in reaching its business objectives, performance and the creation of shareholder value and otherwise contribute to its long-term success. In March 2020, our shareholders approved our amended policy governing the compensation of office holders as required under the Companies Law, or our Compensation Policy. The Compensation Policy was designed to correlate executive compensation with our objectives and goals and otherwise embrace a performance culture that is based on merit, and differentiates and rewards excellent performance in the long term.

The following table sets forth all compensation we paid with respect to all of our directors and executive officers as a group for the period indicated(1):

All directors and executive officers as a group, consisting of 16 persons[(2)] for the year ended	**Salaries, fees, commissions and bonuses**	**Pension, retirement and similar benefits**	**Share-based compensation**
		(in thousands)	
December 31, 2019	$ 2,262	$ 152	$ 938

(1) The cost reflected in this table for the year ended December 31, 2019 is calculated in accordance with IFRS and is as recognized in our financial statements for such year. It is noted that, in accordance with IFRS, cash compensation amounts denominated in currencies other than the U.S. dollar were converted into U.S. dollars at the exchange rate between the NIS and the U.S. dollar as of the end of each month during 2019, the period covered by the table (which, on average for 2019, was approximately NIS 3.56 per $1.00).

(2) Including two persons who served as our executive officers in 2019 and are no longer serving as our executive officers and one executive officer who was appointed during 2019.

We provide leased cars or reimbursement of car expenses to our executive officers in Israel (which amounts are included in the amounts provided in the above table) and reimbursement of other expenses pursuant to our standard policies and procedures.

During the year ended December 31, 2019, we also granted our directors and executive officers:

- options to purchase, in the aggregate, 6,367,241 ordinary shares at a weighted average exercise price per share of NIS 1.21 (equivalent to approximately $0.33), of which (i) 787,721 are performance-based options that will vest in December 2022 if the price of our ordinary shares is, at such time, at least NIS 5.32 per share (equivalent to approximately $1.45), or 50% of such options will vest if the price of our ordinary shares is, at such time, at least NIS 2.66 per share (equivalent to approximately $0.73), or if, on the applicable measurement date, the price of our ordinary shares is between these two vesting-trigger share prices, the percentage of options that will vest will be determined based on linear interpolation, and (ii) 5,579,520 options will vest over a period of four years following the grant date. Of the 6,367,241 options, 1,210,000 options will expire five years from the grant date and the balance of 5,157,241 options will expire in May 2029. The weighted average fair value of these options as of the grant date was NIS 0.53 (equivalent to approximately $0.14) per option; and

- 201,372 ordinary shares issuable upon the vesting of outstanding performance-based RSUs, which will vest in if the price of our ordinary shares is, at such time, at least NIS 5.32 per share (equivalent to approximately $1.45), or 50% of such RSUs will vest if the price of our ordinary shares is, at such time, at least NIS 2.66 per share (equivalent to approximately $0.73), or if, on the applicable measurement date, the price of our ordinary shares is between these two vesting-trigger share prices, the percentage of RSUs that will vest will be determined based on linear interpolation. The weighted average fair value of these RSUs as of the grant date was NIS 0.29 (equivalent to approximately $0.08) per RSU.

On May 20, 2019, our Board of Directors resolved to allow six executive officers to be granted new 4,504,664 performance options and 921,873 performance RSUs, in lieu of 4,504,664 performance options and 921,873 performance RSUs previously granted that have not yet vested. The new performance options and RSUs will vest in December 2022 if the price of our ordinary shares is, at such time, at least NIS 5.32 per share (equivalent to approximately $1.45), or 50% of such options will vest if the price of our ordinary shares is, at such time, at least NIS 2.66 per share (equivalent to approximately $0.73), or if, on the applicable measurement date, the price of our ordinary shares is between these two vesting-trigger share prices, the percentage of options that will vest will be determined based on linear interpolation. Out of the new options and RSUs, a grant of 3,019,864 performance options and 609,232 performance RSUs to our President and Chief Executive Officer was approved by our shareholders on March 18, 2020. All such executive officers, including our President and Chief Executive Officer accepted our proposal and the new options and RSU were granted to all such employees.

Individual Compensation of Covered Executives

The table and summary below outline the compensation granted to our five most highly compensated "office holders" during or with respect to the year ended December 31, 2019 as required by the Companies Law. The Companies Law defines the term "office holder" of a company to include the chief executive officer (referred to in the Companies Law as the general manager), the chief business manager, deputy general manager, vice general manager, any other person assuming the responsibilities of any of these positions regardless of that person's title, a director and any other manager directly subordinate to the general manager. We refer to the five individuals for whom disclosure is provided herein as our "Covered Executives."

For purposes of the table and the summary below, "compensation" includes base salary, bonuses (including sales commissions), equity-based compensation, retirement or termination payments, benefits and perquisites such as car, and social benefits and any undertaking to provide such compensation to each Covered Executive. All amounts reported in the table are in terms of cost to the Company for the year ended December 31, 2019*, as reflected in the financial statements for the year then ended and calculated in accordance with IFRS.

Name and Principal Position[1]	Annual Base Salary [2]	Bonus [3]	Sales Commissions [4]	Share-Based Compensation [5]	All Other Compensation [6]	Total
			(in thousands)			
Gilad Glick, President and Chief Executive Officer	$ 346	$ 194	$ —	$ 421	$ 21	$ 982
Shy Basson, *Chief Financial Officer and U.S. Chief Operating Officer*	202	126	—	141	69	538
Itay Kariv, *Vice President of Research and Development*	163	21	—	66	59	309
Efrat Litman, *Vice President of Advanced Research and Development*	156	21	—	64	49	290
Eilon Livne, *Vice President of Sales and Channel Development EMEA Region*	126	—	71	72	12	281

* The cost reflected in this table is calculated in accordance with IFRS and is as recognized in our financial statements for the year ended December 31, 2019. It is noted that, in accordance with IFRS, cash compensation amounts denominated in currencies other than the U.S. dollar were converted into U.S. dollars at the exchange rate between the NIS and the U.S. dollar as of the end of each month during 2019, the period covered by the table (which, on average for 2019, was approximately NIS 3.56 per $1.00).

(1) Unless otherwise indicated herein, all Covered Executives are engaged on a full-time (100%) basis.

(2) Reflects the annual gross salary of the Covered Executives, other than Mr. Glick and Mr. Livne, who are engaged through consultancy agreements, where such figures reflect their annual fixed compensation, including social benefits.
(3) Amounts reported in this column represent annual bonuses granted to the Covered Executives. Consistent with our Compensation Policy, such bonuses are based upon (i) for Mr. Glick, see note (7) below; and (ii) for the other executive officers — achievement of targets of revenues generated by the individual and/or his/her team or division and/or the Company, as well as, in appropriate circumstances, other measurable criteria, which, in general, may not exceed nine monthly salaries. The calculation of Mr. Glick's $194,000 bonus for 2019 is comprised of: (i) a $119,000 performance bonus based on the achievement of certain milestones under the his bonus plan, as more fully described below; and (ii) a special bonus of $75,000. The calculation of Mr. Basson's $126,000 bonus for 2019 is comprised of: (i) a $71,000 performance bonus based on the achievement of certain milestones under his bonus plan; and (ii) a special bonus of $55,000.
(4) Amounts reported in this column represent sales commission, which are based on the achievement of certain sales targets.
(5) Amounts reported in this column represent the accounting expense recognized by the Company associated with stock-based compensation in accordance with accounting guidance for stock-based compensation. For a discussion of the assumptions used in reaching this valuation, see Note 15 to our audited consolidated financial statements. All of the awards were in the form of stock options or RSUs, and were made pursuant to one of our equity incentive plans. Vesting of the options and RSUs will accelerate upon certain change of control events.
(6) Amounts reported in this column include benefits and perquisites, including those mandated by applicable law. Such benefits and perquisites may include, to the extent applicable to the Covered Executive, payments, contributions and/or allocations for savings funds (e.g., Managers Life Insurance Policy), education funds, or Keren Hishtalmut, pension, severance, vacation, car or car allowance, medical insurances and benefits, risk insurances (e.g., life, or work disability insurance), convalescence or recreation pay, relocation, employers payments for social security, tax gross-up payments and other benefits and perquisites consistent with Itamar's guidelines.
(7) Consistent with our Compensation Policy, and as approved by our shareholders in May 2018, Mr. Glick is entitled to an annual bonus, subject to Mr. Glick achieving certain criteria and milestones set by our Compensation Committee and Board of Directors. The milestone for the annual bonus for the years 2018 through 2022 is based upon our annual revenue in such years, which is tied to our annual budget for the applicable year. The annual bonus payable (not including any special bonus) to Mr. Glick for each year may, generally, not exceed an amount equal to 7.7 monthly base salaries of Mr. Glick in such year, which is currently equal to a maximum annual bonus of approximately $192,200.

Executive Officer Employment and Consultancy Agreements

We have entered into written employment or services agreements with each of our executive officers. All of these agreements contain customary provisions regarding confidentiality, intellectual property assignment and non-solicitation provisions as well as an undertaking not to compete with us or in our field of business. However, the enforceability of the noncompetition provisions may be limited under applicable law. Members of our senior management may also be eligible for bonuses in accordance with our Compensation Policy and as set forth by our Compensation Committee and Board of Directors.

On May 23, 2018, we held our annual meeting of shareholders for 2018, at which our shareholders approved, among other matters, the following changes to the compensation payable to Mr. Glick, our President and Chief Executive Officer:

- monthly payment — effective April 1, 2018, the monthly payment was denominated in NIS (rather than in U.S. dollars) and such payment was increased by 10% (at the time of the shareholder approval), from a monthly payment of $26,176 plus VAT to NIS 102,450 (equivalent to approximately $28,007) plus VAT; this amount includes the equivalent of base salary and the total cost of social benefits payable to Mr. Glick;

- modification of the performance criteria related to the vesting of stock options and RSUs previously granted to our President and Chief Executive Officer — Mr. Glick received in March 2016 a grant of (i) options to purchase up to 2,043,111 ordinary shares, at an exercise price of NIS 1.55 (equivalent to approximately $0.42), of which 510,778 options vest one year after the grant date, with the balance vesting in 12 equal quarterly installments; and (ii) 10,080,824 ordinary shares issuable upon the exercise of 8,388,512 outstanding performance-based stock options and the vesting of 1,692,312 outstanding performance-based RSUs, which will vest on December 20, 2020 if the price of our ordinary shares is, at such time, at least NIS 4.24 per share (equivalent to approximately $1.16), or 50% of such options and RSUs will vest if the price of our ordinary shares is, at such time, at least NIS 2.13 per share (equivalent to approximately $0.58). Our shareholders approved that (i) the above minimum trading price will be reduced from NIS 2.13 (equivalent to approximately $0.58) to NIS 1.70 (equivalent to approximately to $0.46) and (ii) a change of the January 21, 2020 vesting date to December 20, 2020; and

- an annual cash bonus in each of the years 2018 to 2022 (inclusive), or the bonus years, as follows:

    - a maximum bonus of up to 7.7 monthly base salaries per year.

    - the bonus is payable subject to meeting sales revenue goals that reflect growth in our revenues at a rate to be determined by the Compensation Committee and the Board of Directors by the end of the first quarter of each bonus year as part of the annual budget approval. The sales revenue goal for each bonus year is divided into three levels of sales revenues: the minimum goal, the target goal and the maximum entitlement goal.

    - in the event that the actual sales revenues in any bonus year are within the range between two goals (the minimum goal and the target goal or between the target goal and the maximum entitlement goal), the amount of the bonus shall be calculated linearly based on the increase in sales revenue in that bonus year.

    - payment of the bonus is also contingent on meeting a minimum operating income or a maximum operating loss goal. Such operating income or operating loss is on an adjusted, non-IFRS basis, which neutralizes certain non-cash and non-recurring components.

    - for the purpose of examining compliance with the said goals at the end of each relevant year, the effects of the following events (relative to that bonus year's budget) will be neutralized: (1) an increase our expenses for clinical trials (both in view of the entry into a new clinical trial and in light of the expansion of existing clinical trial); (2) increase or decrease in our costs in respect of payments to sales personnel (including costs of recruiting new sales personnel); (3) expenses associated with changing the reimbursement policy of medical insurers during the budget year and/or changes in the standard requirements applicable to our products; (4) expenses related to the process of listing on Nasdaq; (5) expenses incurred by our Company in respect of listing of securities for trading or sale in the United States solely for sales by our shareholders that exercise their registration rights or expenses in respect of unsuccessful capital raising; and (6) expenses related to the annual bonus to our chief executive officer or to any other officer in that year.

    - the annual bonus is payable once a year, following the approval of our annual financial statements for the preceding year.

On May 29, 2019, we held our annual meeting of shareholders for 2019, at which our shareholders approved, among other matters, the grant of a special bonus of NIS 259,000 (equivalent to approximately $72,700) to Mr. Glick in consideration of his performance during 2018.

Additionally, on March 18, 2020, we held a special meeting of shareholders, at which our shareholders approved, among other matters, the following grants to Mr. Glick:

- a special bonus of NIS 258,762 (equivalent to approximately $75,000) in consideration of his performance during 2019;

- a grant of performance-based stock options, exercisable into 3,019,864 ordinary shares at an exercise price per share of NIS 1.22 (equivalent to approximately $0.33), and of performance-based RSUs exercisable into 609,232 ordinary shares at a purchase price per share of NIS 0.30 (equivalent to approximately $0.08),in lieu of 3,019,864 performance-based options and 609,232 performance-based RSUs previously granted that have not yet vested; and

- a grant of service stock options exercisable into 1,676,425 ordinary shares at an exercise price per share of NIS 1.28 (equivalent to approximately $0.35).

For additional details regarding the aforesaid grants approved at the special meeting of shareholders held on March 18, 2020, see Item 3 of the Notice and Proxy Statement filed as Exhibit 99.1 to our Report of Foreign Private Issuer on Form 6-K submitted to the SEC on February 11, 2020, which is incorporated herein by reference.

Non-Employee Directors Remuneration

All of our directors are entitled to reimbursement of expenses. In addition, other than Mr. Cleary (who is entitled only to reimbursement of expenses), our non-employee directors, including external directors, receive the following compensation:

- Dr. Yaron, the chairman of our Board of Directors, is entitled, pursuant to the consultancy agreement we entered into with a company wholly owned by Dr. Yaron in May 2001 (as amended), to a monthly payment of $6,250, plus VAT. Under the agreement, Dr. Yaron is required to provide us with consulting services, including service as a chairman of our Board of Directors, on a part-time basis of 40% of the work week.

- Mr. Biran, Ms. Krindel Sieradzki and Ms. Ozer-Armon are each entitled to an annual fee of NIS 49,305 (equivalent to approximately $13,479) and attendance fees of NIS 3,300 (equivalent to approximately $902) per meeting attended, linked to the Israeli CPI.

- Messrs. Gerstel, Kolber and Totah are each entitled (in the case of Messrs. Kolber and Totah, by payment to an affiliate of Viola) to an annual fee of NIS 37,040 (equivalent to approximately $10,126) and attendance fees of NIS 2,475 (equivalent to approximately $677) per meeting attended, linked to the Israeli CPI.

According to the Compensation Policy, directors and officers may be granted equity-based compensation subject to certain criteria and limitations set forth therein, including the following:

- equity-based awards shall vest as determined by us at the time of grant. However, other than in the event of acceleration, no portion of any grant may vest prior to the end of the one-year anniversary of the date of grant or from the commencement date of the directors' or officers engagement with us;

- the equity-based award shall have a fair value that will not exceed, with respect to each year of vesting (measured on a linear basis), the equivalent of (i) the value of 24 months' salary with respect to the chief executive officer, (ii) 12 months' salary with respect to each other officer, and (iii) NIS 300,000 (equivalent to approximately $82,012) for each director; and

- the exercise price of options whose vesting is subject to the passage of time (and not subject to meeting milestones) will be no less than the average price of the ordinary shares of the Company on the TASE for the thirty (30) trading days prior to the date such grant was approved by our Board of Directors.

Consistent with the Compensation Policy and as further approved by our shareholders, we made the following grants of equity-based awards to our non-employee directors from January 1, 2019 to December 31, 2019:

- In June 2019, we granted 330,000 service options to each of our two external directors which will be divided into three equal portions:

- the first portion of 110,000 options shall vest in four equal installments of 27,500 options each on June 17 of each of the years 2020, 2021, 2022 and 2023. The exercise price of the first portion of options is NIS 1.47 (equivalent to approximately $0.40) per share;

- the second portion of 110,000 options shall vest in four equal installments of 27,500 options each on June 17 of each of the years 2021, 2022, 2023 and 2024. The exercise price of the second portion of options shall be average of the closing share price during the 30 trade days preceding June 17, 2020 plus 10%, but not less than NIS 0.30 (equivalent to approximately $0.08); and the third portion of 110,000 options shall vest in four equal installments of 27,500 options each on June 17 of each of the years 2022, 2023, 2024 and 2025. The exercise price of the third portion of options shall be average of the closing share price during the 30 trade days preceding June 17, 2021 plus 10%, but not less than NIS 0.30 (equivalent to approximately $0.08).

- In June 2019, we granted 110,000 service options to each of our five non-employee directors at an exercise price of NIS 1.47 (equivalent to approximately $0.40) per ordinary share. The options shall vest in four equal installments of 27,500 options each on May 29 of each of the years 2020, 2021, 2022 and 2023.

As approved by our shareholders on March 18, 2020, the vesting of stock options granted to non-employee directors are subject to acceleration as follows: (i) upon the completion of a full term of service of a director (three years for external directors and one year for other directors) without being reelected at the annual or special general meeting of shareholders; or (ii) upon termination of the service of a director in the middle of the term due to the consummation of certain change of control events (the date of such completion of the term or termination for such change of control events, the Trigger Date), all outstanding stock options vested on the Trigger Date shall expire within 180 days thereafter and all outstanding unvested stock options shall accelerate and be fully vested on the Trigger Date and shall expire within 180 days thereafter, similar to the acceleration to which some of our executive officers are entitled. For additional details regarding the vesting terms approved at the special meeting of shareholders held on March 18, 2020, see Item 2 of the Notice and Proxy Statement filed as Exhibit 99.1 to our Report of Foreign Private Issuer on Form 6-K submitted to the SEC on February 11, 2020, which is incorporated herein by reference.

Other than the foregoing payments, fees, reimbursement for expenses and the award of stock options and RSUs, we do not compensate our directors for serving on our Board of Directors.

Change of Control Arrangements

All of our executive officers as well as certain additional key employees are entitled to accelerated vesting of the ordinary shares subject to outstanding options and RSUs granted to them in connection with a sale of the Company or similar change of control events.

C. Board Practices

Introduction

According to the Companies Law and our articles of association, the management of our business is vested in our Board of Directors. The Board of Directors may exercise all powers and may take all actions that are not specifically granted to our shareholders and, according to the Companies Law and our articles of association is primarily responsible for outlining our policies and supervising our chief executive officer.

Election of Directors; Board Meetings

Under our articles of association, our Board of Directors must consist of not less than five and not more than nine members, including two external directors as required by the Companies Law. Our Board of Directors is currently composed of eight directors, including two directors who are intended to qualify as external directors and whose appointment fulfills the requirements of the Companies Law for the Company to have at least two external directors (see below under “External Directors”). Pursuant to applicable Nasdaq rules, director nominees are recommended for the Board of Directors’ selection by a majority of our “independent directors” within the meaning of the Nasdaq rules.

Pursuant to our articles of association, other than the external directors, for whom special election and removal requirements apply under the Companies Law (as further described below), the vote required to appoint a director is a simple majority vote of holders of our ordinary shares participating and voting at the relevant shareholders meeting. Our articles of association provide that, unless otherwise provided by law, our directors (other than external directors and "independent directors" as such term is defined by the Companies Law) may be elected solely at our shareholders annual general meetings, which are required to be held at least once during every calendar year and not more than fifteen months after the last preceding annual general meeting. However, our articles of association allow our Board of Directors to appoint directors to fill vacancies on our Board of Directors, which occur for any reason, or as additional directors, provided that the number of board members shall not exceed the maximum number of directors, as mentioned above. The appointment of a director by the Board of Directors shall remain in effect until the annual general meeting of our shareholders following the appointment or until the end of his tenure, in accordance with our articles of association.

Except for our external directors (as described below), our directors hold office until the next annual meeting of shareholders following the annual meeting at which they were appointed.

Under our articles of association and the Companies Law, (i) directors (other than external directors and "independent directors" as such term is defined by the Companies Law) may be removed by our shareholders before the expiration of their term by a special majority vote of at least 75% of the votes of shareholders present and voting at the meeting, not taking into account abstentions; (ii) external directors may be removed by our shareholders before the expiration of their term only in limited circumstances as described under the section titled "External Directors" below; and (iii) "independent directors" (as such term is defined by the Companies Law) may be removed before the expiration of their term only by a simple majority of the shareholders, or by a court, and then only if the independent directors cease to meet the statutory qualifications with respect to their appointment or if they violate their duty of loyalty to the Company. In addition, under the Companies Law, directors may be removed upon the occurrence of disqualifying events, such as bankruptcy or conviction of the director in certain criminal offenses.

Under the Companies Law, our Board of Directors is required to determine the minimum number of directors who must have "accounting and financial expertise" (as such term is defined in regulations promulgated under the Companies Law). Our Board of Directors determined that the Board of Directors should consist of at least two directors who have "accounting and financial expertise". In this respect, our Board of Directors has determined that each of Ms. Krindel Sieradzki, Ms. Ozer-Armon and Mr. Ilan Biran have the requisite "accounting and financial expertise".

Meetings of the Board of Directors are generally held at least once each quarter, with additional special meetings scheduled when required.

Alternate directors

Our articles of association provide, as allowed by the Companies Law, that any director may, by written notice to us, appoint another person who is qualified to serve as a director to serve as an alternate director. The alternate director will be regarded as a director. However, the appointment of an alternate director does not negate the responsibilities of the appointing director and such responsibilities prior to the appointment will continue to be the responsibilities of the appointing director, giving consideration to the circumstances of the appointment. Under the Companies Law, a person who is not qualified to be appointed as a director, a person who is already serving as a director or a person who is already serving as an alternate director for another director, may not be appointed as an alternate director. Nevertheless, a director who is already serving as a director may be appointed as an alternate director for a member of a committee of the Board of Directors so long as he or she is not already serving as a member of such committee, and if the alternate director is to replace an external director, he or she is required to be an external director and to have either "accounting and financial expertise" or "professional qualifications," depending on the qualifications of the external director he or she is replacing. The term of appointment of an alternate director may be for one meeting of the Board of Directors or until notice is given of the cancellation of the appointment.

External Directors

The Companies Law requires Israeli companies with shares that have been offered to the public, such as the Company, to appoint at least two external directors. Israeli companies whose shares are traded on specified U.S. stock exchanges, including Nasdaq, which do not have a controlling shareholder, may (but are not required to) elect to opt out of the requirement to maintain external directors and the composition requirements under the Companies Law with respect to either or both of the audit and compensation committees, subject to such companies satisfying certain additional conditions. We have not opted out and are currently subject to the foregoing requirements of the Companies Law. However, we may elect to opt out of such requirements in the future.

To qualify as an external director, an individual (or the individual's relative, partner, employer, a person to whom such individual is subordinate (directly or indirectly) or any entity under the individual's control) may not have, and may not have had at any time during the previous two years, (i) in a company that has a controlling shareholder, any "affiliation" with such company, the company's controlling shareholder or its relative, at the time of the appointment, or another entity affiliated with the company or its controlling shareholder, or (ii) in a company without a controlling shareholder (or a shareholder that owns more than 25% of its voting power), such as the Company, any "affiliation" with any person who, at the time of appointment, is the chairman, the chief executive officer, the chief financial officer or a 5% shareholder of the company. The term affiliation includes:

- an employment relationship;
- a business or professional relationship;
- control; and
- service as an "office holder," excluding service as a director that was appointed to serve as an external director of a company that is about to make its initial public offering.

In addition, pursuant to the Companies Law, (i) an external director must have either "accounting and financial expertise" or "professional qualifications" (as such terms are defined in regulations promulgated under the Companies Law); and (ii) at least one of the external directors must have "accounting and financial expertise". Our external directors are Ms. Krindel Sieradzki and Ms. Ozer-Armon. We have determined that both Ms. Krindel Sieradzki and Ms. Ozer-Armon have the requisite "accounting and financial expertise".

No person may serve as an external director if the person's position or other activities create, or may create a conflict of interest with the person's responsibilities as an external director or may otherwise interfere with the person's ability to serve as an external director. If, at the time an external director is to be appointed, all current members of the Board of Directors who are not controlling shareholders or their relatives are of the same gender, then the external director must be of the other gender. External directors are elected by a majority vote of the shareholders, provided that either (i) such majority includes at least a majority of the shares of the non-controlling shareholders of the company who do not have a personal interest in the appointment (excluding a personal interest that did not result from the shareholder's relationship with the controlling shareholder) who voted on the matter; or (ii) the total shareholdings of such non-controlling shareholders who vote against their election represent 2% or less of all of the voting rights in the company.

The initial term of an external director is three years and he or she may be reelected for up to two additional three-year terms. Thereafter, in a company whose shares are listed for trading on, among others, the Nasdaq Capital Market, such as the Company, he or she may be re-elected by our shareholders for additional periods of up to three years each, if our Audit Committee and the Board of Directors confirm that, in light of the external director's expertise and special contribution to the work of the Board of Directors and its committees, the reelection for such additional period is beneficial to the Company. Reelection of an external director may be effected through one of the following mechanisms: (i) the Board of Directors proposed the reelection of the nominee and the election was approved by the shareholders by the majority required to appoint external directors for their initial term as described above; or (ii) a shareholder holding 1% or more of the voting rights proposed the reelection of the nominee or the external director himself or herself proposed their own reelection, and the reelection is approved by a majority of the votes cast by the shareholders of the company, excluding the votes of controlling shareholders and those who have a personal interest in the matter as a result of their relations with the controlling shareholders; provided that the aggregate votes cast in favor of the reelection by such non-excluded shareholders constitute more than 2% of the voting rights in the company.

External directors can be removed from office only by the same special percentage of shareholders as can elect them, or by a court, and then only if the external directors cease to meet the statutory qualifications with respect to their appointment or if they violate their duty of loyalty to the company.

Any committee of the Board of Directors that is authorized to exercise powers of the Board of Directors must include at least one external director and the audit and compensation committees must include all of the external directors. An external director is entitled to compensation as provided in regulations adopted under the Companies Law and is otherwise prohibited from receiving any other compensation, directly or indirectly, in connection with such service.

Independent Directors

Under the Nasdaq rules, a majority of our Board of Directors must qualify as independent directors within the meaning of Nasdaq Listing Rule 5605(a)(2). Our Board of Directors has determined that all of our directors qualify as "independent directors" within the meaning of such rule.

Under the Companies Law, a public company, such as the Company, may classify one or more of its directors as an "independent director" within the meaning of the Companies Law if they are either external directors or directors who: (i) meet the qualification requirements of an external director (as described above), other than the requirement to possess accounting and financial expertise or professional qualifications, with audit committee confirmation of such; and (ii) have been directors in the company for an uninterrupted duration of less than nine years (and any interim period during which such person was not a director which is less than two years shall not be deemed to interrupt the duration). Our Board of Directors has determined, following confirmation of our Audit Committee, to classify Mr. Ilan Biran as an "independent director" within the meaning of the Companies Law.

Committees of the Board of Directors

Subject to the provisions of the Companies Law, our Board of Directors may delegate its powers to committees consisting of board members. Our Board of Directors has established an audit committee and a compensation committee, and, from time to time, establishes other "ad-hoc" committees of members of the Board of Directors for specific duties or assignments and limited duration.

Audit Committee

Pursuant to applicable SEC and Nasdaq rules, we are required to have an audit committee of at least three members, each of whom must satisfy the independence requirements of the SEC and Nasdaq. In addition, pursuant to Nasdaq rules, all of the members of the audit committee must be financially literate and at least one member must possess accounting or related financial management expertise. The audit committee must also have a written charter specifying the committee's duties and responsibilities, which include, among other things, the selection and evaluation of our independent auditors.

Under the Companies Law, our Board of Directors is required to appoint an audit committee, which must be comprised of at least three directors, including all of the external directors, a majority of its members must satisfy the independence standards under the Companies Law, and the chairman of the audit committee is required to be an external director. An audit committee may not include the chairman of a company's board of directors, a controlling shareholder of the company, a relative of a controlling shareholder, a director employed by or providing services on a regular basis to the company, to a controlling shareholder or to an entity controlled by a controlling shareholder, or a director who derives most of his or her income from a controlling shareholder. The duties of an audit committee under the Companies Law include, among other things, identifying flaws in the business management of the company and suggesting remedial measures to its board of directors, assessing the company's internal audit system and the performance of its internal auditor, establishing whistleblower procedures and approval of certain interested party transactions.

Our Audit Committee adopted a written charter specifying the committee's duties and responsibilities, which include, among other things, overseeing the accounting and financial reporting processes of our Company and audits of our financial statements, reviewing our financial statements; reviewing our compliance with legal and regulatory requirements; recommending the appointment of our independent public accountants and reviewing their independence; examining the performance of our internal audit function and the internal auditor; finding any defects in the business management of our Company for which purpose the Audit Committee may consult with our independent auditors and internal auditor and proposing to the Board of Directors ways to correct such defects; approving related party transactions; and such other duties as may be directed by our Board of Directors or required by applicable law or applicable Nasdaq rules.

In addition, pursuant to the audit committee charter, our Audit Committee functions as our Qualified Legal Compliance Committee, or the QLCC. In its capacity as the QLCC, the Audit Committee is also responsible for investigating reports made by attorneys appearing and practicing before the SEC in representing us of perceived material violations of U.S. federal or state securities laws, breaches of fiduciary duty or similar violations by us or any of our agents.

Our Audit Committee is currently composed of Ms. Krindel Sieradzki, the chairperson of our Audit Committee, Ms. Ozer-Armon and Mr. Ilan Biran, all of whom satisfy the respective "independence" requirements of the Companies Law and the SEC and Nasdaq rules for audit committee members.

Compensation Committee

Pursuant to applicable Nasdaq rules, the compensation payable to a company's chief executive officer and other executive officers must generally be approved by a compensation committee comprised solely of independent directors. Under the Companies Law, our Board of Directors is required to appoint a compensation committee, which must be comprised of at least three directors, include all of the external directors, its other members must satisfy certain independence standards under the Companies Law, and the chairman is required to be an external director. Under the Companies Law, the role of the compensation committee is to recommend to the board of directors, for ultimate shareholder approval by a special majority, a policy governing the compensation of office holders based on specified criteria; to recommend to the board of directors, from time to time, modifications to the compensation policy and examine its implementation; to approve, as more fully described under "*Approval of Related Party Transactions Under Israeli Law*" below, the actual compensation terms of office holders prior to approval thereof by the board of directors; and to resolve whether to exempt the compensation terms of a candidate for chief executive officer from shareholder approval.

Our Compensation Committee adopted a written charter specifying the committee's duties and responsibilities, which include, among other things, the duties and roles assigned to it pursuant to the Companies Law and applicable Nasdaq rules described above; and oversight and administration of our equity based plans. In March 2020, our shareholders approved our Compensation Policy.

Our Compensation Committee is currently composed of Ms. Ozer-Armon, the chairperson of our Compensation Committee, Ms. Krindel Sieradzki and Mr. Gerstel, all of whom satisfy the respective "independence" requirements of the Companies Law, SEC and Nasdaq rules for compensation committee members. The committee meets at least once each quarter, with additional special meetings scheduled when required.

Internal Auditor

Under the Companies Law, our Board of Directors is also required to appoint an internal auditor proposed by the audit committee. The role of the internal auditor is to examine, among other things, whether our activities comply with the law and orderly business procedure. The internal auditor may not be an interested party or office holder, or a relative of any interested party or office holder, and may not be a member of our independent accounting firm. The Companies Law defines the term "interested party" to include a person who holds 5% or more of a company's outstanding share capital or voting rights, a person who has the right to appoint one or more directors or the general manager, or any person who serves as a director or as the general manager. Ms. Irena Ben-Yakar of Deloitte Israel & Co. serves as our internal auditor.

Directors' Service Contracts

Our Chairman of the Board. We entered into a services agreement with a company wholly owned by Dr. Giora Yaron, the Chairman of our Board of Directors. See Item 6.B. "*Directors, Senior Management and Employees — Compensation — Individual Compensation of Covered Executives*."

Other. Except as set forth above and in Item 6.B. "*Directors, Senior Management and Employees — Compensation*," there are no arrangements or understandings between us and any of our current directors or executive officers for benefits upon termination of service.

Fiduciary Duties of Office Holders

The Companies Law imposes a duty of care and a duty of loyalty on all office holders of a company.

- The duty of care requires an office holder to act with the level of skill with which a reasonable office holder in the same position would have acted under the same circumstances. The duty of care of an office holder includes a duty to use reasonable means to obtain:
  - information on the advisability of a given action brought for his approval or performed by him by virtue of his position; and
  - all other important information pertaining to these actions.
- The duty of loyalty of an office holder requires an office holder to act in good faith and for the benefit of the company, and includes a duty to:
  - refrain from any conflict of interest between the performance of his duties in the company and his performance of his other duties or personal affairs;
  - refrain from any action that constitutes competition with the company's business;
  - refrain from exploiting any business opportunity of the company to receive a personal gain for himself or others; and
  - disclose to the company any information or documents relating to the company's affairs which the office holder has received due to his position as an office holder.

Each person listed in the table under Item 6.A. "*Directors, Senior Management and Employees — Directors and Senior Management*" is considered an office holder under the Companies Law.

Approval of Related Party Transactions under Israeli Law

General

Under the Companies Law, a company may approve an action by an office holder from which the office holder would otherwise have to refrain, as described above, if:

- the office holder acts in good faith and the act or its approval does not cause harm to the company; and

- the office holder disclosed the nature of his or her interest in the transaction (including any significant fact or document) to the company at a reasonable time before the company's approval of such matter.

Disclosure of Personal Interests of an Office Holder

The Companies Law requires that an office holder disclose to the company, promptly, and, in any event, not later than the board meeting at which the transaction is first discussed, any direct or indirect personal interest that he or she may have and all related material information known to him or her relating to any existing or proposed transaction by the company. If the transaction is an extraordinary transaction, the office holder must also disclose any personal interest held by:

- the office holder's relatives. Relatives are defined to include the spouse, siblings, parents, grandparents, descendants, spouse's descendants and the spouses of any of these people; or

- any corporation in which the office holder or his or her relatives holds 5% or more of the shares or voting rights, serves as a director or general manager or has the right to appoint at least one director or the general manager.

Under the Companies Law, an extraordinary transaction is a transaction:

- not in the ordinary course of business;

- not on market terms; or

- that is likely to have a material impact on the company's profitability, assets or liabilities.

The Companies Law does not specify to whom within the company nor the manner in which required disclosures are to be made. We require our office holders to make such disclosures to our Board of Directors.

Under the Companies Law, once an office holder complies with the above disclosure requirement, the Board of Directors may approve a transaction between the company and an office holder, or a third party in which an office holder has a personal interest, unless the articles of association provide otherwise and provided that the transaction is not detrimental to the company's interest. If the transaction is an extraordinary transaction, first the audit committee and then the board of directors of the company, in that order, must approve the transaction. Under specific circumstances, shareholder approval may also be required. A director who has a personal interest in an extraordinary transaction, which is considered at a meeting of the board of directors or the audit committee, may not be present at this meeting or vote on this matter, unless a majority of the board of directors or the audit committee, as the case may be, has a personal interest. If a majority of the board of directors or the audit committee has a personal interest, then shareholder approval is generally also required.

Approval of Office Holder Compensation

Pursuant to the Companies Law, every Israeli public company, such as the Company, must adopt a compensation policy, recommended by the compensation committee, and approved by the Board of Directors and the shareholders, in that order. The shareholder approval must be by a simple majority of all votes cast, provided that (i) such majority includes a simple majority of the votes cast by non-controlling shareholders having no personal interest in the matter or (ii) the total number of votes of shareholders mentioned in clause (i) above who voted against the approval of the policy does not exceed 2% of the total voting rights in the company. Even if the shareholders do not approve the compensation policy, the board of directors may resolve to approve the compensation policy, subject to certain conditions. In general, all office holders' terms of compensation — including fixed remuneration, bonuses, equity compensation, retirement or termination payments, indemnification, liability insurance and the grant of an exemption from liability — must comply with the company's compensation policy. The compensation policy must take into account certain factors, including advancement of the company's objectives, the company's business plan and its long-term strategy, and creation of appropriate incentives. It must also consider, among other things, the company's risk management, size and the nature of its operations. The compensation policy must include certain principles, such as: a link between variable compensation and long-term performance and measurable criteria; the relationship between variable and fixed compensation; and the minimum holding or vesting period for variable, equity-based compensation. In May 2019, our shareholders approved our Compensation Policy (as then amended).

In addition, the compensation terms of directors, the chief executive officer, and any employee or service provider who is considered a controlling shareholder, must be approved separately by the compensation committee, the board of directors and, subject to certain exceptions, the shareholders of the company (by the same majority noted above), in that order. The compensation terms of other officers require the approval of the compensation committee and the board of directors.

Exculpation, Indemnification and Insurance of Directors and Officers

Exculpation of Office Holders. Under the Companies Law, an Israeli company may not exempt an office holder from his or her liability for a breach of the duty of loyalty to the company, but may exempt an office holder, in advance, from his or her liability, in whole or in part, for a breach of his or her duty of care to the company (except with regard to distributions), if the articles of association so provide. Our articles of association permit us to exempt our office holders, retroactively or in advance, from his or her liability, in whole or in part, for a breach of his or her duty of care to the Company, up to the highest amount permitted by law.

Office Holders' Insurance. As permitted by the Companies Law, our articles of association provide that, subject to the provisions of the Companies Law, we may enter into a contract for the insurance of the liability of any of our office holders concerning an act performed by him or her in his or her capacity as an office holder for:

- a breach of his or her duty of care to us or to another person;
- a breach of his or her duty of loyalty to us, provided that the office holder acted in good faith and had reasonable cause to assume that his or her act would not prejudice our interests;
- a financial liability imposed upon him or her in favor of another person;
- a financial liability that may be instituted against him or her in favor of a payment for a breach offended at an administrative proceeding, or an Administrative Proceeding, pursuant to Section 52(54)(a)(1)(a) of the Israeli Securities Law, 5728-1968, or the Israeli Securities Law, if applicable, and payments made to injured persons under specific circumstances thereunder;
- expenses he or she incurs as a result of administrative proceedings that may be instituted against him or her, including reasonable litigation expenses; and
- any other matter in respect of which it is permitted or will be permitted under applicable law to insure the liability of an office holder in the Company.

Indemnification of Office Holders. As permitted by the Companies Law, our articles of association provide that we may indemnify any of our office holders for an act performed in his or her capacity as an office holder, retroactively (after the liability has been incurred) or in advance against the following:

- a financial liability incurred by, or imposed on, him or her in favor of another person by any judgment, including a settlement or an arbitration award approved by a court;
- provided that our undertaking to indemnify with respect to such events on a prospective basis is, according to the Companies Law, limited to events that our Board of Directors believes are foreseeable in light of our actual operations at the time of providing the undertaking and to a sum or standard that our Board of Directors determines to be reasonable under the circumstances, and further provided that such events and amount or criteria are set forth in the undertaking to indemnify;

- reasonable litigation expenses, including attorney's fees, incurred by the office holder as a result of an investigation or proceeding instituted against him by a competent authority, provided that such investigation or proceeding concluded without the filing of an indictment against him or concluded with the imposition of a financial liability in lieu of criminal proceedings with respect to a criminal offense that does not require proof of criminal intent, all according to the law, or in connection with a financial sanction;

- reasonable litigation expenses, including attorneys' fees, incurred by the office holder or charged to him or her by a court, resulting from the following: proceedings we institute against him or her or instituted on our behalf or by another person; a criminal indictment from which he or she was acquitted; or a criminal indictment in which he or she was convicted for a criminal offense that does not require proof of intent;

- a financial liability that that may be instituted against him or her in favor of a payment for a breach offended at an Administrative Proceeding, if applicable, and payments made to injured persons under specific circumstances thereunder;

- expenses paid in connection with an administrative proceeding which was instituted against him or her, including reasonable litigation expenses, such as attorneys' fees; and

- any other matter in respect of which it is permitted or will be permitted under applicable law to indemnify an office holder in the Company.

Limitations on Exculpation, Insurance and Indemnification. The Companies Law provides that a company may not indemnify an office holder nor exculpate an office holder nor enter into an insurance contract which would provide coverage for any monetary liability incurred as a result of any of the following:

- a breach by the office holder of his or her duty of loyalty, unless with respect to indemnification and insurance for a breach of the duty of loyalty in which the office holder acted in good faith and had a reasonable basis to believe that the act would not prejudice the company;

- a breach by the office holder of his or her duty of care if the breach was committed intentionally or recklessly, unless it was committed only negligently;

- any act or omission committed with the intent to derive an illegal personal benefit; or

- any fine levied against the office holder.

In addition, under the Companies Law, exculpation of, an undertaking to indemnify or indemnification of, and procurement of insurance coverage for, our office holders must be approved by our Compensation Committee and our Board of Directors and, in specified circumstances, such as if the office holder is a director or a controlling shareholder, is generally required to be approved by our shareholders.

We have entered into agreements with each of our current directors and executive officers to indemnify them to the fullest extent permitted by law, subject to limited exceptions. The maximum aggregate amount of indemnification that we may pay to our directors and executive officers based on such indemnification agreements is, generally, NIS 15.0 million (equivalent to approximately $4.1 million) (linked to the Israeli CPI) for all office holders.

We also currently maintain directors' and officers' liability insurance with an aggregate coverage limit of $25 million, with a Side A coverage of an additional $5 million, for an annual premium of approximately $0.9 million.

D. Employees

The following table details certain data on the workforce of Itamar and its consolidated subsidiaries as of the dates indicated:

	As of December 31,		
	2019	**2018**	**2017**
Numbers of employees by geographic location			
United States	80	55	43
Israel	103	97	94
Japan	1	1	1
Total workforce	**184**	**153**	**138**
Numbers of employees by category of activity			
Sales and marketing	53	31	27
Support in sales and marketing	19	21	15
Management and administrative	25	21	20
Operations, engineering and manufacturing	67	63	62
Research, development and technologies	20	17	14
Total workforce	**184**	**153**	**138**

The overall increase in our workforce, from 153 employees in 2018 to 184 employees in 2019, was primarily due to recruitment of sales and marketing personnel (including support in sales and marketing personnel), mainly in the United States, as a result of the expansion into new geographic territories in the United States and an increase in research, development and technologies personnel in Israel. The overall increase in our workforce, from 138 employees in 2017 to 153 employees in 2018, was primarily due to recruitment of sales and marketing personnel (including support in sales and marketing personnel), mainly in the U.S., as a result of the expansion into new geographic territories in the U.S. and an increase in research, development and technologies personnel in Israel.

We consider our relations with our employees to be good and we have never experienced a strike or work stoppage.

Our employees are not represented by labor unions. Nevertheless, with respect to our employees in Israel, certain provisions of the collective bargaining agreements between the 'Histadrut' (General Federation of Labor in Israel) and the Coordination Bureau of Economic Organizations (including the Industrialists' Association) may be applicable to our employees by virtue of an order of the Israeli Ministry of Labor, Social Affairs and Social Services. These provisions concern mainly the length of the workday, minimum daily wages, insurance for work-related accidents, determination of severance pay and other conditions of employment. We generally provide our employees with benefits and working conditions beyond the required minimums.

Pursuant to Israeli law, we are legally required to pay severance benefits upon certain circumstances, including the retirement or death of an employee or the termination of employment of an employee without due cause. Israeli employers and employees are required to pay predetermined amounts to the National Insurance Institute, which is substantially similar to the United States Social Security Administration.

E. Share Ownership

Beneficial Ownership of Executive Officers and Directors

For information regarding the share ownership of directors and officers, see Item 7.A. "*Major Shareholders and Related Party Transactions—Major Shareholders*."

Equity Incentive Plans

Our Equity Incentive Plans

In February 2007, we adopted the 2007 Israeli Share Option Plan, or 2007 Option Plan, under which stock options were granted to employees employed by us or by our affiliates, to permit our Israeli employees to benefit from tax advantages that became available at that time under Section 102 of the Israeli Tax Ordinance. The 2007 Option Plan had a term of 10 years and expired in February 2017, although we still have outstanding options under the 2007 Option Plan. An amendment to the 2007 Option Plan was approved by our Board of Directors on March 12, 2019.

In February 2007, we also adopted the 2007 Equity Incentive Plan, or 2007 Incentive Plan, under which stock options were granted to employees, officers, directors and consultants of our Company and our subsidiaries that are non-Israeli residents. The 2007 Incentive Plan had a term of 10 years and expired in February 2017, although we still have outstanding options under the 2007 Incentive Plan.

In January 2016, we adopted the Israeli Equity Incentive Plan for Israeli directors, officers, employees and consultants, or 2016 Israeli Plan, and the 2016 U.S. Equity Incentive Plan for non-Israeli directors, officers, employees and consultants, or 2016 Non-Israeli Plan. We refer to these two plans together as the 2016 Plans. Under such plans, we may grant stock options, RSUs and other equity-based awards to employees, officers, directors and consultants of our Company and our subsidiaries. The 2016 Plans have a term of ten years and will terminate in January 2026.

Each of the aforesaid equity incentive plans, to which we refer together as the Equity Plans, is administered by our Board of Directors (although our Board of Directors may delegate such authority to any committee thereof). Subject to the Equity Plans and applicable law, our Board of Directors has the authority to make all determinations deemed necessary or advisable for the administration of such plans, including to whom equity awards may be granted, the time and the extent to which these awards may be exercised, the exercise or purchase price of shares covered by each option or other award, the type of awards and how to interpret such plans. Among others, the Board has the authority to provide for, or, where applicable, recommend for approval by the Board of Directors, accelerated vesting of the ordinary shares subject to outstanding awards.

As of March 15, 2020, 25,545,132 ordinary shares remained available for grant of awards under the Equity Plans.

Grants in 2019

In 2019, we granted under the Equity Plans (i) options exercisable into up to 13,601,699 ordinary shares (compared with options exercisable into up to 3,016,330 ordinary shares that we granted in 2018); and (ii) up to 981,472 ordinary shares issuable upon the vesting of performance-based RSUs (compared with up to 295,726 ordinary shares issuable upon the vesting of performance-based RSUs that were granted during 2018).

Total Outstanding Options and RSUs

The following table sets forth, as of December 31, 2019, the number of options outstanding under our Equity Plans and their respective exercise prices and expiration dates:

	Number of Outstanding Options	Range of exercise prices	Weighted average remaining contractual life (in years)
	17,042,814	$0.28 - $0.35	5.96
	21,183,309	$0.36 - $0.43	5.70
	3,544,111	$0.44 - $0.57	3.53
	560,730	$0.58 - $0.68	2.75
Total(*)(**):	**42,330,964**		**5.59**

(*) Includes 10,127,684 options that were vested and exercisable as of December 31, 2019.

(**) Includes:

15,944,306 performance-based options, with exercise prices that ranging between NIS 1.02 and NIS 1.40 (equivalent to approximately $0.28 and $0.38, respectively), which performance criteria is that they will vest in December 2020 if the price of our ordinary shares is, at such time, at least NIS 4.24 per share (equivalent to approximately $1.16), or 50% of such options will vest if the price of our ordinary shares is, at such time, at least NIS 1.70 per share (equivalent to approximately $0.46). If, on the applicable measurement date, the price of our ordinary shares is within the range between these two vesting-trigger share prices, the relative quantity of the options will vest.

4,431,867 performance-based options, with exercise prices ranging between NIS 1.15 and NIS 1.22 (equivalent to approximately $0.31 and $0.33, respectively), which performance criteria is that they will vest in December 2022 if the price of our ordinary shares is, at such time, at least NIS 5.32 per share (equivalent to approximately $1.45), or 50% of such options will vest if the price of our ordinary shares is, at such time, at least NIS 2.66 per share (equivalent to approximately $0.73). If, on the applicable measurement date, the price of our ordinary shares is within the range between these two vesting-trigger share prices, the relative quantity of the options will vest.

The following table sets forth, as of December 31, 2019, the number of RSUs outstanding under our Equity Plans and their respective weighted average grant date fair value:

RSUs	**Number**	**Weighted average grant date fair value**
Outstanding at beginning of the year	3,441,420	$ 0.16
Granted	981,472	$ 0.11
Vested	-	
Forfeited	(94,497)	$ 0.14
Outstanding at end of the year (*)	**4,328,395**	**$ 0.15**

(*) 3,289,898 RSUs are performance-based RSUs, which performance criteria is that they will vest in December 2020 if the price of our ordinary shares is, at such time, at least NIS 4.24 per share (equivalent to approximately $1.16), or 50% of such RSUs will vest if the price of our ordinary shares is, at such time, at least NIS 1.70 per share (equivalent to approximately $0.46). If, on the applicable measurement date, the price of our ordinary shares is within the range between these two vesting-trigger share prices, the relative quantity of the RSUs will vest.

1,038,497 RSUs are performance-based RSUs, which performance criteria is that they will vest in December 2022 if the price of our ordinary shares is, at such time, at least NIS 5.32 per share (equivalent to approximately $1.45), or 50% of such RSUs will vest if the price of our ordinary shares is, at such time, at least NIS 2.66 per share (equivalent to approximately $0.73). If, on the applicable measurement date, the price of our ordinary shares is within the range between these two vesting-trigger share prices, the relative quantity of the RSUs will vest.

Out of these performance-based RSUs, only 1,741,344 RSUs, which were granted to one employee and two consultants (of which 1,790,376 RSUs were granted in 2016 to our President and Chief Executive Officer), have a purchase price. The purchase price for such RSUs is NIS 0.30 per share (equivalent to approximately $0.08).

For additional details and a discussion of the accounting method and assumptions used in valuation of such options and RSUs, see Note 16 to our audited consolidated financial statements included elsewhere in this Annual Report.

Grants Since January 1, 2020

Since January 1, 2020, we also granted (i) options exercisable into 3,942,284 ordinary shares at exercise prices ranging between NIS 1.28 and NIS 1.73 (equivalent to approximately $0.35 and $0.47, respectively) per share, which expire between 2025 and 2029; and (ii) 194,887 performance-based RSUs.

Item 7. Major Shareholders and Related Party Transactions

A. Major Shareholders

The following table sets forth information relating to the beneficial ownership of our ordinary shares as of March 15, 2020, for:

(a) each person, or group of affiliated persons, known by us to beneficially own 5% or more of our outstanding ordinary shares;

(b) each of our executive officers and members of our board of directors individually; and

(c) all of our executive officers and members of our board of directors as a group.

For further information regarding material transactions between us and principal shareholders, see "*Related Party Transactions*" below.

The number of ordinary shares beneficially owned by each entity, person, executive officer or board member is determined in accordance with the rules of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under such rules, beneficial ownership includes any shares over which the individual has sole or shared voting power or investment power, or the right to receive the economic benefit of ownership, as well as any shares that the individual has the right to acquire within 60 days of March 15, 2020 through the exercise of any option, warrant or other right. Except as otherwise indicated, and subject to applicable community property laws, the persons named in the table have sole voting and investment power and the right to receive the economic benefit of ownership with respect to all ordinary shares held by that person.

The percentage of ordinary shares beneficially owned is calculated on the basis of 423,103,011 ordinary shares outstanding as of March 15, 2020. Ordinary shares that a person has the right to acquire within 60 days of March 15, 2020 are deemed outstanding for purposes of computing the percentage ownership of the person holding such rights, but are not deemed outstanding for purposes of computing the percentage ownership of any other person, except with respect to the percentage ownership of all board members and executive officers as a group.

Unless otherwise indicated below, the address for each beneficial owner listed is c/o Itamar Medical Ltd., 9 Halamish Street, Caesarea 3088900, Israel.

	Shares beneficially owned	
Name of beneficial owner	**Number**	**Percent**
5% or Greater Shareholders		
Entities affiliated with the Viola Group(1)	72,841,918	17.2%
MS Pace LP(2)	40,307,413	9.5%
Executive Officers and Board Members		
Giora Yaron, Ph.D.(3)	30,461,062	7.2%
Gilad Glick(4)	3,925,862	*
Shy Basson(5)	275,661	*
Itay Kariv(6)	168,286	*
Dan Shlezak	-	-
Efrat Litman(7)	708,377	*
Eilon Livne(8)	119,346	*
Shiri Shneorson	-	-
Martin Gerstel(9)	15,104,724	3.6%
Ilan Biran(10)	616,316	*
Jonathan Kolber(11)	-	-
Sami Totah(12)	-	-
Christopher M. Cleary(13)	-	-
Yaffa Krindel Sieradzki(14)	337,639	*
Zipora (Tzipi) Ozer-Armon(15)	165,000	*
All executive officers and board members as a group (15 persons)(16)	51,882,274	12.1%

* Indicates beneficial ownership of less than 1% of the total outstanding ordinary shares.

(1) This information is based on information provided to the Company by Viola Growth II GP Ltd., a Cayman Islands company, as of May 2019, in connection with our 2019 annual meeting of shareholders. The number of ordinary shares reported in the table consists of (a) 72,346,918 ordinary shares held by Viola Growth 2 A.V. Limited Partnership, or Viola 2 AV, an Israeli limited partnership; and (b) 495,000 ordinary shares issuable upon exercise of options to purchase ordinary shares held by Viola Growth Management Fund 2 Ltd., or Viola 2, an Israeli company, that are or will be immediately exercisable within 60 days of March 15, 2020. The general partner of Viola 2 AV is Viola Growth II Limited Partnership, a Cayman Island limited partnership. The general partner of Viola Growth II Limited Partnership is Viola Growth II GP Ltd., a Cayman Islands company, which is wholly owned by Viola 2. Messrs. Shlomo Dovrat, Harel Beit-On and Avi Zeevi, all of whom are Israeli citizens, hold indirect interests in, and are the controlling shareholders of, Viola 2 and, consequently, may be deemed to be the beneficial owners of the ordinary shares held by Viola 2 AV and Viola 2. However, each of Messrs. Dovrat, Beit-On and Zeevi disclaims beneficial ownership of all of the foregoing shares, except to the extent of their respective pecuniary interest therein. The business address of Viola is Ackerstein Towers, Building D, 12 Abba Eban Avenue, Herzeliya 4672530, Israel.

(2) This information is based on a Schedule 13G/A filed on August 8, 2019, by MS Pace LP, or MSP, a Delaware limited partnership, MS Pace Management, LLC, or MSP Management, a Delaware limited liability company and Sightline MS GP, LLC, or Sightline, a Delaware limited liability company. The general partner of MSP is MSP Management which is 51% held by an affiliate of Medtronic International Technology, Inc., or Medtronic, and the remaining 49% interest therein is held by Sightline, a third party unrelated to Medtronic. Medtronic also holds 20% of the limited partnership interests in MSP. Medtronic is an indirect wholly owned subsidiary of Medtronic plc, an Irish corporation whose shares are traded on the NYSE. The number of ordinary shares reported in the table consists of 40,307,413 ordinary shares held by MSP The business address of MS Pace is 8500 Normandale Lake Boulevard, Suite 1070, Bloomington, Minnesota 55437.

(3) Consists of (a) 29,944,746 ordinary shares and (b) 516,316 ordinary shares issuable upon exercise of options to purchase ordinary shares that are or will be immediately exercisable within 60 days of March 15, 2020. Some of these securities are held through a company wholly owned by Dr. Yaron.

(4) Consists of (a) 398,622 ordinary shares and (b) 3,527,240 ordinary shares issuable upon exercise of options to purchase ordinary shares that are or will be immediately exercisable within 60 days of March 15, 2020.

(5) Consists of 275,661 ordinary shares issuable upon exercise of options to purchase ordinary shares that are or will be immediately exercisable within 60 days of March 15, 2020.

(6) Consists of 168,286 ordinary shares issuable upon exercise of options to purchase ordinary shares that are or will be immediately exercisable within 60 days of March 15, 2020.

(7) Consists of (a) 50,452 ordinary shares and (b) 657,925 ordinary shares issuable upon exercise of options to purchase ordinary shares that are or will be immediately exercisable within 60 days of March 15, 2020.

(8) Consists of 119,346 ordinary shares issuable upon exercise of options to purchase ordinary shares that are or will be immediately exercisable within 60 days of March 15, 2020.

(9) Consists of (a) 14,838,891 ordinary shares and (b) 265,833 ordinary shares issuable upon exercise of options to purchase ordinary shares that are or will be immediately exercisable within 60 days of March 15, 2020.

(10) Consists of (a) 100,000 ordinary shares and (b) 516,316 ordinary shares issuable upon exercise of options to purchase ordinary shares that are or will be immediately exercisable within 60 days of March 15, 2020.

(11) Mr. Kolber is a partner in Viola Growth, which is an affiliate of Viola.

(12) Mr. Totah is a partner in Viola Growth, which is an affiliate of Viola.

(13) Mr. Cleary is a Vice President of Corporate Development for Medtronic plc, which is an affiliate of MS Pace.

(14) Consists of (a) 172,369 ordinary shares and (b) 165,000 ordinary shares issuable upon exercise of options to purchase ordinary shares that are or will be immediately exercisable within 60 days of March 15, 2020.

(15) Consists of 165,000 ordinary shares issuable upon exercise of options to purchase ordinary shares that are or will be immediately exercisable within 60 days of March 15, 2020.

(16) Consists of (a) 45,505,350 ordinary shares and (b) 6,376,924 ordinary shares issuable upon exercise of options to purchase ordinary shares that are or will be immediately exercisable within 60 days of March 15, 2020.

Change in Control

To our knowledge, (i) we are not directly or indirectly owned or controlled by another corporation, by any foreign government or by any other natural or legal person severally or jointly, except as disclosed in the above table regarding our major shareholders, and (ii) there are no arrangements which would result in our change in control at a subsequent date.

Significant Changes in the Ownership of Major Shareholders

To our knowledge, other than as disclosed in the table above, our other filings with the SEC and this Annual Report, there has been no significant change in the percentage ownership held by any major shareholder since January 1, 2017.

Major Shareholders Voting Rights

Our major shareholders do not have different voting rights.

Record Holders

Bank of New York Mellon, or BNY, is the holder of record for the Company's American Depositary Receipt program, pursuant to which each ADS represents 30 ordinary shares. As of March 31, 2020, BNY held 137,778,111 ordinary shares representing 32.6% of our issued share capital held at that date. To our knowledge, as of March 31, 2020, we had no additional holders of record of our shares with addresses in the United States. As a number of our shares are held in book-entry form, we are not aware of the identity of all of our shareholders.

B. Related Party Transactions

The following is a description of our related party transactions since January 1, 2019.

Medtronic Co-Marketing Agreement

In March 2014, we entered into a co-marketing agreement with Medtronic, Inc., whereby Medtronic, Inc. was granted exclusive rights to co-market our WatchPAT family of products to electrophysiologists (physicians specializing in cardiology arrhythmias) in the United States and undertook to make specified investments in marketing of the product as well as meet minimum sales quotas. In April 2015, as part of several amendments to the marketing agreement, the aforesaid obligation to make specified investments and meet minimum sales quotas was canceled. Pursuant to this agreement, Medtronic, Inc. markets WatchPAT as part of a comprehensive solution offered by Medtronic to physicians. Since June 30, 2017, the term of this agreement (as amended) is automatically renewed for 30-day intervals, unless earlier terminated by either party upon 14 days prior notice.

Medtronic, Inc. is entitled to a portion of the net sales made under this agreement. However, the total net sales under this agreement (and, consequently, the consideration payable to Medtronic, Inc.) have been immaterial to us in the past three years (net sales under this agreement were approximately $0.20 million in the year ended December 31, 2019, $0.21 million in the year ended December 31, 2018, and $0.31 million in the year ended December 31, 2017).

Financing Transactions

See Item 5.B "Operating and Financial Review and Prospects — Liquidity and Capital Resources — Principal Financing Activities" with respect to certain investments and loans made by, or repaid to, our major shareholders and members of our Board of Directors.

Transactions with Our Executive Officers and Directors

We have entered into employment or services agreements with each of our executive officers. See Item 6.B. "*Directors, Senior Management and Employees — Compensation — Executive Officer Employment and Consultancy Agreements*" for additional information. In addition, we have entered into consultancy agreements with certain of our directors. See Item 6.B. "*Directors, Senior Management and Employees — Compensation — Non-Employee Directors Remuneration*" for additional information.

Viola Share Purchase Agreement

In August 2015, we entered into a share purchase agreement with Viola P.E. II A.V. LP and certain of its affiliates, and on November 5, 2015 (and, as a second stage of the transaction, on February 1, 2016), we completed the transaction. As part of the transaction, we granted Viola customary registration rights subject to obtaining the applicable regulatory approvals to the extent required under applicable law, including, at a minimum, two demand registration rights and unlimited piggyback and Form F-3 registrations.

Indemnity Agreements

We have entered into agreements with each of our current directors and executive officers to indemnify them to the fullest extent permitted by law, subject to limited exceptions. See Item 6.B. "*Directors, Senior Management and Employees — Compensation — Insurance and Indemnification*" for additional information.

Related Person Transaction Policy

Our Board of Directors has adopted an interested party transaction policy, which governs the identification, reporting and approval of transactions with interested parties.

C. Interests of Experts and Counsel

Not applicable.

Item 8. Financial Information

A. Consolidated Statements and Other Financial Information

Consolidated Financial Statements

See Item 18. "*Financial Statements*."

Export Sales

In the year ended December 31, 2019, the amount of our export sales (i.e., sales outside of Israel) was approximately $31.0 million, which represents 99.1% of our total sales.

Legal and Arbitration Proceedings

From time to time, we may be involved in various claims and legal proceedings related to claims arising out of our operations. We are not currently a party to any material legal proceedings, including any such proceedings that are pending or threatened, of which we are aware.

Dividend Policy

We have never declared or paid cash dividends on our ordinary shares or ADSs and do not intend to pay cash dividends on our ordinary shares or ADSs in the foreseeable future. Our earnings and other cash resources will be used to continue the development and expansion of our business. Any future dividend policy will be determined by our Board of Directors and will be based upon conditions then-existing, including our results of operations, financial condition, current and anticipated cash needs, contractual restrictions and other conditions.

Subject to any preferential, deferred or other rights or restrictions attached to any special class of shares with regard to dividends, the profits of the Company available for dividend and resolved to be distributed shall be applied in payment of dividends upon the shares of the Company in the same manner with respect to all of the shares granting a right to receive dividends on the date that resolution is adopted (or on later date, as determined by the Board of Directors). Generally, our Board of Directors may declare dividends only out of profits legally available for distribution, in accordance with the provisions of the Companies Law as described below, and is entitled to invest or utilize any unclaimed amount of dividend in any manner to our benefit until it is claimed. We are not obligated to pay interest or linkage on an unclaimed dividend.

The Companies Law imposes restrictions on our ability to declare and pay dividends. According to the Companies Law, a company may distribute dividends only out of its "profits," as such term is defined in the Companies Law and provided that there is no reasonable concern that payment of the dividend will prevent such company from satisfying its existing and foreseeable obligations as they become due. Notwithstanding the foregoing, dividends may be paid with the approval of a court, provided that there is no reasonable concern that payment of the dividend will prevent us from satisfying our existing and foreseeable obligations as they become due. "Profits", for purposes of the Companies Law, means the greater of retained earnings or earnings accumulated during the preceding two years, after deduction of previous distributions that were not already deducted from the surpluses, as evidenced by the most recent audited or reviewed financial statements of the company prepared no more than six months prior to the date of distribution. Our articles of association provide that dividends will be declared and paid at the discretion of, and upon resolution by, our Board of Directors, subject to the provisions of the Companies Law. In addition, the Security Agreements contain a number of customary restrictive terms and covenants, including with respect to the distribution of dividends.

Payment of dividends may be subject to Israeli withholding taxes. See Item 10.E. "*Additional Information—Taxation—Israeli Tax Considerations"* for additional information.

B. Significant Changes

Except as otherwise disclosed in this Annual Report, no significant change has occurred since December 31, 2019.

Item 9. The Offer and Listing

A. Offer and Listing Details

Our ordinary shares have been trading on the TASE under the symbol "ITMR" since March 13, 2007. Our ADSs have been trading on the Nasdaq Capital Market under the symbol "ITMR" since February 27, 2019.

B. Plan of Distribution

Not applicable.

C. Markets

Our ordinary shares are listed and traded on the TASE, and our ADSs, each representing 30 ordinary shares and evidenced by an American Depositary Receipt, or ADR, are traded on the Nasdaq Capital Market under the symbol "ITMR". The ADRs were issued pursuant to a Depositary Agreement entered into with The Bank of New York Mellon.

D. Selling Shareholders

Not Applicable.

E. Dilution

Not applicable.

F. Expenses of the Issue

Not applicable.

Item 10. Additional Information

A. Share Capital

Not applicable.

B. Memorandum and Articles of Association

Copies of our amended and restated memorandum of association and our amended and restated articles of association are filed as Exhibits 1.1 and 1.2 to this Annual Report. The information called for by this Item 10.B. is included in Exhibit 2.6 to this Annual Report and is incorporated herein by reference.

C. Material Contracts

In addition to the contracts described elsewhere in this Annual Report, the following are summaries of each material contract, other than material contracts entered into in the ordinary course of business, to which we are a party for the two years preceding the date of this Annual Report.

Agreement with Kaiser

On April 22, 2019, Itamar Medical, Inc., our wholly owned U.S. Subsidiary, entered into a new master products and services agreement with Kaiser Foundation Health Plan, Inc., or Kaiser, one of the largest medical insurers and hospital systems in the U.S., or the Kaiser Agreement.

The Kaiser Agreement, which replaced the previous master products and services agreement with Kaiser, is essentially a framework agreement that allows Kaiser to place purchase orders for our products from time to time, with no minimum purchase requirements. Under the Kaiser Agreement, we undertook to supply Kaiser and its affiliates with our products as well as offer maintenance services for the products supplied by us. The Kaiser Agreement also contains provisions regarding (1) the pricing terms of the products and services offered by us to Kaiser, (2) payment terms, (3) the warranty we provide with respect to the supply of our products, including in case of product recalls, and (4) our undertaking to indemnify Kaiser in case that our products infringe upon the intellectual property rights of third parties.

Unless terminated earlier in accordance with its terms, the term of the Kaiser Agreement is until March 31, 2022, and may be extended thereafter by prior notice from Kaiser, for two (2) additional one (1) year periods.

Philips Japan Distribution Agreement

On February 24, 2014, we entered into a distribution agreement with Philips Respironics GK, a subsidiary of Koninklijke Philips NV (also known as Royal Philips), or Philips Japan, or the Distribution Agreement (as amended).

The Distribution Agreement is essentially a framework agreement that allows Philips Japan to place purchase orders for our products from time to time, with no minimum purchase requirements except to the limited extent described below. Under the agreement, Philips Japan was granted exclusive rights to distribute our WatchPAT products and ancillary accessories in Japan. The agreement contains other customary provisions, including (1) the pricing terms of the products offered by us to Philips Japan, (2) payment terms, (3) the terms of warranty for defective products, and (4) our undertaking to indemnify Philips in case that our products infringe upon the intellectual property rights of third parties. Philips Japan does not have the right to return the products that we deliver them pursuant to the Distribution Agreement.

We may terminate the agreement if, among other things, Philips Japan does not meet certain minimum annual and quarterly purchase requirements of our products specified in the Distribution Agreement (which, commencing with 2016, were adjusted by Philips Japan and us to reflect the prices for our products under the then prevailing local market conditions, including reimbursement levels). It is clarified that, under the agreement, such termination right is our sole remedy if Philips Japan does not meet such minimum purchase requirements. In addition, each of Philips Japan and us may terminate the agreement for convenience by providing 90 days advance notice to the other party.

The Distribution Agreement provided that its initial term will expire (i) on December 31, 2018, or (ii) three (3) years from the date that the MHLW grants reimbursement approval of therapy for patients diagnosed by HSATs (such as our WatchPAT) with AHI (apnea hypopnea index) above 20, or the "MHLW approval, whichever is earlier. If the MHLW approval were obtained, it would have had the effect of expanding the reimbursement of therapy to patients suffering from moderate, and not only severe OSA. Since the MHLW approval has not been obtained to date, the initial term of the agreement was scheduled to expire on December 31, 2018. However, following an amendment to the Distribution Agreement, the term of the agreement was extended and is currently scheduled to expire on December 31, 2021. It should be noted that, as part of such amendment, the Distribution Agreement contemplates the preparation of a business plan to be mutually agreed by the parties, which business plan is expected to include, among other things, the submission of an application to seek the MHLW approval. There is no assurance, however, that, even if such business plan is agreed and implemented by the parties, the submission of such application will result in obtaining the MHLW approval and, if so, when.

Upon termination of the agreement, Philips Japan, which holds the Japanese's regulatory approval for marketing the WatchPAT in Japan, is required to transfer the regulatory approval to us.

Agreement with VA

On October 12, 2011 and March 12, 2014, our U.S. Subsidiary entered into a Solicitation/Contract/Order for Commercial Items agreement with the Department of Veterans Affairs, or VA, one of the largest U.S. hospital and clinics chains, or the VA Framework Agreement (as amended).

The VA Framework Agreement is essentially a framework agreement that allows VA to place purchase orders for our products from time to time, with no minimum purchase requirements, under the terms of the agreement. Under the agreement, we undertook to supply VA and its affiliates with our WatchPAT and Endo PAT products and ancillary accessories as well as offer maintenance services for the products supplied by us under the agreement. The agreement also contains provisions regarding (1) the pricing terms of the products and services offered by us to VA, (2) payment terms, (3) the warranty we provide with respect to the supply of our products, including in case of product recalls, and (4) our undertaking to indemnify VA in case that our products infringe upon the intellectual property rights of third parties.

The current term of the VA Framework Agreement is until June 14, 2023.

Credit Line

See the summary under Item 5.B. "*Operating and Financial Review and Prospects — Liquidity and Capital Resources — Principal Financing Activities — Credit Line*."

2018 Private Placement

See the summary under Item 5.B. "*Operating and Financial Review and Prospects — Liquidity and Capital Resources — Principal Financing Activities — 2018 Private Placement*."

2019 Private Placement

See the summary under Item 5.B. "*Operating and Financial Review and Prospects — Liquidity and Capital Resources — Principal Financing Activities — 2019 Private Placement*."

D. Exchange Controls

Israeli law and regulations do not impose any material foreign exchange restrictions on non-Israeli holders of our ordinary shares. There are currently no Israeli currency control restrictions on payments of dividends or other distributions with respect to our ordinary shares or the proceeds from the sale of the shares, except for the obligation of Israeli residents to file reports with the Bank of Israel regarding certain transactions. However, legislation remains in effect pursuant to which currency controls can be imposed by administrative action at any time.

The ownership or voting of our ordinary shares by non-residents of Israel, except with respect to citizens of countries which are in a state of war with Israel, is not restricted in any way by our memorandum of association or articles of association or by the laws of the State of Israel.

E. Taxation

Israeli Tax Considerations

The following is a summary of the principal Israeli tax laws applicable to Israeli companies, with special reference to their effect on us. The following also contains a discussion of the material Israeli tax consequences to purchasers of our ordinary shares or ADSs. This summary does not discuss all the aspects of Israeli tax law that may be relevant to a particular investor in light of his or her personal investment circumstances or to some types of investors subject to special treatment under Israeli law, including investors whose business is dealing in securities. Some parts of this discussion are based on tax legislation which has not been subject to judicial or administrative interpretation. We cannot assure you that the views expressed in the discussion will be accepted by the appropriate tax authorities or the courts. The discussion is not intended, and should not be construed, as legal or professional tax advice and is not exhaustive of all possible tax considerations.

YOU ARE URGED TO CONSULT YOUR OWN TAX ADVISORS AS TO THE ISRAELI OR OTHER TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF OUR ORDINARY SHARES OR ADSs, INCLUDING, IN PARTICULAR, THE EFFECT OF ANY FOREIGN, STATE OR LOCAL TAXES.

General Corporate Tax Structure

Most of our production facilities have been granted "Approved Enterprise" and "Benefited Enterprise" status under the Law for the Encouragement of Capital Investments, 1959, or the Investment Law. As such, we may be entitled to tax benefits for taxable income arising from our Approved or Benefited Enterprise status.

Generally, Israeli companies are subject to Israeli corporate tax on their taxable income at the rate of 23% for the 2018 tax year and thereafter. However, the effective tax rate payable by a company that generates income qualifying for benefits under the Investment Law may be considerably less. Israeli companies are generally subject to capital gains tax at the regular corporate tax rate.

We are permitted to measure our Israeli taxable income in U.S. dollars pursuant to regulations published by the Israeli Minister of Finance, subject to satisfying the conditions set forth therein. We believe that we meet, and we expect that we will continue to meet, the necessary conditions and as such, starting with our 2016 tax year, we measure our results for Israeli tax purposes based on the U.S. dollar and the NIS exchange rate on December 31 of the relevant tax year.

Tax Benefits under the Law for the Encouragement of Capital Investments, 1959

Most of our production facilities have been granted "Approved Enterprise" and "Benefited Enterprise" status under the Investment Law. As such, we may be entitled to tax benefits for taxable income arising from our Approved or Benefited Enterprise status. Since our incorporation, we incurred significant losses and therefore we have not benefited from such status to date. To be eligible for these tax benefits, we must continue to meet certain conditions stipulated in the Investment Law and its regulations and the criteria set out in the specific certificate of approval, including that we meet a minimum threshold (25%) of export sales (i.e., sales outside of Israel). In the event that we are considered as having failed to comply with these conditions, in whole or in part, the eligibility for the benefits may be canceled and we may be required to refund the amount of the benefits, as adjusted for inflation and interest. However, since we have accumulated carryforward tax losses of approximately $111 million as of December 31, 2018, we did not benefit from such tax benefits and do not expect to benefit from such tax benefits in the foreseeable future. Once we utilize all of our accumulated tax losses, we expect to derive tax benefits in Israel relating to our "Approved Enterprise" and "Benefited Enterprise" for which we are eligible. Our income from sources other than from our "Approved Enterprise" and "Benefited Enterprise" status are taxable at regular corporate tax rates.

A company having an Approved Enterprise or Benefited Enterprise, like us, that distributes a dividend from income that was tax exempt, will be required in the tax year of the dividend distribution to pay corporate tax on the amount of the dividend distributed (including the company tax required as a result of the distribution) at the corporate tax rate that would have been applicable to it in the year the income was generated if it had not been exempt from tax.

Amendments to the Investment Law in 2011 and in 2017 introduced new tax benefits for income generated by a "Preferred Enterprise," "Preferred Technological Enterprise" and "Special Preferred Technological Enterprise," in accordance with the definition of such terms in the Investment Law. We currently do not have Preferred Enterprise or Preferred Technology Enterprise programs.

Tax Benefits and Grants for Research and Development

Israeli tax law allows, under specified conditions, a tax deduction for expenditures related to scientific research and development projects, including capital expenditures, for the year in which they are incurred, provided that the expenses are approved by the relevant Israeli government ministry, determined by the field of research, and the research and development is conducted for the promotion of the company and carried out by or on behalf of the company seeking such deduction. However, the amount of such deductible expenses will be reduced by the sum of any funds received through government grants for the financing of such scientific research and development projects. In addition, no deduction under these research and development deduction rules is allowed if such deduction is related to an expense invested in an asset depreciable under the general depreciation rules of the Israeli Income Tax Ordinance (New Version) 1961, or the Tax Ordinance. Expenditures not so approved are deductible over a three-year period.

From time to time, we may apply to the IIA for approval to allow a tax deduction for research and development expenses during the year incurred. There can be no assurance that such application will be accepted.

Tax Benefits under the Law for the Encouragement of Industry (Taxes), 1969

Under the Law for the Encouragement of Industry (Taxes), 1969, or the Industry Encouragement Law, Industrial Companies (as defined below) are entitled to the following tax benefits, among others:

- amortization over an eight-year period of the cost of purchased know-how and patents and rights to use a patent and know-how which are used for the development or advancement of the Industrial Enterprise, commencing from the tax year where the Industrial Enterprise began to use them;

- deductions of expenses related to a public offering of its shares on a stock market in equal amounts over a three-year period commencing in the year of the offering;

- the right to elect, under specified conditions, to file a consolidated tax return with other related Israeli Industrial Companies; and

- accelerated depreciation rates on equipment and buildings.

Eligibility for benefits under the Industry Encouragement Law is not subject to receipt of prior approval from any governmental authority. Under the Industry Encouragement Law, an "Industrial Company" is defined as a company which is an Israeli resident for tax purposes and was incorporated in Israel, at least 90% of the income of which, in any tax year, determined in Israeli currency, exclusive of income from government loans, capital gains, interest and dividends, is derived from an "Industrial Enterprise" owned by it. An "Industrial Enterprise" is defined as an enterprise whose major activity in a given tax year is industrial production activity. We believe that we currently qualify as an Industrial Company within the definition of the Industry Encouragement Law. No assurance can be given that we will continue to qualify as an Industrial Company or that the benefits described above will be available to us in the future.

Capital Gains Tax on Sales of our Ordinary Shares and ADSs

The following discussion refers to the sale of our ordinary shares. However, the same tax treatment would apply to the sale of the ADSs.

Israeli law generally imposes a capital gains tax on the sale of any capital assets by Israeli residents, as defined for Israeli tax purposes, and on the sale of assets located in Israel, including shares in Israeli companies, by both Israeli residents and non-Israeli residents, unless a specific exemption is available or unless a tax treaty between Israel and the shareholder's country of residence provides otherwise. The Tax Ordinance distinguishes between real gain and inflationary surplus. The inflationary surplus is a portion of the total capital gain equivalent to the increase of the relevant asset's purchase price attributable to an increase in the Israeli consumer price index, or a foreign currency exchange rate, between the date of purchase and the date of sale. The real gain is the excess of the total capital gain over the inflationary surplus. Inflationary surplus is not currently subject to tax in Israel.

Taxation of Israeli Residents

The tax rate generally applicable to the capital gains derived from the sale of shares, whether listed on a stock market or not, is 25% for Israeli individuals, unless such shareholder is considered a "significant shareholder" at any time during the 12-month period preceding such sale (*i.e.*, such shareholder holds directly or indirectly, including jointly with others, at least 10% of any means of control in the company (which includes, among other things, the right to receive profits of the company, voting rights, the rights to receive proceeds upon the company's liquidation and the right to appoint a director)), in which case the tax rate will be 30%. Israeli companies are subject to the corporate tax rate on capital gains derived from the sale of listed shares.

Taxation of Non-Israeli Residents

Non-Israeli residents are generally exempt from Israeli capital gains tax on any gains derived from the sale of shares purchased upon or after the registration of the shares on the TASE or on a regulated market outside of Israel (such as Nasdaq), provided such gains did not derive from a permanent establishment of such shareholders in Israel. However, non-Israeli corporations will not be entitled to such exemption if Israeli residents, whether directly or indirectly, (i) hold more than 25% of the means of control in such non-Israeli corporation, or (ii) are the beneficiaries of or are entitled to 25% or more of the revenues or profits of such non-Israeli corporation.

In addition, the sale of our ordinary shares by a shareholder who is a U.S. resident (for purposes of the Convention Between the Government of the United States and the Government of the State of Israel with respect to Taxes of Income, as amended, or the U.S.-Israel Tax Treaty), and who holds ordinary shares as a capital asset, is also exempt from Israeli capital gains tax under the U.S.-Israel Tax Treaty unless (i) such shareholder holds, directly or indirectly, shares representing 10% or more of the voting power of our company during any part of the 12-month period preceding such sale, (ii) the capital gains arising from such sale are attributable to a permanent establishment of such shareholder located in Israel, (iii) the gain is from sale of shares of a real estate association (as defined in the Israeli Land Tax Law (Appreciation Tax), 1963), or (iv) the U.S. shareholder, being an individual, is present in Israel for a period or periods aggregating 183 days or more during the relevant taxable year. If the above conditions are not met, the U.S. resident would be subject to Israeli tax, unless exempt under the Israeli domestic law as described above. Under the U.S.-Israel Tax Treaty, the gain may be treated as foreign source income for United States foreign tax credit purposes, upon an election by the U.S. resident, and such U.S. resident may be permitted to claim a credit for such taxes against the United States federal income tax imposed on such sale, subject to the limitations under the United States federal income tax laws applicable to foreign tax credits.

The payment of the consideration on the sale of ordinary shares may be subject to withholding tax in Israel. Shareholders may be required to demonstrate that they are exempt from tax on their capital gains in order to avoid withholding at the time of sale.

Taxation of Dividends Paid on our Ordinary Shares and ADSs

The following discussion refers to dividends paid on our ordinary shares. However, the same tax treatment would apply to dividends paid on the ADSs. We cannot assure you that, in the event we declare a dividend, we will designate the profits that we distribute in a way that will reduce shareholders' tax liability.

Taxation of Israeli Residents

Israeli resident individuals are generally subject to Israeli income tax on the receipt of dividends paid on our ordinary shares. The tax rate generally applicable to such dividends is 25%, or 30% for an individual shareholder that is considered a significant shareholder (described above) at any time during the 12-month period preceding such distribution. Israeli resident companies are generally exempt from income tax from dividends sourced from income produced or accrued in Israel, received directly or indirectly from another company that is liable to Israeli corporate tax. Dividends paid from income derived from our Approved and Benefited Enterprises are subject to withholding tax at the rate of 20%. Dividends paid from income derived from a Preferred Enterprise and Preferred Technology Enterprise will be subject to withholding tax at the rate of 20%.

Taxation of Non-Israeli Residents

Non-Israeli residents, both companies and individuals, are generally subject to Israeli income tax on the receipt of dividends paid on our ordinary shares, at the rate of 25%, or 30% for a shareholder that is considered a significant shareholder (described above) at any time during the 12-month period preceding such distribution, which tax will be withheld at source, unless a different rate is provided in a treaty between Israel and the shareholder's country of residence (subject to the receipt in advance of a valid tax certificate from the Israel Tax Authority allowing for a reduced tax rate).

Under the U.S.-Israel Tax Treaty, the following withholding rates will apply in respect of dividends distributed by an Israeli resident company to a U.S. resident: (i) if the U.S. resident is a corporation which holds during that portion of the taxable year which precedes the date of payment of the dividend and during the whole of its prior taxable year (if any), at least 10% of the outstanding voting shares of the Israeli resident paying corporation and not more than 25% of the gross income of the Israeli resident paying corporation for such prior taxable year (if any) consists of certain type of interest or dividends — the withholding tax rate is 12.5%, (ii) if both the conditions mentioned in (i) above are met and the dividend is paid from an Israeli resident company's income which was entitled to a reduced tax rate applicable to an Approved Enterprise, Benefited Enterprise or Preferred Enterprise — the withholding tax rate is 15% if a certificate for a reduced withholding tax rate would be provided in advance from the ITA and (iii) in all other cases, the withholding tax rate is 25%. The aforementioned rates under the

U.S.-Israel Tax Treaty will not apply if the dividend income was derived through a permanent establishment of the U.S. resident in Israel.

A non-Israeli resident who receives a dividend derived from or accrued in Israel, from which tax was withheld at source, is generally exempt from the duty to file tax returns in Israel with respect to such income, provided that such income was not derived from a business conducted in Israel by the taxpayer and the taxpayer has no other taxable sources of income in Israel with respect to which a tax return is required to be filed.

Israeli Excess Tax

Individuals who are subject to tax in Israel (whether such individual is an Israeli resident or non-Israeli resident) are also subject to an additional tax at a rate of 3% on annual income exceeding a certain threshold (NIS 649,560 (equivalent to approximately $189,874) for 2019), which amount is linked to the Israeli consumer price index, including, but not limited to, income derived from dividends, interest and capital gains.

United States Federal Income Tax Considerations

The following summary describes certain United States federal income tax considerations generally applicable to United States Holders (as defined below) of the ADSs. This summary deals only with the ADSs held as capital assets within the meaning of Section 1221 of the Internal Revenue Code of 1986, as amended, or Internal Revenue Code. This summary also does not address the tax consequences that may be relevant to holders in special tax situations including, without limitation, dealers in securities, traders that elect to use a mark-to-market method of accounting, holders that own the ADSs as part of a "straddle," "hedge," "conversion transaction," or other integrated investment, banks or other financial institutions, individual retirement accounts and other tax-deferred accounts, insurance companies, tax-exempt organizations, United States expatriates, holders whose functional currency is not the U.S. dollar, holders subject to the alternative minimum tax, holders that acquired the ADSs in a compensatory transaction, holders subject to special tax accounting rules as a result of any item of gross income with respect to the ADSs being taken into account in an applicable financial statement, holders which are entities or arrangements treated as partnerships for United States federal income tax purposes or holders that actually or constructively through attribution own 10% or more of the total voting power or value of our outstanding ordinary shares or ADSs.

This summary is based upon the Internal Revenue Code, applicable United States Treasury regulations, administrative pronouncements and judicial decisions, in each case as in effect on the date hereof, all of which are subject to change (possibly with retroactive effect). No ruling will be requested from the Internal Revenue Service, or IRS, regarding the tax consequences described herein, and there can be no assurance that the IRS will agree with the discussion set out below. This summary does not address any United States federal tax consequences other than United States federal income tax consequences (such as the estate and gift tax or the Medicare tax on net investment income).

As used herein, the term "United States Holder" means a beneficial owner of the ADSs that is, for United States federal income tax purposes, (i) a citizen or resident of the United States, (ii) a corporation or other entity taxable as a corporation created or organized under the laws of the United States or any state thereof or therein or the District of Columbia, (iii) an estate the income of which is subject to United States federal income taxation regardless of its source, or (iv) a trust (a) that is subject to the supervision of a court within the United States and the control of one or more United States persons as described in Internal Revenue Code Section 7701(a)(30), or (b) that has a valid election in effect under applicable United States Treasury regulations to be treated as a "United States person."

If an entity or other arrangement treated as a partnership for United States federal income tax purposes acquires the ADSs, the tax treatment of a partner in the partnership generally will depend upon the status of the partner and the activities of the partnership. Partners of a partnership considering an investment in the ADSs should consult their tax advisers regarding the United States federal income tax consequences of acquiring, owning, and disposing of the ADSs.

Generally, a holder of an ADS will be treated for United States federal income tax purposes as holding the ordinary shares represented by the ADS. Accordingly, no gain or loss will be recognized upon an exchange of ADSs for ordinary shares.

THE SUMMARY OF UNITED STATES FEDERAL INCOME TAX CONSEQUENCES SET OUT BELOW IS FOR GENERAL INFORMATION ONLY. ALL PROSPECTIVE INVESTORS SHOULD CONSULT THEIR TAX ADVISERS AS TO THE PARTICULAR TAX CONSEQUENCES TO THEM OF OWNING THE ADSs, INCLUDING THE APPLICABILITY AND EFFECT OF STATE, LOCAL AND NON-U.S. TAX LAWS AND POSSIBLE CHANGES IN TAX LAW.

Dividends

Subject to the discussion below under "Passive Foreign Investment Company," the amount of dividends paid to a United States Holder with respect to ADSs before reduction for any Israeli taxes withheld therefrom generally will be included in the United States Holder's gross income as ordinary income from foreign sources to the extent paid out of our current or accumulated earnings and profits (as determined for United States federal income tax purposes). Distributions in excess of earnings and profits will be treated as a non-taxable return of capital to the extent of the United States Holder's adjusted tax basis in those ADSs and thereafter as capital gain. However, we do not intend to calculate our earnings and profits under United States federal income tax principles. Therefore, United States Holders should expect that a distribution will generally be treated as a dividend even if that distribution would otherwise be treated as a non-taxable return of capital or as capital gain under the rules described above. The amount of any distribution paid in foreign currency will be equal to the U.S. dollar value of such currency, translated at the spot rate of exchange on the date such distribution is received, regardless of whether the payment is in fact converted into U.S. dollars at that time.

Foreign withholding tax (if any) paid on dividends on ADSs at the rate applicable to a United States Holder (taking into account any applicable income tax treaty) will, subject to limitations and conditions, be treated as foreign income tax eligible for credit against such holder's United States federal income tax liability or, at such holder's election, eligible for deduction in computing such holder's United States federal taxable income. Dividends paid on ADSs generally will constitute "passive category income" for purposes of the foreign tax credit. Foreign withholding tax (if any) paid on dividends on ADSs at the rate applicable to a United States Holder (taking into account any applicable income tax treaty) will, subject to limitations and conditions, be treated as foreign income tax eligible for credit against such holder's United States federal income tax liability or, at such holder's election, eligible for deduction in computing such holder's United States federal taxable income. However, if we are a "United States-owned foreign corporation," solely for foreign tax credit purposes, a portion of the dividends allocable to our United States source earnings and profits may be re-characterized as United States source. A "United States-owned foreign corporation" is any foreign corporation in which United States persons own, directly or indirectly, 50% or more (by vote or by value) of the stock. In general, United States-owned foreign corporations with less than 10% of earnings and profits attributable to sources within the United States are excepted from these rules. Although we don't believe we are currently a "United States-owned foreign corporation," we may become one in the future. In such case, if 10% or more of our earnings and profits are attributable to sources within the United States, a portion of the dividends paid on the ADSs allocable to our United States source earnings and profits will be treated as United States source, and, as such, a United States Holder may not offset any foreign tax withheld as a credit against United States federal income tax imposed on that portion of dividends. The rules governing the treatment of foreign taxes imposed on a United States Holder and foreign tax credits are complex, and United States Holders should consult their tax advisors about the impact of these rules in their particular situations.

Dividends paid to a non-corporate United States Holder by a "qualified foreign corporation" may be subject to reduced rates of taxation if certain holding period and other requirements are met. "Qualified foreign corporation" generally includes a foreign corporation (other than a foreign corporation that is a PFIC with respect to the relevant United States Holder for the taxable year in which the dividends are paid or for the preceding taxable year) (i) whose ordinary shares are readily tradable on an established securities market in the United States, or (ii) which is eligible for benefits under a comprehensive United States income tax treaty that includes an exchange of information program and which the United States Treasury Department has determined is satisfactory for these purposes. ADSs are expected to be readily tradable on the Nasdaq Capital Market, an established securities market. United States Holders should consult their tax advisors regarding the availability of the reduced tax rate on dividends paid with respect to ADSs. The dividends will not be eligible for the dividends received deduction available to corporations in respect of dividends received from other United States corporations.

Disposition of ADSs

Subject to the discussion below under "*Passive Foreign Investment Company,*" a United States Holder generally will recognize capital gain or loss for United States federal income tax purposes on the sale or other taxable disposition of ADSs equal to the difference, if any, between the amount realized and the United States Holder's adjusted tax basis in those ADSs. If any Israeli tax is imposed on the sale, exchange or other disposition of ADSs, a United States Holder's amount realized will include the gross amount of the proceeds of the deposits before deduction of the Israeli tax. In general, capital gains recognized by a non-corporate United States Holder, including an individual, are subject to a lower rate under current law if such United States Holder held shares for more than one year. The deductibility of capital losses is subject to limitations. Any such gain or loss generally will be treated as United States source income or loss for purposes of the foreign tax credit. A United States Holder's initial tax basis in shares generally will equal the cost of such shares. Because gain for the sale or other disposition of ADSs will be treated as United States source income, and you may use foreign tax credits against only the portion of United States federal income tax liability that is attributed to foreign source income in the same category, your ability to utilize a foreign tax credit with respect to the Israeli tax imposed on any such sale or other disposition, if any, may be significantly limited. In addition, if you are eligible for the benefit of the income tax convention between the United States and the State of Israel and pay Israeli tax in excess of the amount applicable to you under such convention or if the Israeli tax paid is refundable, you will not be able to claim any foreign tax credit or deduction with respect to such Israeli tax. You should consult your tax advisor as to whether the Israeli tax on gains may be creditable or deductible in light of your particular circumstances and your ability to apply the provisions of an applicable treaty.

If the consideration received upon the sale or other taxable disposition of ADSs is paid in foreign currency, the amount realized will be the U.S. dollar value of the payment received, translated at the spot rate of exchange on the date of taxable disposition. If ADSs are treated as traded on an established securities market, a cash basis United States Holder and an accrual basis United States Holder who has made a special election (which must be applied consistently from year to year and cannot be changed without the consent of the IRS) will determine the U.S. dollar value of the amount realized in foreign currency by translating the amount received at the spot rate of exchange on the settlement date of the sale. An accrual basis United States Holder that does not make the special election will recognize exchange gain or loss to the extent attributable to the difference between the exchange rates on the sale date and the settlement date, and such exchange gain or loss generally will constitute ordinary income or loss.

Passive Foreign Investment Company

We would be a PFIC for any taxable year if, after the application of certain look-through rules, either: (i) 75% or more of our gross income for such year is "passive income" (as defined in the relevant provisions of the Internal Revenue Code of 1986, as amended), or (ii) 50% or more of the value of our assets (determined on the basis of a quarterly average) during such year is attributable to assets that produce or are held for the production of passive income. Based on our anticipated market capitalization and the composition of our income, assets and operations, we do not expect to be a PFIC for United States federal income tax purposes for the current taxable year or in the foreseeable future. However, this is a factual determination that must be made annually after the close of each taxable year. Moreover, the value of our assets for purposes of the PFIC determination may be determined by reference to the public price of ADSs, which could fluctuate significantly. Therefore, there can be no assurance that we will not be classified as a PFIC in the future. Certain adverse United States federal income tax consequences could apply to a United States Holder if we are treated as a PFIC for any taxable year during which such United States Holder holds ADSs. Under the PFIC rules, if we were considered a PFIC at any time that a United States Holder holds ADSs, we would continue to be treated as a PFIC with respect to such holder's investment unless (i) we cease to be a PFIC, and (ii) the United States Holder has made a "deemed sale" election under the PFIC rules.

If we are a PFIC for any taxable year that a United States Holder holds ADSs, any gain recognized by the United States Holder on a sale or other disposition of ADSs would be allocated pro-rata over the United States Holder's holding period for the ADSs. The amounts allocated to the taxable year of the sale or other disposition and to any year before we became a PFIC would be taxed as ordinary income. The amount allocated to each other taxable year would be subject to tax at the highest rate in effect for individuals or the highest rate in effect for corporations, as appropriate, for that taxable year, and an interest charge would be imposed. Further, to the extent that any distribution received by a United States Holder on ADSs exceeds 125% of the average of the annual distributions on the ADSs received during the preceding three years or the United States Holder's holding period, whichever is shorter, that distribution would be subject to taxation in the same manner as gain on the sale or other disposition of ADSs if we were a PFIC, described above. Certain elections may be available that would result in alternative treatments (such as mark-to-market treatment) of the ADSs. If we are treated as a PFIC with respect to a United States Holder for any taxable year, the United States Holder will be deemed to own shares in any of our subsidiaries that also are PFICs. A timely election to treat us as a qualified electing fund under the Internal Revenue Code would result in an alternative treatment. However, we do not intend to prepare or provide the information that would enable United States Holders to make a qualified electing fund election. If we are considered a PFIC, a United States Holder also will be subject to annual information reporting requirements. United States Holders should consult their own tax adviser about the potential application of the PFIC rules to an investment in the ADSs.

Information Reporting and Backup Withholding

Dividend payments and proceeds paid from the sale or other taxable disposition of ADSs may be subject to information reporting to the IRS. In addition, a United States Holder (other than an exempt holder who establishes its exempt status if required) may be subject to backup withholding on cash payments received in connection with dividend payments and proceeds from the sale or other taxable disposition of ADSs made within the United States or through certain U.S.-related financial intermediaries.

Backup withholding will not apply, however, to a United States Holder who furnishes a correct taxpayer identification number, makes other required certification and otherwise complies with the applicable requirements of the backup withholding rules. Backup withholding is not an additional tax. Rather, any amount withheld under the backup withholding rules will be creditable or refundable against the United States Holder's United States federal income tax liability, provided the required information is timely furnished to the IRS.

Foreign Financial Asset Reporting

Certain United States Holders are required to report their holdings of certain foreign financial assets, including equity of foreign entities, if the aggregate value of all of these assets exceeds certain threshold amounts. The ADSs are expected to constitute foreign financial assets subject to these requirements unless the ADSs are held in an account at certain financial institutions. United States Holders should consult their tax advisors regarding the application of these reporting requirements.

F. Dividends and Paying Agents

Not applicable.

G. Statement by Experts

Not applicable.

H. Documents on Display

We are subject to the reporting requirements of the Exchange Act, as applicable to "foreign private issuers" as defined in Rule 3b-4 under the Exchange Act, and in accordance therewith, we file reports and other information with the SEC, including annual reports on Form 20-F and reports on Form 6-K.

As a foreign private issuer, we are exempt from certain provisions of the Exchange Act. Accordingly, our proxy solicitations is not be subject to the disclosure and procedural requirements of Regulation 14A under the Exchange Act and transactions in our equity securities by our officers and directors is exempt from reporting and the "short-swing" profit recovery provisions contained in Section 16 of the Exchange Act.

In addition, we are not required under the Exchange Act to file periodic reports and financial statements as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act.

As permitted under the Israeli Securities Law, 1968, or the ISL, we comply with the Israeli regime for dual listed companies under Chapter E3 of the ISL, which allows us to use in Israel the same periodic reports, financial and other relevant disclosure information (in English) that we submit to the SEC and Nasdaq. Copies of our filings with the Israeli Securities Authority can be retrieved electronically through the MAGNA distribution site of the ISA (www.magna.isa.gov.il) and the TASE website (www.maya.tase.co.il).

The SEC maintains an internet website that contains reports and other information regarding issuers that file electronically with the SEC. This annual report and the exhibits thereto and any other document we file pursuant to the Exchange Act may be viewed on the SEC's website atwww.sec.gov and on our website at www.itamar-medical.com. The information contained on our website is not incorporated by reference into this Annual Report.

The documents concerning our Company which are referred to in this Annual Report may also be inspected at our offices located at 9 Halamish Street, Caesarea 3088900, Israel.

I. Subsidiary Information

Not applicable.

Item 11. Quantitative and Qualitative Disclosures About Market Risk

General

Market risk is the risk of loss related to changes in market prices, including interest rates and foreign exchange rates, of financial instruments that may adversely impact our consolidated financial position, results of operations or cash flows.

We are exposed to a variety of these market risks, primarily changes in interest rates and foreign currency fluctuations. To manage the volatility related to the foreign currency exposure, we may enter from time to time into various derivative transactions. However, we do not use financial instruments for trading purposes and are not a party to any leveraged derivative.

As of December 31, 2019, we had cash and cash equivalents of approximately $15.1 million. As of such date, most of such cash and cash equivalents were held in U.S. dollars and NIS. The majority of our cash and cash equivalents are invested in banks in Israel and, to a smaller extent, in banks in the United States. The Israeli bank deposits are not insured, while the deposits made in the United States are in excess of insured limits and are not otherwise insured.

Interest Rate Risk

We are subject to market risk from exposure to changes in interest rates relating to borrowings under our bank credit line, which carries interest at a rate that is based on the LIBOR. As of March 15, 2020, we had borrowings of approximately $5.0 million under the bank credit line. Based on the scheduled amount of the borrowings expected to be outstanding under such credit line in 2020, we estimate that each 10% increase in our borrowing rates would result in additional interest expense to us of approximately $50,000.

Currently, we invest our free cash in bank deposits which are exposed to market risk due to fluctuation in interest rates, which may affect our interest, except that given the low levels of interest rates worldwide, our interest income is not material and a reduction in interest rates would not cause us a significant reduction in the absolute amounts of interest income to us. Our investment balances are comprised mainly of bank deposits. Because of their short-term nature, the carrying value of the bank deposits usually approximates their fair value.

Foreign Currency Exchange Risk

Our functional and reporting currency is the U.S. dollar. Although the U.S. dollar is our functional currency, a significant portion of our expenses are denominated in NIS and a relatively small portion of our expenses is denominated in Euros, and currently most of our revenues are denominated in U.S. dollars. Therefore, our foreign currency exposures give rise to market risk associated with exchange rate movements of the U.S. dollar, mainly against the NIS and the Euro. Our NIS and Euro expenses consist principally of payroll to our employees in Israel, payments made to subcontractors for purchasing components to our products, research and development activities and marketing and sales activities. We anticipate that a significant portion of our expenses will continue to be denominated in currencies other than the U.S. dollar. If the U.S. dollar fluctuates significantly against either the NIS or the Euro, it may have a negative impact on our results of operations. To date, fluctuations in the exchange rates have not materially affected our results of operations or financial condition.

Due to the fact that exchange rates between the U.S. dollar and the NIS (as well as between the U.S. dollar and other currencies) fluctuate continuously, such fluctuations have an impact on our results and period-to-period comparisons of our results. The effects of foreign currency remeasurements are reported in our consolidated statements of operations. In order to reduce some of this currency exposure, we keep cash balances in NIS. These measures, however, may not adequately protect us from the material adverse effects of such fluctuations.

As of December 31, 2019, we did not enter into any hedge transactions but we may do so in the future. Even if we do enter into such hedge transactions in the future, we cannot guarantee that such measures will effectively protect us from adverse effects due to the impact of fluctuations in currency exchange rates.

In addition, we have balance sheet exposure arising from assets and liabilities denominated in currencies other than the dollar, mainly in NIS and Euros. Any change of the conversion rates between the U.S. dollar and these currencies may create financial gain or loss.

The tables below provide information as of the dates indicated regarding our foreign currency-denominated monetary assets and liabilities as of December 31, 2019 (U.S. dollars in thousands).

Assets:		
New Israeli Shekels	$	1,687
Euros		1,283
Other currencies		96
Total		3,066
Liabilities:		
New Israeli Shekels		4,665
Euros		88
Total		4,753
Net liabilities	$	(1,687)

Item 12. Description of Securities Other than Equity Securities

A. Debt Securities

Not applicable.

B. Warrants and Rights

Not applicable.

C. Other Securities

Not applicable.

D. American Depositary Shares

Set forth below is a summary of certain provisions in relation to charges and other payments under the Deposit Agreement, dated February 26, 2019, among Itamar, the Bank of New York Mellon, as depositary, or Depositary, and the owners and holders from time to time of ADSs issued thereunder, or the Deposit Agreement). A summary of other provisions of the Deposit Agreement and related description of the ADSs is included in Exhibit 2.6 to this Annual Report. These summaries are not complete and are qualified in their entirety by the Deposit Agreement, a form of which has been filed as Exhibit 2.1 to this Annual Report.

Fees and Expenses

Holders of our ADSs are required to pay the following fees under the terms of the deposit agreement:

Persons depositing or withdrawing shares or ADS holders must pay:	***For:***
U.S.$5.00 (or less) per 100 ADSs (or portion of 100 ADSs)	• Issuance of ADSs, including issuances resulting from a distribution of shares or rights or other property Cancellation of ADSs for the purpose of withdrawal, including if the deposit agreement terminates
U.S.$0.05 (or less) per ADS	• Any cash distribution made to ADS holders
A fee equivalent to the fee that would be payable if securities distributed to you had been ordinary shares and the ordinary shares had been deposited for issuance of ADSs	• Distribution of securities distributed to holders of deposited securities (including rights) that are distributed by the depositary to ADS holders
Expenses of the depositary	• Cable (including SWIFT) and facsimile transmissions (when expressly provided in the deposit agreement) • converting foreign currency to U.S. dollars
Taxes and other governmental charges the depositary or the custodian has to pay on any ADSs or shares underlying ADSs, such as stock transfer taxes, stamp duty or withholding taxes Any charges incurred by the depositary or its agents for servicing the deposited securities	• As necessary

* The depositary is only entitled to reimbursement of such fees if its local custodian charges such fees. To our knowledge, the depositary's Israeli local custodians do not currently charge any such fees. However, if you hold your shares or ADSs through a bank or broker, you should check whether your bank or broker charge you any similar fees.

The depositary collects its fees for delivery and surrender of ADSs directly from investors depositing shares or surrendering ADSs for the purpose of withdrawal or from intermediaries acting for them. The depositary collects fees for making distributions to investors by deducting those fees from the amounts distributed or by selling a portion of distributable property to pay the fees. The depositary may collect its annual fee for depositary services by deduction from cash distributions or by directly billing investors or by charging the book-entry system accounts of participants acting for them. The depositary may collect any of its fees by deduction from any cash distribution payable (or by selling a portion of securities or other property distributable) to ADS holders that are obligated to pay those fees. The depositary may generally refuse to provide fee-attracting services until its fees for those services are paid.

From time to time, the depositary may make payments to us to reimburse us for costs and expenses generally arising out of establishment and maintenance of the ADS program, waive fees and expenses for services provided to us by the depositary or share revenue from the fees collected from ADS holders. In performing its duties under the deposit agreement, the depositary may use brokers, dealers, foreign currency dealers or other service providers that are owned by or affiliated with the depositary and that may earn or share fees, spreads or commissions.

The depositary may convert currency itself or through any of its affiliates and, in those cases, acts as principal for its own account and not as agent, advisor, broker or fiduciary on behalf of any other person and earns revenue, including, without limitation, transaction spreads, that it will retain for its own account. The revenue is based on, among other things, the difference between the exchange rate assigned to the currency conversion made under the deposit agreement and the rate that the depositary or its affiliate receives when buying or selling foreign currency for its own account. The depositary makes no representation that the exchange rate used or obtained in any currency conversion under the deposit agreement will be the most favorable rate that could be obtained at the time or that the method by which that rate will be determined will be the most favorable to ADS holders, subject to the depositary's obligations under the deposit agreement. The methodology used to determine exchange rates used in currency conversions is available upon request.

Payment of Taxes

Holders of our ADSs are responsible for any taxes or other governmental charges (including any penalties and/or interest) payable on their ADSs or on the deposited securities represented by any of their ADSs. All registered holders and beneficial owners of ADRs, and all prior holders and beneficial owners thereof, jointly and severally, agree to indemnify us, the depositary and our and the depositary's respective agents in respect of such taxes or other governmental charges. The depositary may refuse to register any transfer of ADSs, to effect any split up or combination of ADRs, or allow holders of our ADSs to withdraw the deposited securities represented by their ADSs until such taxes or other charges are paid. It may deduct from any distributions owed to a holder of our ADSs or sell deposited securities represented by such holder's ADSs to pay any taxes owed and such holder will remain liable for any deficiency. If the depositary sells deposited securities, it will, if appropriate, reduce the number of ADSs to reflect the sale and pay to ADS holders any proceeds, or send to ADS holders any property, remaining after it has paid the taxes.

By holding an ADR or an interest therein, holders of ADRs have agreed to indemnify us, the depositary, its custodian and any of our or their respective officers, directors, employees, agents and affiliates against, and hold each of them harmless from, any claims by any governmental authority with respect to taxes, additions to tax, penalties or interest arising out of any refund of taxes, reduced rate of withholding at source or other tax benefit obtained, which obligations shall survive any transfer or surrender of ADSs or the termination of the deposit agreement.

PART II

Item 13. Defaults, Dividend Arrearages and Delinquencies

None.

Item 14. Material Modifications to the Rights of Security Holders and Use of Proceeds

A. None.

B. None.

C. None.

D. None.

E. Use of Proceeds

In February 2020, we completed a registered public offering of our American Depositary Shares in the United States. In the public offering we issued and sold 2,927,267 ADSs, including 381,817 ADSs issued and sold upon the exercise of the underwriters pursuant to their overallotment option to purchase additional ADSs, at a public offering price of $13.75 per ADS.

The offer and sale of all of the ADSs in the public offering was registered under the Securities Act pursuant to a registration statement on Form F-1 (File No. 333- 236120), which was declared effective by the SEC on January 30, 2020, and a registration statement on Form F-1 to register additional securities (File No. 333- 236179), which was immediately effective upon filing on January 30, 2020, or, together, the Registration Statement. Under the Registration Statement, we registered 2,927,267 ADSs, including 381,817 ADSs issuable upon exercise of the underwriters' option to purchase additional ADSs, at a public offering price of $13.75 per ADS, for a registered aggregate offering price of approximately $40.25 million. Following the sale of the ADSs in connection with the closing of the public offering, the offering terminated. The offering commenced on January 30, 2020, and did not terminate until the sale of all of the shares offered. Piper Sandler acted as sole bookrunner for the offering and Ladenburg Thalmann and A.G.P./Alliance Global Partners acted as co-managers for the offering.

We received aggregate gross proceeds from the offering of approximately $40.25 million, or aggregate net proceeds of approximately $35.45 million after deducting underwriting discounts and commissions of approximately $2.8 million and offering expenses of $1.98 million. No payments for such expenses were made directly or indirectly to (i) any of our officers, members of our board of directors, or their associates, (ii) any persons owning 10% or more of any class of our equity securities or (iii) any of our affiliates.

There has been no material change in our planned use of the net proceeds from the public offering as described in our final prospectus filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act with the SEC on January 31, 2020.

Item 15. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Limitations on Effectiveness of Controls and Procedures

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a- 15(e) and 15d- 15(e) under the Exchange Act), as of the end of the period covered by this Annual Report. Based on such evaluation, our principal executive officer and principal financial officer have concluded that as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting, as such term is defined in Rule 13a-15(f) under the Exchange Act.

Our management conducted an assessment of the effectiveness of our internal control over financial reporting based on the criteria set forth in "Internal Control – Integrated Framework (2013)" issued by the Committee of Sponsoring Organizations of the Treadway Commission.

Based on this assessment, our management concluded that, as of December 31, 2019, our internal control over financial reporting was effective.

Attestation Report of the Registered Public Accounting Firm

This Annual Report does not include an attestation report of our registered public accounting firm due to an exemption established by the JOBS Act for "emerging growth companies."

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) during the period covered by this Annual Report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 16. [Reserved]

Item 16A. Audit Committee Financial Expert

Our Board of Directors has determined that Yaffa Krindel Sieradzki is an "audit committee financial expert" as defined in Item 16.A. of Form 20-F and qualifies as an "independent director" in accordance with applicable Exchange Act rules and Nasdaq rules.

Item 16B. Code of Ethics

We have adopted a Code of Ethics and Business Conduct, or the Code, that applies to all our directors, officers and employees and certain our consultants.

We have also adopted a Code of Ethics for Senior Financial Officers, or the Financial Conduct Code, that applies to our President and Chief Executive Officer, Chief Financial Officer, chief accounting officer or controller, and persons performing similar functions. The Financial Conduct Code has been posted on our website, www.itamar-medical.com.

We intend to satisfy the disclosure requirement under Item 16.B(d) and (e) of Form 20-F regarding amendment to, or waiver from, a provision of the Code or the Financial Conduct Code, as well as Nasdaq's requirement to disclose waivers with respect to directors and executive officers, by posting such information in the "Investors" section of our website at www. itamar-medical.com.

Item 16C. Principal Accounting Fees and Services

Somekh Chaikin, Certified Public Accountants (Israel), a member of KPMG International, or KPMG, has served as our independent public accountants for each of the years in the three-year period ended December 31, 2019. The following table presents the aggregate fees for professional audit services and other services rendered by KPMG in the years indicated.

	Year Ended December 31,	
	2019	2018
	(in thousands)	
Audit fees (1)	$ 172	$ 150
Audit related fees	-	-
Tax services fees (2)	23	36
All other fees	-	-
Total	$ 195	$ 186

(1) Audit fees consist of fees billed for the annual audit of the Company's consolidated financial statements and the statutory financial statements of the Company. They also include fees billed for other audit services, which are those services that only the external auditor reasonably can provide, the provision of consents and the review of documents filed with the SEC.

(2) Tax services fees include fees billed for tax compliance services, including professional services rendered for tax compliance and tax advice, other than in connection with tax audit. Tax compliance involves audit of original and amended tax returns, tax planning and tax advice.

Pre-Approval Policies and Procedures

Our Audit Committee has adopted a policy and procedures for the pre-approval of audit and non-audit services rendered by KPMG, or Policy.

Under the Policy, proposed services either (i) may be pre-approved by the Audit Committee without consideration of specific case-by-case services as general pre-approval; or (ii) require the specific pre-approval of the Audit Committee as specific pre-approval. The Audit Committee may delegate either type of pre-approval authority to one or more of its members. The appendices to the Policy set out the audit, audit-related, tax and other services that have received the general pre-approval of the audit committee, including those described in the notes to the table, above; these services are subject to annual review by the Audit Committee. All other audit, audit-related, tax and other services must receive a specific pre-approval from the Audit Committee.

The Audit Committee pre-approves fee levels annually for the audit services. Non-audit services are pre-approved as required. The Chairperson of the Audit Committee may approve non-audit services of up to $25,000 annually and then request the Audit Committee to ratify his decision.

All of the fees in the table above were approved in accordance with these policies and procedures.

Item 16D. Exemptions from the Listing Standards for Audit Committees

Not applicable.

Item 16E. Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 16F. Change in Registrant's Certifying Accountant

None.

Item 16G. Corporate Governance

As a "foreign private issuer," as defined by the SEC, we are permitted to follow home country corporate governance practices, instead of certain corporate governance practices required by Nasdaq for U.S. domestic issuers. While we follow most Nasdaq corporate governance rules, we follow Israel corporate governance practices in lieu of Nasdaq corporate governance rules as follows:

- We currently do not follow Nasdaq Rule 5620(c) regarding quorum requirements applicable to meetings of shareholders that requires that an issuer have a quorum requirement for shareholders meetings of at least one-third of the outstanding shares of the issuer's common voting stock. As permitted under the Companies Law, our Articles of Association provide that the quorum for any meeting of shareholders is $33\frac{1}{3}\%$ or more of the voting rights in the Company, similar to Nasdaq requirements, however, if the meeting is adjourned for lack of quorum, the quorum for such adjourned meeting will be two shareholders who hold or represent between them at least 10% of the issued and outstanding share capital, instead of $33\frac{1}{3}\%$ of the voting rights in the Company.

- We currently do not follow Nasdaq Rule 5635(c) that requires shareholder approval of stock option plans and other equity compensation arrangements available to officers, directors or employees and any material amendments thereto. We have decided to follow home country practice in lieu of obtaining shareholder approval for our current or future equity incentive plans. However, subject to exceptions permitted under the Companies Law, we are required to seek shareholder approval of any grants of equity incentive awards to directors, chief executive officer and controlling shareholders or plans that require shareholder approval for other reasons.

- We currently do not follow Nasdaq Rules 5635(a), 5635(b) and 5635(d) that require shareholder approval for certain dilutive events (such as issuances that will result in a change of control, certain transactions other than a public offering involving issuances of a 20% or greater interest in us and certain acquisitions of the stock or assets of another company). Instead, we intend to follow the Companies Law in respect of private placements.

- Also, we have chosen to follow our home country practice in lieu of the requirements of Nasdaq Listing Rule 5250(d)(1) relating to an issuer's furnishing of its annual report to shareholders. Specifically, we file annual reports on Form 20-F, which contain financial statements audited by an independent accounting firm, electronically with the SEC and post a copy on our website.

Although we may rely on certain home country corporate governance practices, we must comply with Nasdaq Rule 5640 Notification of Noncompliance and Rule 5640 Voting Rights. Further, we must have an audit committee that satisfies Rule 5605(c)(3), which addresses audit committee responsibilities and authority, and that consists of committee members that meet the independence requirements of Rule 5605(c)(2)(A)(ii).

We may in the future elect to follow Israel corporate governance practices in lieu of Nasdaq corporate governance rules with regard to other matters.

Item 16H. Mine Safety Disclosure

Not applicable.

PART III

Item 17. Financial Statements

We have provided financial statements pursuant to Item 18.

Item 18. Financial Statements

The audited consolidated financial statements as required under Item 18 are attached hereto starting on page F-1 of this Annual Report. The audit report of KPMG, independent registered public accounting firm, is included herein preceding the audited consolidated financial statements.

Item 19. Exhibits

Exhibit No.	Description	Incorporation by Reference				Filed/ Furnished
		Form	File No.	Exhibit No.	Date	
1.1#	Memorandum of Association of the Registrant, as amended and restated.	20-F	001-38775	1.1	12/31/2018	
1.2#	Amended and Restated Articles of Association of the Registrant.	20-F	001-38775	1.2	12/31/2018	
2.1	Form of Deposit Agreement between the Registrant, The Bank of New York Mellon as Depositary, and owners and holders from time to time of ADSs issued thereunder, including the Form of American Depositary Shares.	20-F	001-38775	2.1	12/31/2018	
2.2	Specimen of Ordinary Share Certificate.	20-F	001-38775	2.2	12/31/2018	
2.3	Closing Warrant Agreement by and between the Registrant and Viola P.E. 2 A.V. Limited Partnership, dated as of November 5, 2015.	20-F	001-38775	2.3	12/31/2018	
2.4##	Warrant Agreement by and between the Registrant and Mizrahi Tefahot Bank Ltd., or Mizrahi, dated as of May 14, 2017, as amended on July 9, 2017, and as further amended on January 29, 2018.	20-F	001-38775	2.4	12/31/2018	
2.4/A	Warrant extension agreement by and between the Registrant and Mizrahi, dated February 9, 2020.					*
2.5	Warrant Agreement by and between the Registrant and Mizrahi, dated as of February 9, 2020.					*
2.6	Description of the Rights of Each Class of Securities Registered under Section 12 of the Securities Exchange Act of 1934.					*
4.1†	2007 Israeli Share Option Plan.	F-1	333-236120	10.4	1/28/2020	

Exhibit No.	Description	Incorporation by Reference Form	File No.	Exhibit No.	Date	Filed/ Furnished
4.2†	2007 Equity Incentive Plan.	20-F	001-38775	4.2	12/31/2018	
4.3†	Israeli Equity Incentive Plan 2016.	20-F	001-38775	4.3	12/31/2018	
4.4†	2016 U.S. Equity Incentive Plan.	20-F	001-38775	4.4	12/31/2018	
4.5†	Form of Indemnification Letter.	20-F	001-38775	4.5	12/31/2018	
4.6#†	Compensation Policy for Executive Officers and Directors, as amended on March 18, 2020.	6-K	001-38775	99.1 (Appendix A to the Proxy Statement)	2/11/2020	
4.7#	Lease Agreement by and between the Registrant and The Caesarea Edmond Benjamin De Rothschild Assets Corp. (2001) Ltd., dated July 19, 2007, as amended by Amendment No. 1 on December 25, 2008, and as further amended by Amendment No. 2 in 2013, and as further amended by Amendment No. 3 on March 23, 2015, and as further amended by Amendment No. 4 on August 9, 2015, and as further amended by Amendment No. 5 on January 19, 2019.	20-F/A	001-38775	4.7	1/30/2019	
4.8+	Distribution Agreement by and between the Registrant and Philips Respironics GK, dated February 24, 2014, as amended by the Amendment to the Distribution Agreement, dated December 22, 2018.	20-F	001-38775	4.8	12/31/2018	
4.9++	Master Products and Services Agreement, by and between Kaiser Foundation Health Plan, Inc. and Itamar Medical, Inc., a wholly owned subsidiary of the Registrant, or Itamar US, dated April 1, 2019.	F-1	333-236120	10.13	1/28/2020	
4.10	Solicitation/Contract/Order for Commercial Items issued by Department of Veterans Affairs, or VA, to Itamar US, dated October 12, 2011 as amended by the Solicitation/Contract/Order for Commercial Items issued by VA to Itamar US, dated March 12, 2014, and as further amended by the Amendment of Solicitation/Modification of Contract, dated August 1, 2018, and as further amended by the Product Addition Request for Modification Form, dated September 25, 2018, and as further amended by the Amendment of Solicitation/Modification of Contract, dated October 15, 2018, and as further amended by the Amendment of Solicitation/Modification of Contract, dated December 1, 2018.	20-F/A	001-38775	4.10	2/13/2019	
4.11++	Amendments to the Solicitation/Contract/Order for Commercial Items issued by VA to Itamar US, dated August 13, 2019, September 25, 2019, and December 23, 2019.	F-1	333-236120	10.15	1/28/2020	
4.12##	Credit Framework Agreement by and between the Registrant and Mizrahi, dated February 9, 2020; the Deed of Amendment, February 9, 2020, to The Secured Debenture issued by the Registrant to Mizrahi, dated May 28, 2017; the Continuing Guarantee in an Unlimited Amount to Secure all Debts issued by Itamar US to Mizrahi, dated March 12, 2019; the Unlimited Security Agreement by and between Itamar US and Mizrahi, dated March 12, 2019					*
4.13	Form of Securities Purchase Agreements, dated March 22, 2018, by and between the Registrant and the Purchasers signatory thereto.	20-F	001-38775	4.12	12/31/2018	
4.14	Form of Securities Purchase Agreements, dated January 16, 2019, by and between the Registrant and the Purchasers signatory thereto, for the issuance of ADSs of the Registrant.	20-F/A	001-38775	4.13	1/30/2019	
4.15	Form of Securities Purchase Agreements, dated January 16, 2019, by and between the Registrant and the Purchasers signatory thereto, for the issuance of ordinary shares of the Registrant.	20-F/A	001-38775	4.14	1/30/2019	
4.16	Form of Securities Purchase Agreements, dated January 28, 2019, by and between the Registrant and the Purchasers signatory thereto, for the issuance of ADSs of the Registrant.	20-F/A	001-38775	4.15	1/30/2019	
4.17	The Secured Debenture issued by the Registrant to Mizrahi, dated May 28,	20-F	001-38775	4.11	4/10/2019	

	2017; the Negative Charge Irrevocable Undertaking issued by I.M.E. 2016 B.V. to Mizrahi, dated May 29, 2017.				
4.18	Lease Agreement, dated July 8, 2019, by and between the Registrant and Willer Properties (1985) Ltd.	F-1	333-236120	10.11	1/28/2020
8.1	List of Subsidiaries.	20-F	001-38775	8	12/31/2018

Exhibit No.	Description	Incorporation by Reference Form	File No.	Exhibit No.	Date	Filed/ Furnished
12.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.					*
12.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.					*
13.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350					**
13.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350					**
15.1	Consent of Somekh Chaikin, Certified Public Accountants (Israel), a member of KPMG International.					*
101.INS	XBRL Instance Document.					*
101.SCH	XBRL Taxonomy Extension Schema Document.					*
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.					*
101.DEF	XBRL Taxonomy Definition Linkbase Document.					*
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.					*
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document					*

*	Filed herewith.
**	Furnished herewith.
#	Unofficial English translation from Hebrew original.
##	Certain parts, as indicated therein, contain unofficial English translation from Hebrew original.
+	Confidential treatment has been granted with respect to certain portions of this exhibit pursuant to 17.C.F.R. §240.24b-2. Omitted portions were filed separately with the SEC.
++	Portions of this exhibit have been redacted in compliance with Regulation S-K Item 601(b)(10)(iv).
†	Indicates management contract or compensatory plan or arrangement.

Certain agreements filed as exhibits to this Annual Report contain representations and warranties that the parties thereto made to each other. These representations and warranties have been made solely for the benefit of the other parties to such agreements and may have been qualified by certain information that has been disclosed to the other parties to such agreements and that may not be reflected in such agreements. In addition, these representations and warranties may be intended as a way of allocating risks among parties if the statements contained therein prove to be incorrect, rather than as actual statements of fact. Accordingly, there can be no reliance on any such representations and warranties as characterizations of the actual state of facts. Moreover, information concerning the subject matter of any such representations and warranties may have changed since the date of such agreements.

SIGNATURES

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this Annual Report on its behalf.

Itamar Medical Ltd.

Date: April 3, 2020

By: /s/ Gilad Glick
Name: Gilad Glick
Title: Chief Executive Officer

ITAMAR MEDICAL LTD.

CONSOLIDATED FINANCIAL STATEMENTS

AS OF DECEMBER 31, 2019

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Report of Independent Registered Public Accounting Firm

To the Shareholders and Board of Directors
Itamar Medical Ltd.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated statements of financial position of Itamar Medical Ltd. and its subsidiaries (the "Company") as of December 31, 2019 and 2018, and the related consolidated statements of operations, comprehensive income (loss), changes in equity, and cash flows, for each of the years in the three-year period ended December 31, 2019, and the related notes (collectively, the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2019, in conformity with International Financial Reporting Standards, as issued by the International Accounting Standards Board.

Change in Accounting Principle

As discussed in Note 2g to the consolidated financial statements, the Company has changed its method of accounting for leases as of January 1, 2019 due to the adoption of International Financial Reporting Standards 16, *Leases*.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Somekh Chaikin

Certified Public Accountants (Isr.)
Member firm of KPMG International

We have served as the Company's auditor since 1997.
Tel-Aviv, Israel, March 30, 2020

ITAMAR MEDICAL LTD.
CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

	Note	December 31, 2019	December 31, 2018*
		U.S. dollars in thousands	
Assets			
Current assets			
Cash and cash equivalents		$ 15,115	$ 6,471
Trade receivables	3	8,384	6,549
Other receivables	3	1,404	1,018
Inventories	4	3,363	2,235
Total current assets		28,266	16,273
Non-current assets			
Long-term restricted deposits and prepaid expenses		476	365
Long-term trade receivables	3	156	243
Property and equipment	5	1,472	1,213
Intangible assets	6	395	298
Right-of-use assets	7	2,442	-
Total non-current assets		4,941	2,119
Total assets		$ 33,207	$ 18,392
Liabilities			
Current liabilities			
Short-term bank loan	8a	$ 5,000	$ 5,000
Current maturities of lease liabilities	7	890	-
Trade payables		2,028	1,517
Other accounts payable	9	3,455	2,063
Accrued expenses		1,317	1,034
Provisions	10	273	215
Short-term employee benefits	11	352	222
Total current liabilities		13,315	10,051
Non-current liabilities			
Lease liabilities, net of current maturities	7	1,708	-
Derivative instruments	12	-	442
Recognized liability for defined benefit plan, net	11	260	159
Other long-term liabilities	13	1,260	1,052
Total non-current liabilities		3,228	1,653
Total liabilities		16,543	11,704
Equity	15		
Ordinary share capital		878	748
Additional paid-in capital		125,435	111,486
Accumulated deficit		(109,649)	(105,546)
Total equity		16,664	6,688
Total liabilities and equity		$ 33,207	$ 18,392

* See Note 2g regarding initial application of IFRS 16, *Leases*. According to the transitional method that was chosen, comparative data was not restated.

The accompanying notes are an integral part of these consolidated financial statements.

ITAMAR MEDICAL LTD.
CONSOLIDATED STATEMENTS OF OPERATIONS

	Note	Year Ended December 31,		
		2019	2018*	2017*
		U.S. dollars in thousands (except per share data)		
Revenues	17	$ 31,258	$ 24,189	$ 20,701
Cost of revenues	18	6,984	5,726	5,002
Gross profit		24,274	18,463	15,699
Operating expenses:				
Selling and marketing		18,294	12,699	12,140
Research and development		4,520	3,638	4,129
General and administrative		6,354	5,247	5,278
Total operating expenses		29,168	21,584	21,547
Operating loss		(4,894)	(3,121)	(5,848)
Financial income (expenses):				
Financial income from cash, bank deposits and investments	19	454	244	1,591
Financial expenses from leases, notes, loans and other	19	(1,233)	(1,161)	(4,884)
Gain from derivatives instruments, net	19	442	2,433	3,925
Financial income (expenses), net		(337)	1,516	632
Loss before taxes on income		(5,231)	(1,605)	(5,216)
Taxes on income	14	(37)	(124)	(85)
Net loss		$ (5,268)	$ (1,729)	$ (5,301)
Loss per share (in U.S. dollars):	20			
Basic		$ (0.02)	$ (0.01)	$ (0.02)
Diluted		$ (0.02)	$ (0.01)	$ (0.02)

* See Note 2g regarding initial application of IFRS 16, *Leases*. According to the transitional method that was chosen, comparative data was not restated.

The accompanying notes are an integral part of these consolidated financial statements.

ITAMAR MEDICAL LTD.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

	Note	Year Ended December 31,		
		2019	2018*	2017*
		U.S. dollars in thousands		
Net loss		$ (5,268)	$ (1,729)	$ (5,301)
Other comprehensive income (loss) items that will not be carried to the statements of operations				
Actuarial gains (losses) of defined benefit plan, net of tax	11	(94)	166	(112)
Total other comprehensive income (loss) for the year that will not be carried to the statements of operations, net of tax		(94)	166	(112)
Other comprehensive income (loss) items that after preliminary recognition in comprehensive income (loss), were or will be carried to the statements of operations				
Net change in fair value of marketable securities available-for-sale, net of tax		-	-	158
Net change in fair value of marketable securities through other comprehensive income (loss), net of tax that was transferred to the statements of operations		-	(113)	-
Total other comprehensive income (loss) items that after preliminary recognition in comprehensive income, were or will be carried to the statements of operations, net of tax		-	(113)	158
Total other comprehensive income (loss)		(94)	53	46
Total comprehensive loss		$ (5,362)	$ (1,676)	$ (5,255)

* See Note 2g regarding initial application of IFRS 16, *Leases*. According to the transitional method that was chosen, comparative data was not restated.

The accompanying notes are an integral part of these consolidated financial statements.

ITAMAR MEDICAL LTD.
CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

	Ordinary share capital	Additional paid-in capital	Capital reserve from marketable securities available-for-sale	Accumulated deficit	Total
	U.S. dollars in thousands				
For the year ended December 31, 2017					
Balance as of January 1, 2017	$ 679	$ 105,492	$ (45)	$ (100,885)	$ 5,241
Total comprehensive loss:					
Net loss	-	-	-	(5,301)	(5,301)
Other comprehensive income, net of tax	-	-	158	(112)	46
Total comprehensive loss	-	-	158	(5,413)	(5,255)
Transactions carried directly to equity:					
Issuance of shares due to the exercise of stock options	4	93	-	-	97
Share-based payment	-	-	-	1,294	1,294
Balance as of December 31, 2017	$ 683	$ 105,585	$ 113	$ (105,004)	$ 1,377
For the year ended December 31, 2018					
Balance as of January 1, 2018	$ 683	$ 105,585	$ 113	$ (105,004)	$ 1,377
Total comprehensive loss:					
Net loss	-	-	-	(1,729)	(1,729)
Other comprehensive income, net of tax	-	-	(113)	166	53
Total comprehensive loss	-	-	(113)	(1,563)	(1,676)
Transactions carried directly to equity:					
Issuance of shares due to the exercise of stock options	3	77	-	-	80
Issuance of shares, net of issuance costs in the amount of $103 thousand	62	5,739	-	-	5,801
Share-based payment	-	-	-	1,021	1,021
Capital reserve from transactions with shareholders	-	85	-	-	85
Balance as of December 31, 2018	$ 748	$ 111,486	$ -	$ (105,546)	$ 6,688
For the year ended December 31, 2019					
Balance as of January 1, 2019	$ 748	$ 111,486	$ -	$ (105,546)	$ 6,688
Total comprehensive loss:					
Net loss	-	-	-	(5,268)	(5,268)
Other comprehensive loss, net of tax	-	-	-	(94)	(94)
Total comprehensive loss	-	-	-	(5,362)	(5,362)
Transactions carried directly to equity:					
Issuance of shares due to the exercise of stock options	4	109	-	-	113
Issuance of shares, net of issuance costs in the amount of $714 thousands	126	13,840	-	-	13,966
Share-based payment	-	-	-	1,259	1,259
Balance as of December 31, 2019	$ 878	$ 125,435	$ -	$ (109,649)	$ 16,664

The accompanying notes are an integral part of these consolidated financial statements.

ITAMAR MEDICAL LTD.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,		
	2019	**2018***	**2017***
	U.S. dollars in thousands		
Cash flows from operating activities:			
Net loss	$ (5,268)	$ (1,729)	$ (5,301)
Adjustments for:			
Depreciation and amortization	1,446	481	509
Share-based payment	1,259	1,021	1,294
Capital gain from sale of property and equipment	-	-	(8)
Change in provision for doubtful and bad debt	349	104	147
Net financial cost	490	914	3,133
Gain from reevaluation of derivatives	(442)	(2,433)	(3,925)
Increase in trade receivables	(2,097)	(1,061)	(833)
Decrease (increase) in other accounts receivable	(410)	(330)	169
Increase in inventories	(1,579)	(340)	(711)
Increase (decrease) in trade payables	537	237	(66)
Increase in other accounts payable and accrued expenses	1,650	61	669
Increase in provisions	58	32	16
Increase in employee benefits	137	14	67
Income tax expenses	37	124	85
Taxes paid during the year	(22)	(176)	(83)
Net interest paid during the year	(377)	(802)	(1,344)
Net cash used in operating activities	(4,232)	(3,883)	(6,182)
Cash flows from investing activities:			
Sale of marketable securities	-	3,109	-
Purchase of property and equipment, intangible assets and capitalization of development expenditure	(547)	(310)	(296)
Investment in restricted long-term deposits	(68)	-	(22)
Net cash provided by (used in) investing activities	(615)	2,799	(318)
Cash flows from financing activities:			
Proceeds from issuance of shares and warrants, net of issuance costs	13,966	5,209	-
Short-term bank loan	-	5,000	-
Payment of principal of lease liabilities	(787)	-	-
Repayment of convertible notes	-	(9,939)	(10,421)
Repayment of shareholders' loans	-	(435)	-
Issuance of shares due to the exercise of stock options	113	80	97
Net cash provided by (used in) financing activities	13,292	(85)	(10,324)
Increase (decrease) in cash and cash equivalents	8,445	(1,169)	(16,824)
Cash and cash equivalents at beginning of year	6,471	7,643	23,358
Effect of exchange rate fluctuations on balances of cash and cash equivalents	199	(3)	1,109
Cash and cash equivalents at end of year	$ 15,115	$ 6,471	$ 7,643
Non-cash financing activity – conversion of notes to loans from shareholders and to shares	$ -	$ 1,076	$ -

* See Note 2g regarding initial application of IFRS 16, *Leases*. According to the transitional method that was chosen, comparative data was not restated.

The accompanying notes are an integral part of these consolidated financial statements.

NOTE 1 – GENERAL

a. Reporting Entity

Itamar Medical Ltd. (the "Company") is a company incorporated in Israel, with registered office at 9 Halamish Street, North Industrial Zone, Caesarea, Israel. The consolidated financial statements of the Company and its subsidiaries as of December 31, 2019 and 2018 and for each of the three years in the period ended December 31, 2019 comprise the Company and its subsidiaries (together referred to as the "Group"). The Company is a medical technology company focused on the development and commercialization of non-invasive medical devices and solutions to aid in the diagnosis of respiratory sleep disorders. The Company uses a digital healthcare platform to facilitate the continuum of care for effective sleep apnea management with a focus on the core sleep, cardiology and direct to consumer ("DTC") markets. The Company offers a Total Sleep Solution ("TSS"), to help physicians provide comprehensive sleep apnea management in a variety of clinical environments to optimize patient care and reduce healthcare system costs. In addition, the Company has recently begun offering its WatchPAT™ family of products and certain components of TSS to the DTC market. The ordinary shares of the Company are listed on the Tel Aviv Stock Exchange Ltd. ("TASE"). On February 27, 2019, the Company's American Depositary Shares ("ADSs"), each of which represents 30 ordinary shares of the Company, represented by American Depositary Receipts ("ADRs"), were registered for trade on the Nasdaq Capital Market.

b. 2020 Public Offering

On February 4, 2020, the Company completed a public offering of 2,927,267 ADSs, which included the full exercise of the underwriters' option to purchase 381,817 additional ADSs, at a public offering price of $13.75 per ADS, for total gross proceeds of approximately $40.25 million, before deducting underwriting discounts and commissions of 7% and estimated offering expenses of approximately $2.0 million payable by the Company.

NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES

The accounting policies set out below have been consistently applied for all years presented in these consolidated financial statements, except for the new accounting standards and amendments to accounting standards, that the Group adopted commencing January 1, 2019, as described below:

a. International financial reporting standards

These consolidated financial statements have been prepared in accordance with International Financial Reporting Standards ("IFRS"), as issued by the International Accounting Standards Board ("IASB").

These consolidated financial statements were approved by the Company's Board of Directors on March 30, 2020.

b. Reporting and functional currency

These consolidated financial statements are presented in U.S. dollars ("dollar" or "$"), which is the Company's functional currency representing the principal economic environment in which the Company operates and have been rounded to the nearest thousand unless otherwise indicated.

c. Basis of measurement

These consolidated financial statements have been prepared on the historical cost basis, except for certain investments and derivatives and other financial instruments measured at fair value through profit or loss, provisions, and assets and liabilities with respect to employee benefits.

d. Principles of consolidation

Subsidiaries are entities controlled by the Company. The financial statements of the subsidiaries, which are wholly owned, are included in the consolidated financial statements of the Company from the date of their incorporation. Intercompany balances and transactions between Group companies are eliminated in consolidation.

e. Use of estimates and critical assumptions

The preparation of financial statements in accordance with IFRS requires management to make estimates and assumptions that affect reported amounts of assets and liabilities, and the disclosure of contingent assets and liabilities at the date of the financial statements as well as affect the reported amounts of revenues and expenses during the period. These estimates and assumptions are reviewed on an ongoing basis using available information. Actual results could differ from these estimates and assumptions. The items subject to significant estimates and assumptions by management include share-based compensation (see Note 16), the discount rate for lease liabilities (see g. below), the measurement of financial instruments at fair value, the fair value of the embedded warrant component of convertible notes, and the fair value of warrants where there is no active market (see Note 12).

f. Foreign currency transactions and balances

Transactions in foreign currency are translated to the respective functional currency of the Group entities at exchange rates as of the transaction dates.

Monetary assets and liabilities denominated in foreign currencies at the reporting date are translated to the functional currency at the exchange rate at that date. The foreign currency gain or loss on monetary items is the difference between the amortized cost in the functional currency at the beginning of the year, adjusted for effective interest and payments during the year, and the amortized cost in foreign currency, translated at the exchange rate at the end of the year. Non-monetary assets and liabilities denominated in foreign currency that are measured in terms of historical cost, are translated using the exchange rate at the date of the transaction.

Foreign currency differences arising from translation into the functional currency are recognized in the statements of operations.

g. Changes in accounting policies - initial application of new standards and interpretations

IFRS 16, *Leases* ("IFRS 16")

As of January 1, 2019 (the "date of initial application"), the Group applied IFRS 16, which replaced IAS 17, *Leases*.

The main effect of the application of IFRS 16 is expressed by eliminating the existing requirement for lessees to classify the lease as operating (off-balance sheet) or as finance lease, and to present a uniform model for lessees to account for all leases in a similar manner to the accounting treatment of finance leases in accordance with IAS 17. Through the date of initial application of IFRS 16, the Group has classified most of the leases in which it leases as operating leases, as it has not materially borne all the risks and returns from the assets.

In accordance with IFRS 16, for agreements in which the Group is the lessee, the Group recognizes a right-of-use asset and a lease liability at the inception of the lease contract for all the leases in which the Group has a right to control identified assets for a specified period of time, other than exceptions specified in IFRS 16. Accordingly, the Group recognizes depreciation and amortization expenses in respect of a right-of-use asset, tests a right-of-use asset for impairment in accordance with IAS 36, *Impairment of Assets*, and recognizes financial expenses on a lease liability. Therefore, from the date of initial application, lease payments relating to assets leased under an operating lease, which were presented in operating expenses in the statement of operations, are capitalized to assets and the depreciation expenses related to those assets are presented as depreciation and amortization expenses.

The Group elected to apply IFRS 16 using the modified retrospective approach, with an adjustment to the balance of retained earnings as at January 1, 2019 and without restating comparative data. In respect of all the leases, the Group elected to apply the transitional provisions such that on the date of initial application, it recognized a liability at the present value of the balance of future lease payments discounted at its incremental borrowing rate at that date calculated according to the average duration of the remaining lease period as from the date of initial application, and concurrently recognized a right-of-use asset at the same amount of the liability, adjusted for any prepaid or accrued lease payments that were recognized as an asset or liability before the date of initial application. Therefore, application of IFRS 16 had no effect on the Group's equity at the date of initial application.

Furthermore, as part of the initial application of IFRS 16, the Group elected to adopt the following expedients:

(1) Applying the practical expedient regarding the recognition and measurement of leases where the underlying asset has a low value on an individual lease basis;

(2) Applying a single discount rate for lease contracts having similar characteristics in a reasonable manner;

(3) Applying the practical expedient regarding the recognition and measurement of short-term leases, for both leases that end within 12 months from the date of initial application and leases for a period of up to 12 months from the date of their inception for all groups of underlying assets to which the right-of-use relates; and

(4) Excluding initial direct costs from the measurement of the right-of-use asset at the date of initial application.

As a result of the application of IFRS 16, in respect of operating leases under IAS 17, the Group recognized the right-of-use assets and lease liabilities for leases as of January 1, 2019 in the amount of approximately $1,149 thousand. The range of nominal discount rates used for measuring lease liabilities ranges from 8.5% - 11.5% in respect of NIS-denominated leases to 5.3% in respect of dollar-denominated leases. This range is affected by differences in the length of the lease period, differences in the various asset groups, and a change between the discount rates of the Group companies.

The impact of IFRS 16 implementation for the reported year:

As a result of the implementation of IFRS 16, in connection with leases classified as operating leases under IAS 17, the Group recognized the right-of-use assets and lease liabilities as of December 31, 2019 in the amount of $2,442 thousand and $2,598 thousand, respectively, see Note 7. In addition, instead of recognition of rental expenses relating to such leases for the year ended December 31, 2019, the Group recognized additional depreciation expenses of $830 thousand and additional financial expenses of $279 thousand.

h. Cash and Cash Equivalents

Cash and cash equivalents are comprised of available amounts of cash and cash equivalents, mainly represented by highly-liquid short-term investments (with original maturities of three months or less), which are readily convertible into known amounts of cash, and which are not subject to significant risks of changes in their values.

i. Financial instruments:

The accounting policy applied as from January 1, 2018

As from January 1, 2018, the Group applies the following accounting policies under IFRS 9 (2014), *Financial Instruments* ("IFRS 9").

Non-derivative financial assets

Initial recognition and measurement of financial assets

The Group initially recognizes trade receivables and debt instruments issued on the date that they are created. All other financial assets are recognized initially on the trade date at which the Group becomes a party to the contractual provisions of the instrument. A financial asset is initially measured at fair value plus transaction costs that are directly attributable to the acquisition or issuance of the financial asset. A trade receivable without a significant financing component is initially measured at the transaction price. Receivables originating from contract assets are initially measured at the carrying amount of the contract assets on the date classification was changed from contract asset to receivables.

Derecognition of financial assets

Financial assets are derecognized when the contractual rights of the Group to the cash flows from the asset expire, or the Group transfers the rights to receive the contractual cash flows on the financial asset in a transaction in which substantially all the risks and rewards of ownership of the financial asset are transferred. When the Group retains substantially all of the risks and rewards of ownership of the financial asset, it continues to recognize the financial asset.

Classification of financial assets into categories and the accounting treatment of each category

Financial assets are classified at initial recognition, based on the business model objectives and nature of the investment: amortized cost; fair value through other comprehensive income (loss) – investment in equity instruments; or fair value through profit and loss.

Financial assets are not reclassified in subsequent periods unless, and only if, the Group changes its business model for the management of financial debt assets, in which case the affected financial debt assets are reclassified at the beginning of the period following the change in the business model.

A financial asset (including debt instrument) is measured at amortized cost if it meets both of the following conditions and is not designated at fair value through profit or loss:

- it is held within a business model whose objective is to hold assets so as to collect contractual cash flows; and

- the contractual terms of the financial asset give rise to cash flows representing solely payments of principal and interest ("SPPI") on the principal amount outstanding on specified dates.

A debt instrument can also be classified to fair value through other comprehensive income category if its business model objective is achieved by both collecting contractual cash flows and selling financial assets, and it meets the SPPI criteria as above. In certain cases, a debt instrument can be designated at initial acquisition to fair value through profit or loss.

As applicable to the Group, the Group's debt instruments that are classified to amortized cost category include: deposits, trade and other accounts receivable (including long-term trade receivables). These assets are subsequently measured at amortized cost using the effective interest method. The amortized cost is reduced by impairment losses. Interest income, foreign exchange gains and losses and impairment are recognized in profit or loss. Any gain or loss on derecognition is recognized in profit or loss. The Group's debt instruments that were classified at fair value through other comprehensive income include debt marketable securities. These securities were realized in the beginning of 2018.

The Group classifies its financial assets to fair value through profit and loss category, when:

- it is a debt instrument that does not meet the above criteria;

- it is an investment at fair value through other comprehensive income (loss) in equity securities; or

- it is part of a portfolio of financial assets that are held for trading or are managed and whose performance is evaluated on a fair value basis.

These assets are subsequently measured at fair value. As of December 31, 2019 and 2018, the Group did not have such assets.

Financial assets are not reclassified in subsequent periods unless, and only if, the Group changes its business model for the management of financial debt assets, in which case the affected financial debt assets are reclassified at the beginning of the period following the change in the business model.

Impairment of financial assets

IFRS 9 replaces the impairment model of IAS 39 ("incurred loss" model), with an 'expected credit loss' ("ECL") model. The model applies to financial assets measured at amortized cost, investments in debt instruments measured at fair value through other comprehensive income, contract assets (as defined in IFRS 15) and lease receivables, but not to investments in equity instruments.

Under the new model, the Group assesses the expected credit losses in advance as follows:

- for debt instruments that have low credit risk or for which no significant deterioration has occurred in their credit quality since initial recognition, the impairment loss will be assessed based on the expected credit loss in the period during the 12 months following the reporting date; and

- for debt instruments for which a significant deterioration has occurred in their credit quality since initial recognition and their credit risk is not low, the impairment loss will be assessed based on the remaining life of the instrument.

The Group applies the IFRS 9 simplified approach to measuring expected credit losses which uses a lifetime expected loss allowance for all trade receivables and contract assets.

Non-derivative financial liabilities

Non-derivative financial liabilities include loans and borrowings from banks and others, convertible notes, and trade and other payables.

Initial recognition of financial liabilities

The Group initially recognizes debt securities issued on the date that they originated. All other financial liabilities are recognized initially on the trade date at which the Group becomes a party to the contractual provisions of the instrument. Liabilities, which are convertible into shares, denominated in a currency different than the functional currency of the Company or linked to the Israeli Consumer Price Index (the "Israeli CPI"), constitute a hybrid instrument presented in full as a financial liability. For measurement, the instrument is separated into two components: (i) a liability component with no conversion feature, which is classified to amortized cost category, and (ii) a conversion option, which constitutes an embedded derivative accounted for as a derivative financial instrument at fair value and is measured through the statements of operations as part of "Financial income (expenses), net".

Subsequent measurement of financial liabilities

Financial liabilities (other than financial liabilities at fair value through profit or loss) and the liability component of the hybrid instrument above are recognized initially at fair value, less any directly attributable transaction costs. Subsequent to initial recognition these financial liabilities are measured at amortized cost using the effective interest method. Financial liabilities are designated at fair value through profit or loss, if the Group manages such liabilities and their performance is assessed based on their fair value in accordance with the Group's documented risk management strategy, providing that the designation is intended to prevent an accounting mismatch, or the liability is a combined instrument including an embedded derivative.

Derecognition of financial liabilities

Financial liabilities are derecognized when the obligation of the Group, as specified in the agreement, expires or when it is discharged or cancelled.

Substantial modification in terms of debt instruments

An exchange of debt instruments having substantially different terms, is accounted for as an extinguishment of the original financial liability and the recognition of a new financial liability. Furthermore, a substantial modification of the terms of an existing financial liability, or an exchange of debt instruments having substantially different terms between an existing borrower and lender, are accounted for as an extinguishment of the original financial liability and the recognition of a new financial liability at fair value.

In such cases, the entire difference between the amortized cost of the original financial liability and the fair value of the new financial liability is recognized in profit or loss as financial income or expense.

The terms are substantially different if the discounted present value of the cash flows according to the new terms, including any commissions paid, less any commissions received and discounted using the original effective interest rate, is different by at least ten percent from the discounted present value of the remaining cash flows of the original financial liability.

Upon the swap of debt instruments with equity instruments, equity instruments issued at the extinguishment and de-recognition of all or part of a liability, are a part of “consideration paid” for purposes of calculating the gain or loss from de-recognition of the financial liability.

The equity instruments are initially recognized at fair value, unless fair value cannot be reliably measured, in which case the issued instruments are measured at the fair value of the derecognized liability. Any difference between the amortized cost of the financial liability and the initial measurement amount of the equity instruments is recognized in profit or loss under financial income or expenses.

Non-substantial modification in terms of debt instruments

In a non-substantial modification in terms (or exchange) of debt instruments, the new cash flows are discounted using the original effective interest rate, and the difference between the present value of the new financial liability and the present value of the original financial liability is recognized in profit or loss.

Offset of financial instruments

Financial assets and liabilities are offset and the net amount presented in the statement of financial position when, and only when, the Group currently has a legal right to offset the amounts and intends either to settle on a net basis or to realize the asset and settle the liability simultaneously.

Issuance of bundle of securities

The consideration received from the issuance of a bundle of securities is attributed initially to financial liabilities measured each period at fair value, and then to financial liabilities measured only upon initial recognition at fair value. The remaining amount is the value of the equity component. Direct issuance costs are attributed to the specific securities in respect of which they were incurred, whereas joint issuance costs are attributed to the securities on a proportionate basis according to the grant of the consideration from the issuance of the bundle, as described above.

Derivative financial instruments

The Group recognizes all derivative instruments as assets or liabilities in the statements of financial position at their estimated fair values, and the changes in such fair values are recognized in the statements of operations within “Financial income (expenses), net” for the period in which they occur. During the reported years, the Group did not have derivatives designated as hedges. The Group reviews its contracts to identify the existence of embedded derivatives. Identified embedded derivatives in hybrid contracts where the host is not an asset, are analyzed to determine if they need to be separated from the host contract and recognized in the statements of financial position as assets or liabilities, applying the same valuation rules used for other derivative instruments.

Fair value measurements

Under IFRS, fair value represents an "Exit Value", which is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date, considering the counterparty's credit risk in the valuation. The concept of Exit Value is premised on the existence of a market and market participants for the specific asset or liability. When there is no market and/or market participants willing to make a market, IFRS establishes a fair value hierarchy that gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to measurements involving significant unobservable inputs (Level 3 measurements).

The three levels of the fair value hierarchy are as follows:

Level 1 — Quoted prices (unadjusted) in active markets for identical assets or liabilities that the Group has the ability to access at the measurement date. A quote price in an active market provides the most reliable evidence of fair value and is used without adjustment to measure fair value whenever available.

Level 2 — Inputs, other than quoted prices in active markets, that are observable for the asset or liability, either directly or indirectly, and are used mainly to determine the fair value of securities, investments or loans that are not actively traded.

Level 3 — Unobservable inputs for the asset or liability are used when little or no market data is available. The Group used unobservable inputs to determine fair values, to the extent there are no Level 1 or Level 2 inputs, in valuation models such as Black-Scholes, binomial, discounted cash flows or multiples, including risk assumptions consistent with what market participants would use to arrive at fair value.

The accounting policy applied in periods prior to January 1, 2018

Trade accounts receivable and other accounts receivable

Trade accounts receivable and other accounts receivable are classified as loans and receivables and are recorded at their amortized cost representing the net present value of the consideration receivable or payable as of the transaction date.

Due to their short-term nature, the Group initially recognizes these receivables at the original invoiced amount. Allowances for doubtful accounts are recognized, based on incurred loss estimates against general and administrative expenses.

Long-term trade receivables and other investments

Long-term trade receivables are initially recognized at their amortized cost. Subsequent changes in net present value are recognized in the statements of operations as part of "Financial income (expenses), net".

Investments in financial instruments held for trading as well as those investments available-for-sale, are recognized at their estimated fair value, in the first case through the statements of operations as part of "Financial income (expenses), net" and in the second case, changes in valuations are recognized as part of "Other comprehensive income (loss)" for the year within "Capital reserve" until their time of disposition, when all valuation effects accrued in equity are reclassified to "Financial income (expenses), net" in the statements of operations. These investments are tested for impairment upon the occurrence of a significant adverse change or at least once a year during the last quarter.

Debt and other financial obligations

Bank loans and notes payable, are recognized at their amortized cost. Interest accrued on financial instruments is recognized within "Other accounts payable and accrued expenses" against financial expenses. Direct costs incurred in debt issuances or borrowings, adjust the carrying amount of the related debt and are amortized as interest expense as part of the effective interest rate of each instrument over its maturity. These costs include commissions and professional fees.

In the statements of cash flows, interest received and interest paid on bank loans and notes payable are presented in cash flows from operating activities.

Liabilities, which are convertible into shares, denominated in a currency different than the functional currency of the Company or linked to the Israeli CPI, constitute a hybrid instrument presented in full as a financial liability. For measurement, the instrument is separated into two components: (i) a liability component with no conversion feature, which is measured at amortized cost according to the effective interest method, and (ii) a conversion option, which constitutes an embedded derivative accounted for as a derivative financial instrument at fair value and is measured through the statements of operations as part of "Financial income (expenses), net".

Issuance of bundle of securities

The consideration received from the issuance of a bundle of securities is attributed initially to financial liabilities measured each period at fair value, and then to financial liabilities measured only upon initial recognition at fair value. The remaining amount is the value of the equity component. Direct issuance costs are attributed to the specific securities in respect of which they were incurred, whereas joint issuance costs are attributed to the securities on a proportionate basis according to the grant of the consideration from the issuance of the bundle, as described above.

Derivative financial instruments

The Group recognizes all derivative instruments as assets or liabilities in the statements of financial position at their estimated fair values, and the changes in such fair values are recognized in the statements of operations within "Financial income (expenses), net" for the period in which they occur. During the reported years, the Group did not have derivatives designated as hedges. The Group reviews its contracts to identify the existence of embedded derivatives. Identified embedded derivatives are analyzed to determine if they need to be separated from the host contract and recognized in the statements of financial position as assets or liabilities, applying the same valuation rules used for other derivative instruments.

j. Inventories

Inventories are valued using the lower of cost and net realizable value. The cost of inventories is based on the "moving-average" method, including expenditures incurred in acquiring the inventories and the costs incurred in bringing it to its existing location and condition. The Group analyzes its inventory balances to determine if, as a result of internal events, such as physical damage, or external events, such as technological changes or market conditions, certain portions of such balances have become obsolete or impaired. When an impairment situation arises, the inventory balance is adjusted to its net realizable value, whereas, if an obsolescence situation occurs, the inventory obsolescence reserve is increased. In both cases, these adjustments are recognized against the results of the period. Net realizable value is the estimated selling price in the ordinary course of business, less the estimated costs to complete and sell the inventories.

k. Property and equipment

Property and equipment are recognized at their acquisition or construction cost, as applicable, less accumulated depreciation and accumulated impairment losses. Depreciation of property and equipment is recognized as part of operating expenses, and is calculated using the straight-line method over the estimated useful lives of the assets. As of December 31, 2019, the average useful lives by category of property and equipment were as follows:

	%
Office furniture and equipment	10
Equipment and devices for leasing and for internal use	15
Computers	33

Leasehold improvements are amortized over the shorter of the lease term and their useful lives.

Depreciation methods and useful lives are reviewed at the end of each reporting year and adjusted if appropriate.

l. Intangible assets

The Group capitalizes intangible assets acquired, as well as costs incurred in the development of certain intangible assets for internal use, when future economic benefits associated are identified and there is evidence of control over such benefits.

Intangible assets are recognized at their acquisition or development cost, as applicable. All of the Group's intangible assets are definite life intangible assets, and are amortized on straight-line basis over the useful life of the asset, which on average is approximately three years.

Expenditure on research activities undertaken with the prospect of gaining new scientific or technical knowledge and understanding, are recognized in the statements of operations when incurred. Development activities are related to a plan to produce new products or processes, or to significantly improve existing products or processes. Development expenditure is capitalized only if: (i) the expenditure can be measured reliably; (ii) the product or process is technically and commercially feasible; and (iii) future economic benefits are probable, and the Group intends to and has sufficient resources to complete development and to use or sell the asset. The expenditure capitalized in respect of development activities includes the cost of materials, direct labor and overhead costs that are directly attributable to preparing the asset for its intended use. Other development expenditure is recognized in the statements of operations as incurred.

In subsequent periods, capitalized development expenditure is measured at cost less accumulated amortization and any accumulated impairment losses.

Amortization methods and useful lives are reviewed at the end of each reporting year and adjusted if appropriate.

m. Impairment of property and equipment, intangible assets of definite life, right-of use assets and other investments

These assets are tested for impairment upon the occurrence of factors such as the occurrence of a significant adverse event, changes in the Group's operating environment or in technology, as well as expectations of lower operating results, in order to determine whether their carrying amounts may not be recovered. An impairment loss is recorded in the statements of operations for the period within "Other expenses, net", for the excess of the asset's carrying amount over its recoverable amount, corresponding to the higher of the fair value less costs to sell the asset, and the asset's value in use, the latter represented by the net present value of estimated cash flows related to the use and eventual disposal of the asset.

No impairment loss was recorded during the reported years.

n. Leases

The accounting policy applied as from January 1, 2019

As from January 1, 2019, the Group applies the following accounting policies under IFRS 16. See also section g. above as to the effect of initial application.

Determining if an arrangement contains a lease

At inception of a lease contract, the Group assesses whether the contract is, or contains, a lease, while examining whether the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration. In its assessment whether a contract conveys the right to control the use of an identified asset, the Group assesses whether it has the following two rights throughout the lease term:

(1) the right to substantially obtain all the economic benefits from using the identified asset; and

(2) the right to direct the use of the identified asset.

For lease contracts that contain non-lease components, such as services or maintenance, that are related to a lease component, the Group elected to account for the contract as one lease component without separating the components.

Leased assets and lease liabilities

Contracts that convey the Group control over the use of a leased asset for a period of time for consideration, are accounted for as leases. Upon initial recognition, the Group recognizes a liability at the present value of the balance of future lease payments (these payments do not include certain variable lease payments), and concurrently recognizes a right-of-use at the same amount of the lease liability, adjusted for prepaid or accrued lease payments, plus any direct costs incurred in respect of the lease.

Since the interest rate implicit in the Group's lease cannot be readily determinable, the Group uses the lessee's incremental borrowing rate.

Subsequent to initial recognition, the right-of use asset is treated as a right-of-use asset is accounted for using the cost model, and is depreciated over the term of the lease, or the useful life of the asset, whichever is shorter.

The Group has elected to adopt the practical expedient by which short-term leases of up to one year and/or leases in which the underlying asset has a low value, are accounted for such that lease payments are recognized in the statement of operations on a straight-line basis, over the lease term, without recognizing an asset and/or liability in the statement of financial position.

The lease term

The lease term is the non-cancellable period of the lease together with periods covered by an option to extend or cancel the lease if it is reasonably certain that the lessee will or will not exercise the option, respectively.

Variable lease payments

Variable lease payments that depend on an index or rate, are initially measured using the existing index or rate as of the commencement date of the lease and are included in the measurement of the lease liability. When there is a change in the cash flow of future lease payments resulting from the change in the index or rate, the balance of the liability is updated against the right-of-use asset.

Other variable lease payments not included in the measurement of the lease liability are recognized in the statement of operations at the date the terms for such payments are met.

Depreciation of right-of-use asset

Subsequent to the date of the lease, a right-of-use asset is measured using the cost method, less accumulated depreciation and less accumulated impairment losses and adjusted for remeasurement of the lease liability.

Depreciation is calculated on a straight-line basis over the useful life or contractual lease term, whichever is shorter, as follows.

	Years
Buildings	2.50-10.67
Motor vehicles	3-4

Reassessment of lease liability

Upon the occurrence of a significant event or a significant change in circumstances that is under the control of the Group and had an effect on the decision whether it is reasonably certain that the Group will exercise an option, which was not included before in the lease term, or will not exercise an option, which was previously included in the lease term, the Group remeasures the lease liability according to the revised leased payments using a new discount rate. The change in the carrying amount of the liability is recognized against the right-of-use asset, or recognized in the statement of operations, if the carrying amount of the right-of-use asset was reduced to zero.

Lease modifications

When a lease modification increases the scope of the lease by adding a right to use one or more underlying assets, and the consideration for the lease increased by an amount commensurate with the stand-alone price for the increase in scope and any appropriate adjustments to that stand-alone price to reflect the contract's circumstances, the Group accounts for the modification as a separate lease.

In all other cases, on the initial date of the lease modification, the Group allocates the consideration in the modified contract to the contract components, determines the revised lease term and measures the lease liability by discounting the revised lease payments using a revised discount rate.

For lease modifications that decrease the scope of the lease, the Group recognizes a decrease in the carrying amount of the right-of-use asset in order to reflect the partial or full cancellation of the lease, and recognizes in the statement of operations a profit (or loss) that equals the difference between the decrease in the right-of-use asset and remeasurement of the lease liability.

For other lease modifications, the Group remeasures the lease liability against the right-of-use asset.

The accounting policy applied in periods prior to January 1, 2019

Determining whether an arrangement contains a lease

At inception or upon reassessment of an arrangement, the Group determines whether such an arrangement is or contains a lease. An arrangement is a lease or contains a lease if the following two criteria are met:

(1) the fulfillment of the arrangement is dependent on the use of a specific asset or assets; and

(2) the arrangement contains rights to use the asset.

At inception or upon reassessment of the arrangement, the Group separates payments and other consideration required by such an arrangement into those for the lease and those for other elements on the basis of their relative fair values.

All the Group's leases are classified as operating leases, and the leased assets are not recognized in the Group's statement of financial position.

Lease payments

Payments made under operating leases are recognized in the statement of operations on a straight-line basis over the term of the lease. Minimum lease payments made under operating leases are recognized in the statement of operations as incurred.

Minimum lease payments made under finance leases are apportioned between the financing expense and the reduction of the outstanding liability. The financing expense is allocated to each period during the lease term so as to produce a constant periodic rate of interest on the remaining balance of the liability. Contingent lease payments are accounted for by revising the minimum lease payments over the remaining term of the lease when the lease adjustment is confirmed.

o. Provisions

The Group recognizes provisions when it has a legal or constructive obligation resulting from past events, whose resolution would imply cash outflows, or the delivery of other resources owned by the Group.

Obligations or losses related to contingencies are recognized as liabilities in the statements of financial position only when present obligations exist resulting from past events and it is probable to result in an outflow of resources and the amount can be measured reliably. Otherwise, a qualitative disclosure is included in the notes to the financial statements. The provisions are determined by discounting the future cash flows at a pre-tax interest rate, reflecting the current market estimates of the time value of the money and the specific risks of the liability without weighting the Group's credit risk. The carrying value of the provision is then adjusted in every period so as to reflect the passage of time and the adjustment amount is credited to financial expenses.

p. Post-employment benefits

The costs of defined contribution plans are recognized in the operating results as they are incurred. Liabilities arising from such plans are settled through cash transfers to the employees' retirement accounts with insurance companies or with funds managed by others, without generating future obligations. The majority of the Israeli employees are under defined contribution plans.

The rest of the Israeli employees are under defined benefit plans. The costs associated with defined benefit plans are recognized as services are rendered, based on actuarial estimations of the benefits' present value with the advice of external actuaries.

q. Share-based payment transactions

The grant-date fair value of share-based payment awards granted to employees and directors is recognized as a salary expense, with a corresponding increase in equity, over the period that the employees and directors become unconditionally entitled to the awards. The amount recognized as an expense in respect of share-based payment awards that are conditional upon meeting service and non-market performance conditions, is adjusted to reflect the number of awards that are expected to vest.

For share-based payment awards with non-vesting conditions or with market performance vesting conditions, the grant date fair value of the share-based payment awards is measured to reflect such conditions, and therefore the Group recognizes an expense in respect of the awards whether or not the conditions have been met.

The fair value at the time of grant of share-based payment awards to consultants and service providers are recognized over the consultants' and the service providers' period of service against an increase in equity. The fair value of the services is calculated on the basis of the fair value of the awards and not on the basis of the fair value of the services, since it is not possible to reliably estimate the fair value of the services rendered.

The Group elected to record the increase in equity against salary expense directly to accumulated deficit.

r. Revenue recognition

The accounting policy applied as from January 1, 2018

As from January 1, 2018, the Group applies the following accounting policies under IFRS 15, *Revenues from Contracts with Customers*.

The Group recognizes revenues when the customer obtains control over the products or services that have been secured, net of provision for returns and discounts. The revenue is measured according to the amount of consideration that the Group expects to be entitled to in return for the transfer of products or services promised to the customer, other than amounts collected in favor of third parties.

The Group recognizes estimated sales discounts as a reduction of sales in the same period revenue is recognized. The Group adjusts reserves to reflect differences between estimated and actual. The Group estimates its sales returns reserve based on historical return rates and analysis of specific accounts.

When the Group sells its products through distributors, revenue is being recognized upon delivery of the product to the distributor, as the distributors does not have the right to return and the control over the products is transferred at this point in time.

Identifying the contract

The Group accounts for a contract with a customer only when the following conditions are met:

(1) the parties to the contract have approved the contract (in writing, orally or according to other customary business practices) and they are committed to satisfying the obligations attributable to them;

(2) the Group can identify the rights of each party in relation to the products or services that will be transferred;

(3) the Group can identify the payment terms for the products or services that will be transferred;

(4) the contract has a commercial substance (i.e. the risk, timing and amount of the entity's future cash flows are expected to change as a result of the contract); and

(5) it is probable that the consideration, to which the Group is entitled to in exchange for the products or services transferred to the customer, will be collected.

If a contract with a customer does not meet all of the above criteria, consideration received from the customer is recognized as a liability until the criteria are met or when one of the following events occurs: (i) the Group has no remaining obligations to transfer products or services to the customer and any consideration promised by the customer has been received and cannot be returned; or (ii) the contract has been terminated and the consideration received from the customer cannot be refunded.

Identifying performance obligations

The Group identifies products or services promised to the customer as being distinct performance obligations when the customer can benefit from the products or services on their own or in conjunction with other readily available resources and the Group's promise to transfer the products or services to the customer is separately identifiable from other promises in the contract. In order to examine whether a promise to transfer products or services is separately identifiable, the Group examines whether it is providing a significant service of integrating the products or services with other products or services promised in the contract into one integrated outcome that is the purpose of the contract.

Products or services that are not considered as being distinct are grouped together as a single performance obligation. The revenue from each such performance obligation is recognized upon transfer of control over the promised products or services to customer. In general, the Group allocates the transaction price to the identified performance obligations in the contract, based on the relative stand-alone selling prices when the products or services are sold separately. In cases where the products or services are not sold separately, for example, in the case of installations or training, the Group establishes the stand-alone selling price assigned to that performance obligation, based on estimated costs plus a reasonable margin.

Significant financing component in installment sales is separated in determining the transaction price.

As applicable to the Group, revenues from sales agreements consisting of multiple products or services, such as devices, consumables, access to the CloudPAT application, WatchPAT Direct logistic services and support, extended warranty and other service agreements, are separated into different performance obligations, based on their relative fair values, and revenue is separately recognized for each performance obligation.

The Group recognizes revenue from renting its products over the rent term, in conformity with the agreement with the customer.

Since 2015, the Group has focused on offering Total Sleep Solution ("TSS") to the cardiology market through various business models; however, the Test as a Service ("TaaS") model, is the primary model the Group utilized to date. In the TaaS model, the medical practice or physician ordering the TaaS pays a fixed fee per home sleep apnea test ("HSAT") that includes all the components associated with the test, including the disposable biosensor, hardware rental fees and access to the Group's CloudPAT platform. Under the TaaS model, some rent agreements of the WatchPAT devices are made for a period of one to two years. The rental fees are separated under the relative fair value approach.

In some cases, the Group handles sale transactions of these devices as a finance lease and recognizes revenue in respect of the products supplied at the commencement date of the lease. When these transactions include multiple performance obligations, revenue is recognized based on the relative stand-alone selling prices of each performance obligation in the transaction when they are sold separately.

Satisfaction of performance obligations

Revenue is recognized when the Group satisfies a performance obligation by transferring control over the promised products or services to the customer. Sale of devices and disposables are generally recognized upon shipment. Services (including extended warranty) are recognized ratably over the service period.

Contract assets and liabilities

A contract asset is recognized when the Group has a right to consideration for products or services it transferred to the customer that is conditional on other than the passing of time, such as future performance of the Group. Contract assets are classified as receivables when the rights in their respect become unconditional.

A contract liability is recognized when the Group has an obligation to transfer products or services to the customer for which it received consideration (or the consideration is payable) from the customer.

An asset and liability relating to the same contract are presented on a net basis in the statement of financial position. On the other hand, a contract asset and contract liability deriving from different contracts are presented on a gross basis in the statement of financial position.

The accounting policy applied in periods prior to January 1, 2018

Revenue is measured at the fair value of the consideration received or receivable, net of returns and discounts. The Group recognizes revenue from the sale of its products, net of provision for returns, when persuasive evidence exists (usually in the form of an executed sales agreement) that the significant risks and rewards of ownership of the products have been transferred to the buyer, recovery of the consideration is probable, the associated costs and possible return of products can be estimated reliably, there is no continuing management involvement with the products, and the amount of revenue can be measured reliably. Revenue is recognized when title to the products and risk of loss transfers to customers, provided there are no material remaining performance obligations required of the Group or any matters requiring customer acceptance. The timing of the transfer of risks and rewards may be upon shipment or upon delivery to the customer site, based on the contract terms or legal requirements.

The Group recognizes estimated sales discounts as a reduction of sales in the same period revenue is recognized. The Group adjusts reserves to reflect differences between estimated and actual. The Group estimates its sales returns reserve based on historical return rates and analysis of specific accounts.

Revenues from sales agreements consisting of multiple elements, such as devices, consumables, access to the CloudPAT application, WatchPAT Direct logistic services and support and other service agreements, are separated into different components and are separately recognized for each component. A component constitutes a separate accounting unit if, and only if, it has value, separately, for the customer. Components not separated, are grouped together. The revenue from each such component is recognized upon fulfillment of the conditions for recognition of revenue, based on the nature of the component, i.e., as products or as services. In general, the Group determines the fair value for each element, based on selling prices when the product or service is sold separately. In cases where the components are not sold separately, for example, in the case of installations or training, the Group establishes the value assigned to this element, based on estimated costs plus a reasonable margin.

The Group recognizes revenue from leasing its products over the lease term, in conformity with the agreement with the customer. In some cases, the Group handles sale transactions in these devices as finance lease and recognizes revenues in respect of the products supplied, based on their relative fair value compared to all the components in the transaction.

When the Group sells its products through distributors, revenue is being recognized upon delivery of the product to the distributor, as the distributors does not have the right to return and the material risks and rewards inherent to the ownership of the products are transferred at this time.

s. Income taxes

The effects reflected in the statements of operations for income taxes include the amounts incurred during the period and the amounts of deferred income taxes, determined according to the income tax law applicable to each Group company. Consolidated deferred income taxes represent the addition of the amounts determined in each Group company by applying the enacted statutory income tax rate to the total temporary differences resulting from comparing the book and taxable values of assets and liabilities, considering tax assets such as loss carryforwards and other recoverable taxes, to the extent that it is probable that future taxable profits will be available against which they can be utilized. The measurement of deferred income taxes at the reporting period reflects the tax consequences that follow the manner in which the Group expects to recover or settle the carrying amount of its assets and liabilities. Deferred income taxes for the period represent the difference between balances of deferred income taxes at the beginning and the end of the period. Deferred income tax assets and liabilities relating to different tax jurisdictions are not offset. According to IFRS, all items charged or credited directly in shareholders' equity or as part of other comprehensive income or loss for the period are recognized net of their current and deferred income tax effects. The effect of a change in enacted statutory tax rates is recognized in the period in which the change is officially enacted.

Deferred tax assets that were not recognized are reevaluated at each reporting date and recognized if it has become probable that future taxable income will be available against which they can be utilized.

t. Loss per share

The Group presents basic and diluted loss per share data for its ordinary shares. Basic loss per share is calculated by dividing the net loss attributable to holders of ordinary shares of the Company, by the weighted average number of ordinary shares outstanding during the period.

Diluted loss per share is determined by adjusting the loss attributable to ordinary shareholders and the weighted average number of ordinary shares outstanding for the effects of all potentially dilutive ordinary shares, which include convertible notes and options and warrants issued to shareholders employees, directors and consultants.

u. Transactions with controlling shareholders

Assets and liabilities, which are subject to a transaction with a controlling shareholder, are measured at fair value upon the transaction date.

As the transaction is on the equity level, the Company recognized the difference between fair value and the consideration from the transaction in its equity.

NOTE 3 - TRADE AND OTHER RECEIVABLES

	December 31,	
	2019	2018
	U.S. dollars in thousands	
Trade receivables:		
Open accounts	$ 8,996	$ 7,040
Checks receivable	37	22
	9,033	7,062
Less - allowance for doubtful accounts	493	270
	$ 8,540	$ 6,792
Presented in the statements of financial position as follows:		
Under current assets	$ 8,384	$ 6,549
Under non-current assets	156	243
	$ 8,540	$ 6,792

	December 31,	
	2019	2018
	U.S. dollars in thousands	
Other receivables:		
Institutions	$ 591	$ 181
Advances to suppliers	236	187
Employees	114	91
Prepaid expenses	411	556
Miscellaneous	52	3
	$ 1,404	$ 1,018

The Group’s exposure to credit risk, currency risk and impairment loss in respect of trade and other receivables is described in Note 21.

NOTE 4 – INVENTORIES

	December 31,	
	2019	2018
	U.S. dollars in thousands	
Raw materials and auxiliary materials	$ 1,651	$ 1,158
Work in process	531	277
Finished products	1,181	800
	$ 3,363	$ 2,235

NOTE 5 – PROPERTY AND EQUIPMENT

	Computers and equipment	Equipment and devices for leasing and for internal use	Office furniture and equipment	Leasehold improvements	Total
	U.S. dollars in thousands				
Cost:					
Balance as of January 1, 2019	$ 2,009	$ 1,527	$ 476	$ 326	$ 4,338
Additions	137	574	5	-	716
Balance as of December 31, 2019	2,146	2,101	481	326	5,054
Accumulated depreciation:					
Balance as of January 1, 2019	1,695	854	345	231	3,125
Depreciation	58	381	15	3	457
Balance as of December 31, 2019	1,753	1,235	360	234	3,582
Depreciated balance as of December 31, 2019	$ 393	$ 866	$ 121	$ 92	$ 1,472
Cost:					
Balance as of January 1, 2018	$ 1,947	$ 1,093	$ 467	$ 317	$ 3,824
Additions	62	434	9	9	514
Balance as of December 31, 2018	2,009	1,527	476	326	4,338
Accumulated depreciation:					
Balance as of January 1, 2018	1,632	649	319	202	2,802
Depreciation	63	205	26	29	323
Balance as of December 31, 2018	1,695	854	345	231	3,125
Depreciated balance as of December 31, 2018	$ 314	$ 673	$ 131	$ 95	$ 1,213

The Group has assets that have been fully depreciated and are still in use. As of December 31, 2019 and 2018, the original cost of such assets is $3,379 thousand and $2,928 thousand, respectively.

NOTE 6 – INTANGIBLE ASSETS

	Computer software	Capitalized development cost	Marketing rights for a medical product	Total
	U.S. dollars in thousands			
Cost:				
Balance as of January 1, 2019	$ 769	$ 806	$ 375	$ 1,950
Additions	106	150	-	256
Balance as of December 31, 2019	875	956	375	2,206
Accumulated amortization:				
Balance as of January 1, 2019	716	561	375	1,652
Amortization for the year	41	118	-	159
Balance as of December 31, 2019	757	679	375	1,811
Amortized balance as of December 31, 2019	$ 118	$ 277	$ -	$ 395
Cost:				
Balance as of January 1, 2018	$ 746	$ 716	$ 375	$ 1,837
Additions	23	90	-	113
Balance as of December 31, 2018	769	806	375	1,950
Accumulated amortization:				
Balance as of January 1, 2018	678	507	375	1,560
Amortization for the year	38	54	-	92
Balance as of December 31, 2018	716	561	375	1,652
Amortized balance as of December 31, 2018	$ 53	$ 245	$ -	$ 298

The capitalized development costs are in respect of the Group's CloudPAT, a cloud-based information technology platform designed to allow customers to transfer the data of the sleep apnea test results of the Group's products. The amortization expenses are included in cost of revenues.

NOTE 7 – LEASES

Leases in which the Group is the lessee

The Group applies IFRS 16, *Leases*, as from January 1, 2019. The Group has lease agreements with respect to buildings of offices, manufacturing facilities and warehouses and motor vehicles.

a. Information regarding material lease agreements:

Buildings

The Group's leases approximately 14,000 square feet of office and manufacturing space in Caesarea, Israel pursuant to a lease that is currently scheduled to expire in July 2021. In addition, the Group leases approximately 1,900 square feet of storage space in Caesarea, Israel pursuant to a lease that is scheduled to expire in June 2021.

During the year ended December 31, 2019, the Group entered into a lease agreement for new manufacturing facilities located in Caesarea, Israel, where it leases approximately 14,000 square feet. This lease is currently scheduled to expire in February 2023 but provides for two optional extensions until February 2030.

In addition, the Group leases approximately 10,900 square feet of office space in Atlanta, Georgia, U.S. pursuant to a lease that expires in March 2022, with an optional extension until March 2025.

Motor vehicles

The Group leases vehicles for three-year periods from several different leasing companies and from time to time changes the number of leased vehicles according to its current needs. The leased vehicles are identified by means of license numbers and the vehicle's registration, with the leasing companies not being able to switch vehicles, other than in cases of deficiencies. The leased vehicles are used by the Group's headquarter staff, marketing and salespersons and other employees whose employment agreements include an obligation of the Group to put a vehicle at their disposal. The Group accounted for the arrangement between it and the leasing companies as a lease arrangement in the scope of IFRS 16 and for the arrangement between it and its employees as an arrangement in the scope of IAS 19. The agreements with the leasing companies do not contain extension and/or termination options that the Group is reasonably certain to exercise.

b. Right-of-use assets

	Buildings	Motor Vehicles	Total
	U.S. dollars in thousands		
Cost:			
Balance as of January 1, 2019, date of initial application	$ 681	$ 468	$ 1,149
Additions in respect of new leases	1,788	335	2,123
Balance as of December 31, 2019	2,469	803	3,272
Accumulated depreciation:			
Depreciation for the year	567	263	830
Balance as of December 31, 2019	567	263	830
Depreciated balance as of December 31, 2019	$ 1,902	$ 540	$ 2,442

c. Lease liabilities

Maturity analysis of the Group's lease liabilities

	December 31, 2019
	U.S. dollars in thousands
Less than one year	$ 890
One to five years	1,011
More than five years	697
Total lease liabilities	2,598
Less - current maturities	890
Long-term lease liability	$ 1,708

The cash outflow in the year ended December 31, 2019 amounted to $937 thousand.

d. Lease payments prior to the application of IFRS 16

The lease payments prior to the application of IFRS 16, which were included in the statement of operations among operating expenses amounted to $1,009 and $999 thousand in the years ended December 31, 2018 and 2017, respectively.

NOTE 8 – CREDIT FACILITY WITH A BANK AND CONVERTIBLE NOTES

a. Credit facility with a bank

In March 2017, the Company received a bank credit line in a total amount of up to $10 million. The credit line is comprised of up to $6 million long-term loan and up to $4 million credit facility against trade accounts receivable, based on specific customer invoices.

The long-term loan is repayable in equal quarterly installments over three years from the date of the draw and bears annual interest of the quarterly dollar LIBOR rate plus 5.5%. The credit facility against trade accounts receivable bears annual interest of the monthly dollar LIBOR rate plus 4.25%.

On January 30, 2018, the terms of the bank credit line were amended such that the exercise period of the loan and the credit facility against trade accounts receivable were extended until February 28, 2019 and January 12, 2019, respectively. The framework of the long-term loan component was changes so that it can be utilized as a long-term loan or as a short-term loan.

In addition, the Company undertook that upon the withdrawal of credit, the balance of the cash in the Company's account with the bank will not be less than 40% of the total amount drawn.

As part of the bank credit, the Company issued to the bank warrants exercisable into 798,088 of the Company's ordinary shares at an exercise price of NIS 1.36 per share (equivalent to $0.39 per share as of December 31, 2019), which were initially exercisable until March 28, 2022 (see extensions below). The fair value of the warrants was measured using a Black-Scholes valuation model and the cost of $137 thousand was accounted for as an integral part of the effective interest rate of the bank credit.

On March 12, 2019, the Company and the bank entered into a new agreement (the" 2019 Agreement") under which the total credit line to be available under the credit facility increased from up to $10 million to up to $11 million, comprised of: (i) up to $6 million in long-term or short-term loan; and (ii) up to $5 million of credit facility against trade accounts receivable. In July 2019, as a result of achievement of certain revenue targets, the total credit line to be available under the credit facility increased from up to $11 million to up to $15 million, comprised of: (i) up to $10 million in long-term or short-term loan; and (ii) up to $5 million of credit facility against trade accounts receivable.

As part of the 2019 Agreement, the Company issued to the bank additional warrants exercisable into 399,044 ordinary shares at an exercise price of NIS 1.30 per share (equivalent to $0.38 per share as of December 31, 2019), which will be exercisable until March 28, 2023 (see extension below). In addition, the Company extended the exercise period of the original warrants from March 28, 2022 to March 28, 2023. The fair value of the additional warrants was measured using a Black-Scholes valuation model and the cost of $62 thousand will be accounted for as an integral part of the effective interest rate of the bank credit.

On February 9, 2020, the Company and the bank entered into a new agreement (the "2020 Agreement") under which the total credit line to be available under the credit facility increased from up to $15 million to up to $17 million, comprised of: (i) up to $10 million in long-term or short-term loan; and (ii) up to $7 million of credit facility against trade accounts receivable. The amount of $10 million may increase in July 2020 to $13 million (and the total amount of the credit line may increase from up to $17 million to up to $20 million), if the Company will achieve certain revenue targets. The additional $3 million of long-term or short-term loan will bear annual interest of the quarterly dollar LIBOR rate plus 7.0%. The loans under the credit line may be drawn until October 25, 2020. In addition, the Company undertook that upon the withdrawal of credit, the balance of the cash in the Company's account with the lending bank will not be less than 30% of the total amount drawn for draws of up to $10 million in the aggregate and 40% of the aggregate amount exceeding $10 million.

As part of the 2020 Agreement, the Company issued to the bank additional warrants exercisable into 359,140 ordinary shares at an exercise price of NIS 1.044 per share (equivalent to $0.30 per share as of the date of grant), which will be exercisable until November 30, 2023. In addition, the Company extended the exercise period of the previously issued warrants from March 28, 2023 to November 30, 2023.

As of December 31, 2019, the Company withdrew $5.0 million out of the bank credit as follows: $1.6 million as a short-term loan and $3.4 million as a short-term loan against trade accounts receivable. On February 20, 2020, the Company repaid the above $5.0 million and withdrew again $5.0 million from the bank credit, as follows: $1.2 million as a short-term loan and $3.8 million as a short-term loan against trade accounts receivable. The loans are for a period of three months until May 20, 2019. As mentioned above, the Company undertook that upon the withdrawal of credit, the balance of the cash in the Company's account with the bank will not be less than 30% of the amount of the outstanding credit actually provided to the Company, such that an amount of $1.5 million is not currently available for the Company's current use.

In order to secure its obligations to the bank, the Company pledged and granted to the bank a first priority floating charge on all of its assets and a first priority fixed charge on (i) its intellectual property, goodwill, holdings in its subsidiaries and certain other, immaterial, assets; and (ii) all of the assets of the Company's U.S. Subsidiary.

b. Convertible notes

In March 2013, the Company issued, NIS 72,256 thousand par value convertible notes listed for trading on the TASE for total net proceeds of $19.5 million. The notes matured in two principal repayments on February 28, 2017 and on February 28, 2018, and bore fixed interest at 8.65% per annum, payable semi-annually: on August 28 and on February 28, through February 28, 2018.

The net proceeds from the issuance of the convertible notes were split into two components for measurement purposes: (i) a liability component without a conversion feature that was measured at amortized cost according to the effective interest method; and (ii) a conversion option that was an embedded derivative and is measured at fair value at each reporting date.

The effective interest rate as of the date of the issuance was 27.7%. The attributed transaction costs were allocated to the different components pro-rata to the amounts of their initial recognition before allocation of the said costs.

The notes were convertible, so that each NIS 1.92 par value notes could have been converted into one ordinary share (which, as a result of a rights offering conducted by the Company in December 2015, was adjusted such that every 1.92 NIS par value of the notes could be converted to 1.00904 ordinary shares).

On February 28, 2017, the first installment of the notes in a total amount of NIS 38,128 thousand par value (approximately $10,421 thousand) was repaid and on February 28, 2018, the second and last installment of the notes in a total amount of NIS 38,128 thousand par value (approximately $10,940 thousand) was repaid, other than NIS 6.0 million (approximately $1.700 thousand) owed to three shareholders who held notes, of which $500 thousand was repaid to one shareholder in June 2018 and the balance owed to the other two shareholders was invested by them in the 2018 Private Placement described in Note 15c. None of the notes were converted.

NOTE 9 – OTHER ACCOUNTS PAYABLE

	December 31,	
	2019	2018
	U.S. dollars in thousands	
Employees	$ 2,685	$ 1,403
Institutions	412	319
Interest payable	10	11
Deferred revenues and advances from customers	308	255
Miscellaneous	40	75
	$ 3,455	$ 2,063

For information about the Group's exposure to currency and liquidity risks in respect of the payables' balances, see Note 21.

NOTE 10– PROVISIONS

	Warranties	Returns	Total
	U.S. dollars in thousands		
Balance as of January 1, 2018	$ 100	$ 83	$ 183
Provisions made during the year	86	81	167
Provisions reversed during the year	(5)	-	(5)
Provisions realized during the year	(62)	(68)	(130)
Balance as of December 31, 2018	119	96	215
Provisions made during the year	154	91	245
Provisions reversed during the year	(4)	-	(4)
Provisions realized during the year	(121)	(62)	(183)
Balance as of December 31, 2019	$ 148	$ 125	$ 273

NOTE 11 – EMPLOYEE BENEFITS

Employee benefits include retirement benefit obligations, short-term benefits and share-based payments. As for retirement benefit obligations, the Group has defined benefit plans for which it contributes to insurance policies and pension funds.

As for share-based payments, see Note 16 and as for benefits to key executives, see Note 22.

	December 31,	
	2019	2018
	U.S. dollars in thousands	
Presented as part of current liabilities:		
Short-term employee benefits	$ 352	$ 222
Presented as part of non-current liabilities:		
Recognized liability for defined benefit plan, net	$ 260	$ 159

Retirement benefit plans - defined benefit plan

1) Movement in net liabilities for defined benefit plans:

	Year Ended December 31,	
	2019	2018
	U.S. dollars in thousands	
Balance at beginning of year	$ 159	$ 310
Expense recognized in the statements of operations:		
Current service costs and interest costs	22	29
Recognized gains (losses) including other:		
Actuarial gains (losses) carried to other comprehensive income	94	(166)
Other movements:		
Benefits paid	(11)	(5)
Deposits made by the Group	(4)	(9)
Balance at end of year	$ 260	$ 159

2) Expenses recognized in the statements of operations:

	Year Ended December 31,	
	2019	2018
	U.S. dollars in thousands	
Current service costs	$ 4	$ 16
Interest costs	5	7
Transfer of profits to benefits	43	28
Total	$ 52	$ 51

3) The principal actuarial assumptions as of the report date (based on weighted average):

	December 31,		
	2019	2018	2017
	%	%	%
Discount rate at the end of the year	2.62	3.82	2.74
Future salary growth	3.00	3.00	3.27

NOTE 12 – DERIVATIVE INSTRUMENTS

Composition

	December 31, 2018
	U.S. dollars in thousands
Liabilities	
Viola Warrants (non-traded)	$ 371
Warrants (Series 4) (traded) issued in the 2015 rights offering, see below	71
	$ 442

The Viola Warrants were issued to the Viola Growth II A.V. LP, Viola Growth II (A) LP and Viola Growth II (B) LP (collectively, "Viola") as part of a private placement in August 2015 and January 2016. The Warrants (Series 4) were issued to the public as part of a rights offering in December 31, 2015. Both warrants expired on May 4, 2019.

The above derivatives had an exercise price that was denominated in NIS, a currency different than the functional currency of the Company and as a result were accounted for as a derivative financial instrument measured at fair value through profit or loss on each reporting date and constitute a liability.

The following parameters were used in the calculation of the fair value of the above derivatives, using the binomial model:

	December 31, 2018
The discount rate of the Viola Warrants and Warrants (Series 4) (risk free interest)	0.30%
Share price (in NIS)	1.280
Standard deviation of the share price	54.59%

The fair value of the Viola Warrants and the Warrants (Series 4) as of December 31, 2015 and during the nine month period ended September 30, 2016 was measured at quoted market value of the Warrants (Series 4), due to the fact that the Viola Warrants and the Warrants (Series 4) are essentially identical in their conditions. Starting with the fourth quarter of 2016 and until the first quarter of 2019, the Company believed that there was no active market for the traded Warrants (Series 4) primarily due to an ongoing gradual decline in the frequency and volume of trading in such warrants with significant variance in the transactions prices of the warrants without a corresponding material change in the share price, and often with a negative correlation between the change in the share price and the change in the warrants price. Consequently, the Company estimated the fair value of the Viola Warrants and the Warrants (Series 4) as of December 31, 2016 and for periods thereafter, based on observable market data, directly or indirectly, based on the binomial model and based on relevant parameters of the terms of the Viola Warrants and the Warrants (Series 4).

NOTE 13 – OTHER LONG-TERM LIABILITIES

Obligation to pay royalties to the Israeli Government's Innovation Authority ("IIA")

The Company has received royalty-bearing grants from the IIA in a total amount of $1.06 million (including interest accrued through December 31, 2019) for the development of EndoPAT 3000 (the development of which was discontinued before its completion with no sales to date). In 2009, the IIA notified the Company that under the terms of such grant, it must pay royalties on the sale of all of its products commencing as of 2012. The Company believes that under the terms of the said grant it is not required to repay these grants to the IIA from the sale of its past and currently marketed products. There is no assurance that the Company will prevail in its efforts opposing the IIA's position. The Company anticipates that, in 2021, it will begin selling its newly developed EndoPATX, for which it recently received authorization to affix a CE mark. The Company developed EndoPATX using some of the know-how developed under the EndoPAT 3000 grant program, and therefore anticipates paying royalties on sales of EndoPATX against the grants received for the development of EndoPAT 3000. The Company accrued for the royalties' obligation once the grants became repayable.

NOTE 14 – INCOME TAXES

a. Israeli taxation:

1) Corporate tax rates in Israel

The tax rates relevant to corporates in Israel in the years 2017 – 2019 were as follows: 2017 – 24%; 2018 and 2019 – 23%.

On December 22, 2016, the Knesset (the Israeli parliament) approved the Economic Efficiency Law (Legislative Amendments to Achieve Budget Targets for the 2017 and 2018 Budget Years), 2016, which stipulates, among other things, the reduction of corporate tax rates from 25% to 23% in two phases. The first phase is to a rate of 24%, starting on January 2017 and the second phase is to a rate of 23% starting on January 2018 and thereafter.

2) Measurement of taxable income in U.S. dollars

The Company has elected, starting in the 2016 tax year, to measure its taxable income and file its tax return under the Israeli Income Tax Regulations (Principles Regarding the Management of Books of Account of Foreign Invested Companies and Certain Partnerships and the Determination of Their Taxable Income), 1986. Accordingly, results for tax purposes are measured in terms of earnings in dollars.

3) Tax benefits under the Law for the Encouragement of Capital Investments, 1959 (the "Investment Law")

Approved enterprise, benefited enterprise and preferred enterprise

Most of the production facilities of the Company have been granted "Approved Enterprise", "Benefited Enterprise" and "Preferred Enterprise" status under Investment Law. The Company is a "Foreign Investors' Company" as defined by the Investment Law, which means it is entitled to tax benefits for taxable income arising from its Approved, Benefited or Preferred Enterprise status.

Since its incorporation, the Company incurred significant losses and therefore it did not start benefiting from such status. To be eligible for these tax benefits, one must continue to meet certain conditions stipulated in the Investment Law and its regulations and the criteria set out in the specific certificate of approval. The only material condition applicable to the Company is to meet a minimum threshold (25%) of export sales (i.e., sales outside of Israel). In the event the Company is considered as having failed to comply with these conditions, in whole or in part, the eligibility for the benefits may be canceled and the Company may be required to refund the relevant amount, including inflation adjustments and interest. However, since the Company had accumulated carryforward tax losses of approximately $115 million as of December 31, 2019 (see section d. below), it did not benefit from such tax benefits and does not expect to benefit from such tax benefits in the foreseeable future. Once the Company utilizes all of its accumulated tax losses, it expects to derive tax benefits in Israel relating to its Benefited Enterprise and Preferred Enterprise programs for which it is eligible.

A company having an Approved or Benefited Enterprise, like the Company, that distributes a dividend from income that was tax exempt, will be required in the tax year of the dividend distribution to pay corporate tax on the amount of the dividend distributed (including the corporate tax required as a result of the distribution) at the corporate tax rate that would have been applicable to it in the year the income was generated if it had not been exempt from tax.

4) Tax benefits under the law for the Encouragement of Industry (Taxes), 1969 (the "Encouragement Law"):

The Encouragement Law provides several tax benefits for industrial companies. An industrial company is defined as a company resident in Israel, that at least 90% of the income of which in a given tax year exclusive of income from specified government loans, capital gains, interest and dividends, is derived from an industrial enterprise owned by it. An industrial enterprise is defined as an enterprise whose major activity in a given tax year is industrial production activity.

Management believes that the Company is currently qualified as an "industrial company" under the Encouragement Law and, as such, is entitled to tax benefits, including: (i) deduction of purchase of know-how and patents and/or right to use a patent over an eight-year period; (ii) accelerated depreciation rates on equipment and buildings; and (iii) expenses related to a public offering on the TASE and on recognized stock markets outside of Israel, such as Nasdaq, are deductible in equal amounts over three years.

Eligibility for benefits under the Encouragement Law is not subject to receipt of prior approval from any governmental authority. No assurance can be given that the Israel Tax Authority will agree that the Company qualifies and will continue to qualify as an industrial company, or that the benefits described above will be available to the Company in the future.

b. Taxation of Non-Israeli subsidiaries

Subsidiaries incorporated outside of Israel are assessed for tax under the tax in their countries of residence. The primary tax rates applicable to the non-Israeli subsidiaries in the Group are:

(1) U.S. – federal corporate tax rate of 35% during 2017 and 21% during 2018 and thereafter. The reduction did not have a material impact on the tax expenses of the U.S. subsidiary in the years ended December 31, 2018 and 2017.

(2) The Netherlands – corporate tax rate of 20% during 2017 (the year in which the Netherlands subsidiary was formed) and 2018 on the first Euro 200,000 of taxable income and 25% for taxable income exceeding Euro 200,000; corporate tax rate of 19% during 2019 on the first Euro 200,000 of taxable income and 25% for taxable income exceeding Euro 200,000; corporate tax rate of 16.5% during 2020 on the first Euro 200,000 of taxable income and 25% for taxable income exceeding Euro 200,000; and corporate tax rate of 15% during 2021 on the first Euro 200,000 of taxable income and 25% for taxable income exceeding Euro 200,000.

(3) Japan – tax rate of 23.4% during 2017, and 23.2% during 2018 and 2019.

c. Tax expenses in the statements of operations mainly refer to operations of the subsidiaries in the U.S., the Netherlands and Japan. The Company does not pay taxes in Israel, as it has tax losses carryforward to future years. No deferred tax asset was recognized in respect of those carryforward tax losses, in the absence of expected utilization thereof in the foreseeable future.

The Company did not include a calculation of the theoretical tax due to the fact that the total tax expenses in the statements of operations are not material.

d. Carryforward tax losses

The Company has carryforward tax losses (including carryforward research and development expenses) as of December 31, 2019, amounting to $115 million.

e. Tax assessment

The Company has not received final tax assessments since its incorporation. The Company has self-assessments deemed to be final through the 2013 tax year.

NOTE 15 – EQUITY

a. Ordinary shares of NIS 0.01 par value

	Year Ended December 31,		
	2019	2018	2017
	Number of shares in thousands		
Issued and outstanding share capital (ordinary shares):			
Outstanding shares at the beginning of the year	287,616	264,495	262,917
Shares issued in private placements during the year	46,115	22,014	-
Shares issued in exercise of stock options during the year	1,554	1,107	1,578
Outstanding at the end of the year	335,285	287,616	264,495
Authorized share capital at the end of the year	750,000	750,000	750,000

The rights of the ordinary shares include voting rights at the general meeting of shareholders, the rights to receive dividends and rights to participate in the distribution of the surplus assets of the Company in the event of liquidation.

b. 2019 Private Placement

On January 16, 2019 and January 28, 2019, the Company entered into separate securities purchase agreements with several U.S. and Israeli accredited investors. Under the securities purchase agreements, the Company undertook to issue to the investors, upon and subject to the closing:, (i) a total of 1,170,707 ADSs, at a price per ADS of $9.55, to the investors (other than the Israeli investor) (the "U.S. Tranche"); and (ii) a total of 10,944,185 ordinary shares to the Israeli investor, at a price per ordinary share of NIS 1.1693 (equivalent to $0.32 as of February 3, 2019) (the "Israeli Tranche"), or, in the aggregate, the Company undertook to issue to the investors a total of 46,115,395 ordinary shares (including ordinary shares underlying the ADSs) representing, as of January 28, 2019, approximately 13.8% of the Company's issued and outstanding shares on a post-issuance basis, resulting in aggregate proceeds (before expenses) of approximately $14.7 million. On February 3, 2019, the Company completed the private placement of the Israeli Tranche and issued to the Israeli investor, 10,994,185 ordinary shares, and on March 6, 2018, the Company completed the private placement of the U.S. Tranche and issued to the investors under the U.S, Tranche a total of 1,170,707 ADSs. The ordinary shares and ADSs issued to the investors are subject to resale restrictions under applicable U.S. and Israeli securities laws. None of the investors were granted registration rights under the securities purchase agreements. The securities purchase agreements contain other customary terms and conditions, including customary representations and warranties of the parties which survive the completion of the transaction until the date on which the investors no longer hold any of the ADSs or shares, as applicable.

c. 2018 Private Placement

On March 22, 2018, the Company entered into separate securities purchase agreements with Viola, the Company's largest shareholder; Medtronic International Technology, Inc. ("Medtronic"), a then major shareholder of the Company; Dr. Giora Yaron (through a company wholly owned by him), the Company's Chairman of the Board of Directors and a major shareholder, and various funds affiliated with three Israeli institutional investors, Yelin Lapidot Mutual Funds Management Ltd., a major shareholder; Meitav Dash Investments Ltd., and The Phoenix Holdings Ltd. On May 27, 2018, following approval by the Company's shareholders of the private placement contemplated by these securities purchase agreements, the Company completed the transaction and issued to the investors a total of 22,013,893 ordinary shares (representing as of such date approximately 7.7% of the Company's issued and outstanding shares on a post-issuance basis) at a purchase price of NIS 0.947 per share (equivalent to $0.27 as of May 7, 2018) (reflecting a 7% discount on the average share price during the 15 consecutive trading days preceding March 15, 2018 (inclusive), the date of publication of the Company's 2017 financial statements), resulting in aggregate proceeds (before expenses) of NIS 20.8 million (equivalent to approximately $6.0 million). Out of the total NIS 20.8 million investment, Viola, Medtronic and Dr. Giora Yaron, invested NIS 5.2 million, NIS 2.4 million and NIS 2.1 million, respectively. Since then Medtronic transferred the shares issued to it to MS Pace LP, a limited partnership.

NOTE 16 – SHARE-BASED PAYMENTS

a. Description of share-based payment arrangements and grants:

1) Performance-based options

Unvested performance-based options as of December 31, 2015 were cancelled and replaced on January 21, 2016, with new grants of options and restricted share units ("RSUs") that are either contingent upon the continued employment only or are also contingent on meeting performance criteria, as detailed in (2) below.

2) Options and RSUs with service conditions and market conditions

On January 21, 2016, the Company's Board of Directors approved a new share-based plan for options and RSUs for key employees that will vest on January 21, 2020 (or earlier in case of an acceleration event), if the share price is at least NIS 2.13 (equivalent to $0.61 as of December 31, 2019) (the "First Trigger Price"), at which time 50% of the RSUs will vest and if the share price is NIS 4.24 (equivalent to $1.23 as of December 31, 2019), 100% will vest. In the range between these two share prices, a relative quantity will vest. An acceleration event is defined as an event in which all the issued and outstanding share capital of the Company (including by way of a merger in which the Company's shareholders prior to the merger will hold less than 10% of the issued and outstanding share capital and voting rights in the company surviving the merger) is sold for consideration reflecting a price per share that is not lower than NIS 2.13 (equivalent to $061 as of December 31, 2019). The above vesting is also contingent upon continued employment.

On March 21, 2017, the Company's Board of Directors resolved to extend by five years, till January 20, 2026, the exercise period of a total of 18,890,695 options, consisting of 3,699,208 options with service conditions and 15,191,487 options with service conditions and market conditions, granted to officers and key employees of the Company and its subsidiaries. There was no change in the other terms of the options, including the exercise price and the vesting terms. The new exercise period is in line with the Company's compensation policy which allows an exercise period of up to ten years. On May 14, 2017 the Company's shareholders approved such extension with respect to the portion of such options granted to the Company's President and Chief Executive Officer (the "CEO").

The fair value of the extension of the exercise period of the options was $475 thousand. The assessment of the fair value of change on the service-based options has been executed using Black-Scholes valuation model. The assessment of the fair value of change on the options with service conditions and market conditions has been executed using a Monte-Carlo Simulation.

On March 14, 2018, the Company's Board of Directors approved a change of the First Trigger Price from NIS 2.13 (equivalent to $0.61 as of December 31, 2016) to NIS 1.70 (equivalent to $0.49 as of December 31, 2019) and a change of the January 21, 2020 vesting date to December 20, 2020. On May 23, 2018 the Company's shareholders approved such changes with respect to the portion of such options and RSUs granted to the CEO.

Such change triggered a new measurement of the fair value of the options and the RSUs. The fair value of the above changes was $239 thousand. The assessment has been executed using a Monte-Carlo Simulation.

3) Options to key employees, employees and directors with only service condition

On January 21, 2016, the Company's Board of Directors, as part of the share-based plan described in (2) above, also approved a grant of options that will vest as followed: 25% will vest and become exercisable one year following the date of grant and the remaining 75% will vest and become exercisable in 12 equal quarterly portions, beginning on the first anniversary of the date of grant.

Grants to other employees not participating in the key employees share-based plan, usually vest over three years, as follows: 2/3 will vest and be exercisable two years following the date of grant, and the remaining 1/3 will vest and become exercisable in four equal quarterly portions, at the end of each calendar quarter commencing on the second anniversary of the date of grant.

Options granted to directors during the years ended December 31, 2016, 2017 and 2019, were usually divided into three tranches, each equal to 33% of the amount of options granted. The allotment and the vesting period for the first tranche began on the date of grant; the allotment and the vesting period for the second tranche will begin on first anniversary of the date of grant; and the allotment and the vesting period for the third tranche will begin on the third anniversary of the date grant. Each tranche vests in four equal portions annually over four years. Upon the completion of a full term of service of a director (three years for external directors and one year for other directors) without being reelected; or (ii) upon termination of the service of a director in the middle of the term due to the consummation of an exit event, all outstanding stock options vested on the date of completion of the term or termination upon consummation of an exit event shall expire within 180 days thereafter and all outstanding unvested stock options shall accelerate and be fully vested on such date and shall expire within 180 days thereafter. The exercise price for each tranche is set on the date of allotment and is based on the average market price of the ordinary share prior to such allotment date plus 10%. The grants to directors were measured on the grant date for all three tranches using the binomial model. The option data in d. below include only options already allotted.

4) Grants of options and RSUs under the January 2016 plan

Grants in the reported years

In February 2017, the Company granted 711,000 options to 15 employees.

In May 2017, the Company granted 440,000 options to directors and 100,000 options were granted to a consultant.

In September 2017, the Company granted 2,281,218 options and 362,858 RSUs to 11 employees. In addition, 100,000 options were granted to a consultant.

In March 2018, the Company granted 1,802,512 options and 229,534 RSUs to 20 employees and officers. In addition, 263,681 options and 49,032 RSUs were granted to a consultant.

In August 2018, the Company granted 530,137 options and 17,160 RSUs to12 employees.

In January 2019, the Company granted 1,968,954 options and 339,495 RSUs to four grantees.

In May 2019, the Company granted 4,712,779 options and 610,829 RSUs to 41 grantees.

On May 20, 2019, the Company's Board of Directors resolved to allow nine grantees to be granted new 5,076,583 performance options and 1,039,314 performance RSUs in lieu of 5,076,583 performance options and 1,039,314 performance RSUs granted in the past that have not yet vested. The new performance options and RSUs will vest in December 2022 if the price of the Company's ordinary shares is, at such time, at least NIS 5.32 per share (equivalent to $1.54 as of December 31, 2019), or 50% of such options will vest if the price of our ordinary shares is, at such time, at least NIS 2.66 per share (equivalent to $0.77 as of December 31, 2019), or if, on the applicable measurement date, the price of the Company's ordinary shares is between these two vesting-trigger share prices, the percentage of options that will vest will be determined based on linear interpolation. Out of the new options and RSUs a grant of 3,019,864 performance shares and 609,232 performance RSUs to the CEO were approved by the Company's shareholders on March 18, 2020. All such employee accepted the Company's proposal and the new options and RSU were granted to all such employees.

In May 2019, the Company granted 1,210,000 options to seven directors.

In August 2019, the Company granted 4,884,966 options and 31,148 RSUs to 19 grantees.

In November 2019, the Company's Board of Directors approved a grant of a total of 825,000 options to 13 grantees.

Grants subsequent to December 31, 2019

In January 2020, the Company's Board of Directors approved a grant of a total of 3,942,284 options and 194,887 RSUs to 12 employees. The grant of 1,332,195 options and 194,887 RSUS was subject to the effectiveness of a Registration Statement on Form S-8, which became effective on March 4, 2020 and the grant of 1,676,425 options to the CEO was approved by the Company's shareholders on March 18, 2020.

b. Measurement of fair value of share-based payments

The fair value of the options with service conditions granted to employees, directors and consultants is measured according to the Black-Scholes valuation model. The fair value of performance options and performance RSUs granted to officers and key employees where vesting is made on the basis of the increase in the Company's share price and is measured by implementing the Monte Carlo Simulation. The options granted to directors, but which have not yet been allocated, nor set an exercise price, were priced using the binomial model.

Following are the parameters used to measure the fair value on the date of grant of share-based awards during the year ended December 31, 2019:

	Options with service conditions only	Options with service conditions and market conditions	RSUs
The number of shares arising from the exercise of the options and from the vesting of the RSUs (in thousands)	9,509	4,093	981
The parameters included when calculating fair value:			
The share price (at the grant date) (in NIS)	1.08 – 1.23	1.08 – 1.23	1.08 – 1.23
The exercise price (in NIS)	1.04 – 1.47	1.15 – 1.34	0.00 – 0.30
Expected volatility	51% – 54%	54%	54%
Expected lifetime	3.5– 7.5 years	6.98 years	N/A
Risk-free interest rate	0.34% – 1.50%	1.74%	N/A
Expected dividend rate	0%	0%	0%

The expected volatility was determined based on the historical volatility of the share price. The expected lifetime of the options is determined in accordance with management's estimation of the duration of the employees' holdings of such awards, given their position in the Company and the Company's past experience with respect to employee attrition. The risk-free interest rate is based on interest rates of Israeli government bonds denominated in NIS, whose remaining period is equal to the expected lifetime of the options.

c. Reconciliation of outstanding options and RSU's

The number of options and RSUs and the range of exercise price for every option:

	Year Ended December 31,					
	2019		2018		2017	
	Number of awards	Range of exercise price (NIS)	Number of awards	Range of exercise price (NIS)	Number of awards	Range of exercise price (NIS)
Outstanding at beginning of year	32,360,793	0.23 – 2.50	32,649,852	0.23 – 2.50	36,779,259	0.23 – 2.50
Granted during the year	13,601,699	1.04 – 1.47	3,016,330	1.02 – 1.29	3,742,218	1.17 – 1.68
Forfeited and expired during the year	(2,091,128)	-	(2,208,589)	-	(6,306,575)	-
Exercised during the year (2) (3)	(1,540,400)	0.23 – 0.48	(1,096,800)	0.23 – 0.51	(1,565,050)	0.23
Outstanding at end of year (1)	42,330,964	1.02 - 2.50	32,360,793	0.23 - 2.50	32,649,852	0.23 - 2.50
Exercisable at end of year	10,127,684	1.12 - 2.50	10,114,392	0.23 - 2.50	9,716,559	0.23 - 2.50
(1) Including:						
Options with service conditions only	21,954,791		15,661,344		16,753,449	
Options with service conditions and market conditions	20,376,173		16,699,449		15,896,403	
Total	42,330,964		32,360,793		32,649,852	

(2) The weighted average share price upon exercise of the options, for options exercised in the year ended December 31, 2019 and 2018 and 2017 was $0.36, $0.35 and $0.35, respectively.

(3) The weighted average remaining contractual life of the options and RSUs outstanding as of December 31, 2019, 2018 and 2017 was 5.59 years, 5.74 years and 6.23 years, respectively.

The number of RSUs with service conditions and market conditions and the range of exercise price for every RSU:

	Year Ended December 31,					
	2019		2018		2017	
	Number of awards	Range of exercise price (NIS)	Number of awards	Range of exercise price (NIS)	Number of awards	Range of exercise price (NIS)
Outstanding at beginning of year	3,441,420	0.00 – 0.30	3,242,632	0.00 – 0.30	3,398,889	0.00 – 0.30
Granted during the year	981,472	0.00	295,726	0.00 – 0.30	362,858	0.00
Forfeited and expired during the year	(94,497)	-	(96,938)	-	(519,115)	-
Outstanding at end of year	4,328,395	0.00 – 0.30	3,441,420	0.00 – 0.30	3,242,632	0.00 – 0.30

As a result of the grant of options and RSUs, the Company recorded for the years ended December 31, 2019, 2018 and 2017, a non-cash expense of $1,259 thousand, $1,021 thousand and $1,294 thousand, respectively. The balance of expenditure amounting to $1,868 thousand will be recorded by the Company over the remaining vesting period of the options and RSUs.

The total share-based compensation expenses relating to all of the Company's share-based awards recognized for the years ended December 31, 2019, 2018 and 2017 were included in items of the consolidated statements of operations, as follows:

	Year Ended December 31,		
	2019	2018	2017
	U.S. dollars in thousands		
Cost of revenues	$ 10	$ 10	$ 9
Selling and marketing expenses	382	295	336
Research and development expenses	171	104	87
General and administrative expense	672	612	740
Financial expenses from notes and loans	24	-	122
	$ 1,259	$ 1,021	$ 1,294

NOTE 17 – REVENUES

The Company operates in one business sector.

The following is a breakdown of revenues according to product groups:

	Year Ended December 31,		
	2019	2018	2017
	U.S. dollars in thousands		
WatchPAT and other related services	$ 28,988	$ 22,384	$ 18,105
EndoPAT and other related services	2,270	1,805	2,596
	$ 31,258	$ 24,189	$ 20,701

The following is a breakdown of revenues on the basis of geographical regions (based on the geographical location of the customer):

	Year Ended December 31,		
	2019	2018	2017
	U.S. dollars in thousands		
United States and Canada	$ 22,960	$ 17,582	$ 14,764
Japan	3,489	3,374	2,965
Europe	3,383	1,885	1,746
Asia Pacific (excluding Japan)	912	849	759
Israel	274	281	260
Others	240	218	207
	$ 31,258	$ 24,189	$ 20,701

The majority of the Company's long-lived assets are in Israel.

Revenue from major customers

	Year Ended December 31,		
	2019	2018	2017
	U.S. dollars in thousands		
Customer A	$ 7,002	$ 4,571	$ 3,622
Customer B	3,443	3,229	2,621
Customer C	2,048	2,870	2,510
	$ 12,493	$ 10,670	$ 8,753

NOTE 18 – COST OF REVENUES

	Year Ended December 31,		
	2019	2018	2017
	U.S. dollars in thousands		
Raw materials, auxiliary materials, subcontractors (including changes in inventories)	$ 2,555	$ 2,538	$ 1,767
Payroll and related expenses (including share-based payment)	2,470	1,806	1,956
Shipping	815	443	500
Depreciation and amortization	552	255	190
Other	592	684	589
	$ 6,984	$ 5,726	$ 5,002

NOTE 19 – FINANCIAL INCOME AND EXPENSES

	Year Ended December 31,		
	2019	2018	2017
	U.S. dollars in thousands		
Financial income from cash, deposits and investments:			
In respect of cash and investments in bank deposits and marketable securities*	$ 359	$ 93	$ 1,389
Other financial income	95	151	202
	$ 454	$ 244	$ 1,591
Financial expenses from lease, notes, loans and other:			
Convertible notes*	$ -	$ 393	$ 4,427
Short-term bank loan	364	316	-
Lease liabilities	279	-	-
Short-term shareholders' loans	-	85	-
Other financial expenses	432	359	427
Exchange rate differences	158	8	30
	$ 1,233	$ 1,161	$ 4,884
Gain on derivative financial instruments:			
Gain on revaluation to fair value of the warrants embedded in the convertible notes	$ -	96	2,141
Gain on revaluation to fair value of warrants	442	2,337	1,784
	$ 442	$ 2,433	$ 3,925

* Including the effect of changes in the exchange rate of the NIS against the dollar.

NOTE 20 – LOSS PER SHARE

a. Basic loss per share

The computation of basic loss per share was based on the net loss attributable to ordinary shares divided by the weighted average number of ordinary shares outstanding.

	Year Ended December 31,		
	2019	2018	2017
	U.S. dollars in thousands		
Net loss attributed to the ordinary shares	$ (5,268)	$ (1,729)	$ (5,301)

Weighted average number of ordinary shares

	Year Ended December 31,		
	2019	2018	2017
	Number of shares in thousands		
Balance at the beginning of the year	287,616	264,495	262,917
The effect of private placement	44,726	12,908	-
The effect of exercise of options into shares	306	262	1,192
Weighted average number of ordinary shares used in computation of basic loss per share	332,648	277,665	264,109

b. Diluted loss per share

The computation of diluted loss per share was based on the net loss attributed to the ordinary shares divided by the weighted average number of ordinary shares outstanding, after adjustment for all potentially dilutive ordinary shares, as follows:

	Year Ended December 31,		
	2019	2018	2017
	U.S. dollars in thousands		
Net loss used in computation of basic earnings per share	$ (5,268)	$ (1,729)	$ (5,301)
Changes in the fair value of the Viola warrants and Warrants (Series 4) (and in the year ended December 31, 2018 also of the warrants embedded in the convertible notes), which are classified as a liability	(442)	(2,433)	(1,784)
Net loss attributed to the ordinary shares (diluted)	$ (5,710)	$ (4,162)	$ (7,085)

Weighted average number of ordinary shares (diluted)

	Year Ended December 31,		
	2019	2018	2017
	Number of shares in thousands		
Weighted average number of ordinary shares used in computation of basic loss per share	332,648	277,665	264,109
Effect of the exercise of the Viola warrants and Warrants (Series 4) (and in the year ended December 31, 2018 also of the conversion of the convertible notes)	13,547	43,246	39,877
Weighted average number of ordinary shares used in computation of diluted loss per share	346,195	320,911	303,986

In the calculation of the weighted average number of ordinary shares (diluted) for the year ended December 31, 2019, 42,365,681 shares in respect of options and 4,328,395 shares in respect of RSUs granted to employees, directors and consultants were not included, due to their anti-dilutive effect.

In the calculation of the weighted average number of ordinary shares (diluted) for the year ended December 31, 2018, 32,412,199 shares in respect of options and 3,441,420 shares in respect of RSUs granted to employees, directors and consultants were not included, due to their anti-dilutive effect.

In the calculation of the weighted average number of ordinary shares (diluted) for the year ended December 31, 2017, 23,588,582 shares in respect of convertible notes, 32,719,056 shares in respect of options and 3,242,632 shares in respect of RSUs granted to employees, directors and consultants were not included, due to their anti-dilutive effect.

NOTE 21 – FINANCIAL INSTRUMENTS

This note provides qualitative information regarding the exposure to each of the following risks, and the Group's objectives, policy and processes relating to measurement of such risks. Quantitative disclosure is provided throughout these consolidated financial statements.

Credit risk

As of December 31, 2019 and 2018, the maximum exposure to credit risk is represented by the balance of financial assets. Management has developed policies for the authorization of credit to customers. The accounting exposure to credit risk is monitored constantly according to the behavior of payment of the debtors. Credit is assigned on a customer-by-customer basis and is subject to assessments which consider the customers' payment capacity, as well as past behavior regarding due dates, balances past due and delinquent accounts. Approximately 40%, 44% and 42%, respectively, of the Group's revenues in the years ended December 31, 2019, 2018 and 2017, arise from sales to single customers. Other than this, there are no other concentrations of credit risk.

The Group's revenues are primarily derived from sales to customers in the U.S., Japan and Europe. Management regularly monitors trade receivables and the financial statements include specific provisions for doubtful debt, which properly reflect, in the opinion of management, the inherent loss in debt whose collection is in doubtful.

The Group limits its exposure to credit risk by investing exclusively in bank deposits.

The maximum exposure to credit risk in respect of cash and cash equivalents, trade receivables, other accounts receivable and other investments, as of the report date, by geographic locations was as follows:

	December 31,	
	2019	2018
	U.S. dollars in thousands	
Israel	$ 12,894	$ 5,378
United States and Canada	9,362	6,337
Asia Pacific (including Japan)	409	936
Europe	1,773	998
Other	5	194
	$ 24,443	$ 13,843

Aging of receivables and impairment and weighted average loss rate:

	Weighted average loss rate	December 31, 2019		December 31, 2018	
		Gross amount	Impairment	Gross amount	Impairment
	%	U.S. dollars in thousands		U.S. dollars in thousands	
Not in arrears	1.5	$ 7,851	$ 117	$ 5,464	$ 64
In arrears up to three months	1.5	703	10	1,030	12
In arrears up to six months	1.5	98	1	221	3
In arrears up to 12 months	17.5	20	4	188	32
In arrears over 12 months	100.0	361	361	159	159
		$ 9,033	$ 493	$ 7,062	$ 270

Movements in the allowance for impairment of receivables during the year were as follows:

	Year Ended December 31,	
	2019	2018
	U.S. dollars in thousands	
Balance at beginning of year	$ 270	$ 540
Recognized impairment loss	349	104
Bad debt	(126)	(374)
Balance at end of year	$ 493	$ 270

Liquidity risk

The Group's approach to managing liquidity is to ensure, as far as possible, that it will always have sufficient liquidity to meet its liabilities when due, under both normal and stressed conditions, without incurring unacceptable losses or risking damage to the Group's reputation.

The Group ensures that it has sufficient cash on hand for payment of expected operating expenses, including any amounts required to fulfill financial obligations. In addition to cash flows provided by its operating activities, in order to meet the Company's overall liquidity needs for operations, servicing debt and funding capital expenditures, the Company relies on cost-cutting and operating improvements to optimize capacity utilization and minimizing loss, as well as borrowing under credit facilities, proceeds of debt and equity offerings.

Below is an analysis of contractual maturities of financial liabilities, including estimated interest payments, as of December 31, 2019 and 2018:

	Carrying Amount	Contractual Cash flow	Up to 6 months	6-12 months	1-2 years	2-5 years	Over 5 years
	U.S. dollars in thousands						
December 31, 2019							
Non-derivative financial liabilities							
Short-term bank loans	$ 5,000	$ 5,056	$ 5,056	$ -	$ -	$ -	$ -
Trade payables	2,028	2,028	2,028	-	-	-	-
Other long-term liabilities	1,260	1,260	-	-	123	382	755
Lease liabilities (including current maturities)	2,598	3,424	553	528	804	613	926
Other accounts payable	4,361	4,361	4,361	-	-	-	-
Total	$ 15,247	$ 16,129	$ 11,998	$ 528	$ 927	$ 995	$ 1,681
December 31, 2018							
Non-derivative financial liabilities							
Convertible notes, including current maturities and accrued interest	$ 5,000	$ 5,065	$ 5,065	$ -	$ -	$ -	$ -
Trade payables	1,517	1,517	1,517	-	-	-	-
Other long-term liabilities	1,052	1,052	-	-	-	-	1,052
Other accounts payable	2,767	2,767	2,668	99	-	-	-
Total	$ 10,336	$ 10,401	$ 9,250	$ 99	$ -	$ -	$ 1,052

Equity Risk

Changes in the fair value of the Viola Warrants and the Warrants (Series 4) that were denominated in a currency other than the Company's functional currency affect the statements of operations. However, they did not imply any risk or variability in cash flows, considering that through their exercise, the Company would have settled the aforementioned derivatives through issuance of its own shares rather than in cash.

Foreign Currency risk

The Group is exposed to foreign currency risk with respect to sales, purchases, payroll and services expenses and loans denominated in non-dollar currencies (primarily NIS, but also Euro and Japanese yen) used by the companies in the Group. The currencies in which most expenses are denominated are the dollar, NIS, Euro and Japanese yen.

Most of the Group's revenues are denominated in its functional currency (the dollar) and some in Euro, whereas the Group's payroll expenses in Israel are denominated in NIS. Therefore, the Group is exposed to fluctuations in the dollar/NIS and dollar/Euro exchange rates and strives to mitigate currency risk by maintaining liquid investments and cash positions in short-term NIS-denominated deposits, in NIS and in Euro.

The Group's exposure to the Israeli CPI and foreign currency risk is as follows:

	Dollars	Currency different from dollar			Non-monetary items	Total
		NIS	Euro	Other currencies		
	U.S. dollars in thousands					
December 31, 2019						
Assets						
Cash and cash equivalents	$ 13,178	$ 1,254	$ 587	$ 96	$ -	$ 15,115
Trade receivables (including long-term trade receivables)	7,750	96	694	-	-	8,540
Other receivable	338	62	2	-	1,002	1,404
Inventories	-	-	-	-	3,363	3,363
Long-term restricted deposits	111	275	-	-	-	386
Long-term prepaid expenses	-	-	-	-	90	90
Property and equipment and intangible assets	-	-	-	-	1,867	1,867
Right-of-use assets	-	-	-	-	2,442	2,442
	21,377	1,687	1,283	96	8,764	33,207
Liabilities						
Sort-term bank loan	5,000	-	-	-	-	5,000
Trade payables	779	1,215	34	-	-	2,028
Other accounts payable (including accrued expenses)	2,940	1,366	54	-	412	4,772
Provisions	-	-	-	-	273	273
Lease liabilities (including current maturities)	714	1,884	-	-	-	2,598
Employee benefits	-	-	-	-	612	612
Other long-term accounts payable	1,060	200	-	-	-	1,260
	10,493	4,665	88	-	1,297	16,543
Total exposure in the statements of financial position in respect of financial assets and financial liabilities	$ 10,884	$ (2,978)	$ 1,195	$ 96	$ 7,467	$ 16,664
December 31, 2018						
Assets						
Cash and cash equivalents	$ 4,088	$ 1,885	$ 426	$ 72	$ -	$ 6,471
Trade receivables (including long-term trade receivables)	6,236	229	327	-	-	6,792
Other receivable	247	32	2	-	737	1,018
Inventories	-	-	-	-	2,235	2,235
Long-term restricted deposits	109	190	-	-	-	299
Long-term prepaid expenses	-	-	-	-	66	66
Property and equipment and intangible assets	-	-	-	-	1,511	1,511
	10,680	2,336	755	72	4,549	18,392
Liabilities						
Sort-term bank loan	5,000	-	-	-	-	5,000
Trade payables	714	798	5	-	-	1,517
Other accounts payable (including accrued expenses)	1,965	761	50	-	321	3,097
Provisions	-	-	-	-	215	215
Derivative instruments	-	442	-	-	-	442
Employee benefits	-	-	-	-	381	381
Other long-term accounts payable	947	105	-	-	-	1,052
	8,626	2,106	55	-	917	11,704
Total exposure in the statements of financial position in respect of financial assets and financial liabilities	$ 2,054	$ 230	$ 700	$ 72	$ 3,632	$ 6,688

Sensitivity analysis

A stronger dollar against the following currencies at the end of each reporting period, and an increase in the Israeli CPI would have increased (decreased) equity and net income/loss by the following amounts (after-tax). The following analysis is based on changes to exchange rates, which the Group believes to be reasonably possible as of the end of the reported year. This analysis assumes all other variables, especially interest rates, remain constant.

	December 31, 2019	
	Equity	Profit (loss)
	U.S. dollars in thousands	
An increase in the exchange rate of the following currencies against the dollar:		
NIS/dollar by 5%	$ (149)	$ (149)
Euro/dollar by 5%	60	60

The weakening of these currencies against the dollar at a similar rate as of December 31, 2019 had a similar effect, albeit in the opposite direction, assuming that all other variables remain constant.

	December 31, 2018	
	Equity	Profit
	U.S. dollars in thousands	
An increase in the exchange rate of the following currencies against the dollar:		
NIS/dollar by 5%	$ 12	$ 12
Euro/dollar by 5%	35	35

The weakening of these currencies against the dollar at a similar rate as of December 31, 2018 had a similar effect, albeit in the opposite direction, assuming that all other variables remain constant.

Fair value of financial instruments measured at fair value, for disclosure purposes only

The carrying amount of the cash and cash equivalents, trade receivables, other accounts receivable, bank deposits, pledged deposits, trade payables, and other accounts payable, lease liabilities and derivatives is identical or approximate to their fair values due to the lifetime of these items.

The fair value of other financial liabilities and their carrying amounts, as presented in the statements of financial position, are as follows:

	December 31, 2019		December 31, 2018	
	Carrying amount	Fair value	Carrying amount	Fair value
	U.S. dollars in thousands			
Liabilities:				
Liability in respect of royalties to the IIA and other government institutions	$ 1,260	$ 527	$ 1,151	$ 490

Fair value hierarchy of financial instruments measured at fair value

The following table shows an analysis of the financial instruments measured at fair value using the valuation method.

	December 31, 2018
	Level 3
	U.S. dollars in thousands
Financial instruments - derivative instruments	$ 442

The change from the opening balance to the closing balance of the financial instruments measured at fair value, categorized within Level 3 hierarchy, in the years ended December 31, 2019, 2018 and 2017, respectively, was caused by the revaluation to fair value of the derivatives in the amount of $442 thousand, $2,433 thousand and $3,925 thousand, as described in Note 19.

NOTE 22 – RELATED PARTIES

a. Compensation

Compensation to key executives includes:

	Year Ended December 31,					
	2019		2018		2017	
	Number of persons	Amount U.S. dollars in thousands	Number of persons	Amount U.S. dollars in thousands	Number of persons	Amount U.S. dollars in thousands
Employee compensation	8	$ 2,201	7	$ 1,835	7	$ 1,384
Share-based payment	8	850	7	702	7	1,083
Total		$ 3,051		$ 2,537		$ 2,467

Compensation to directors who are not employed by the Company includes:

	Year Ended December 31,					
	2019		2018		2017	
	Number of persons	Amount U.S. dollars in thousands	Number of persons	Amount U.S. dollars in thousands	Number of persons	Amount U.S. dollars in thousands
Director compensation	8	$ 213	8	$ 208	9	$ 195
Share-based payment	8	88	8	76	9	111
Total		$ 301		$ 284	9	$ 306

	Year Ended December 31,			December 31,	
	2019	2018	2017	2019	2018
	Transaction amounts U.S. dollars in thousands			Carrying amount U.S. dollars in thousands	
Key executives (including directors) of the Company	$ 3,352	$ 2,821	$ 2,773	$ 383	$ 341

b. Capital reserve for transactions with shareholders

Any difference between the nominal value, i.e., the cash amount received, of the loans provided by shareholders, acting in the capacity of shareholders, and their fair value on initial recognition is reflected in equity as a shareholder contribution. Upon an early extinguishment of such debt, any cost incurred as a result of the early extinguishment is reflected in equity as a shareholder distribution.

c. Insurance and indemnification of key management personnel

The Company's directors and officers are covered by a directors' and officers' liability insurance policy. In addition, the Company has undertaken to enter into indemnification agreements with each of its directors and officers undertaking to indemnify them to the fullest extent permitted by law.

d. Marketing agreement with a former controlling shareholder in the Company

In 2014, the Company entered into a co-marketing agreement with Medtronic, Inc. ("Medtronic") (which at the time was a controlling shareholder) that was subsequently amended in 2015. According to the agreement (as amended), Medtronic was granted exclusive rights to co-market, with the Company, the Company's WatchPAT products within the Company's Total Sleep Solution framework to electrophysiologists (physicians who specialize in cardiology arrhythmias) in the U.S. Pursuant to this agreement, Medtronic markets WatchPAT as part of a comprehensive solution offered by Medtronic to physicians. The agreement is currently renewable automatically for 30 day-periods, unless earlier terminated by either party upon 14 days prior notice.

In the years ended on December 31, 2019, 2018 and 2017, the Company recognized revenues from sales to customers (third parties) under this agreement in the amount of approximately $203 thousand, $207 thousand and $307 thousand, respectively. The total sales commissions to Medtronic in these years under this agreement totaled approximately $41 thousand, $41 thousand and $61 thousand, respectively.

NOTE 23 – SUBSEQUENT EVENTS:

a. 2020 Public Offering

See Note 1b.

b. Grant of stock options and RSUs

See Note 16a(4).

c. Amendment of the bank line of credit

See Note 8a.

d. Effects of the coronavirus outbreak

In December 2019, a novel strain of coronavirus was reported in Wuhan, China. While, initially, the coronavirus outbreak was largely concentrated in China, it has now spread globally, including to the U.S., Europe, Japan and Israel. Many countries around the world, including in the U.S., Europe, Japan and Israel, have since implemented significant measures in an attempt to control the spread of the virus, including temporary limitations on travel, public gatherings, including work place gathering access to various facilities as well as in healthcare institutes, and other material limitations. These measures have resulted in work stoppages, in many countries as well as in China where part of the Company's suppliers are located, which disrupted the Company's supply chain. As such, there is no assurance that the Company will not suffer additional supply chain interruptions.

Furthermore, limitations on access to healthcare facilities, including those who typically service the Company's products, could adversely impact demand for the Company's multi-use reusable products. At the same time, in the U.S., the American Academy of Sleep Medicine (AASM) has recently issued guidance encouraging sleep clinicians to use disposable single use home sleep tests, instead of traditional in-lab polysomnography (PSG) tests or multi use reusable home sleep test, to reduce risk of infections, especially during the coronavirus outbreak. While demand for the Company's multi use reusable home sleep test devices may be adversely impacted by the coronavirus outbreak, the Company is changing its manufacturing mix to prioritize WatchPAT ONE production and accelerating its efforts to obtain regulatory approvals for its disposable WatchPAT ONE in Europe and other parts of the world. To that end, the Company is also currently investing considerable resources to increase its WatchPAT ONE production capacity, while given the rapidly changing market environment, there is no certainty as to when such investments and regulatory approvals will materialize into additional WatchPAT ONE sales.

The extent to which the coronavirus impacts the Company's manufacturing, operations, demand for its products and business results, will depend on future developments, which are rapid and highly uncertain and cannot be predicted with confidence, including the duration and severity of the outbreak, and the actions that may be implemented in an attempt to contain the coronavirus or treat its impact. As such, the continued spread of the coronavirus globally and uncertainty about current global economic conditions, could adversely impact the Company's operations and workforce, including its manufacturing and sales and marketing activities, which in turn, could have a material adverse impact on the Company's business, financial condition and results of operation.

Exhibit 2.4/A

February 9, 2020

To:

Mizrahi Tefahot Bank Ltd. ("Holder")

Dear Holder,

RE: EXTENSION OF PREVIOUS WARRANTS

Itamar Medical Ltd. (hereinafter: the "**Company**") currently intends to enter into an amendment to the framework agreement with Holder, under which the existing framework agreement shall be extended, and certain additional terms shall be amended.

In the framework of the negotiations, and in order to induce the Holder to extend the term of the existing framework agreement and to amend it, Company has agreed to extend the warrant period for all outstanding warrants granted to Holder, as set forth below.

In light of the above, we hereby confirm that, effective as of the date of this letter:

1. The original Warrant issued to the Holder on May 14, 2017, is hereby extended until November 30, 2023 (clause 3.1 to the Warrant Agreement will be amended accordingly).
2. The original Warrant issued to the Holder on March 12, 2019, is hereby extended until November 30, 2023 (clause 3.1 to the Warrant Agreement will be amended accordingly).

All other terms and conditions of the abovementioned Warrants shall remain unchanged, in full force and effect.

Sincerely,

_____
Itamar Medical Ltd.
By: _____
Title:_____
Date: February 9, 2020

Exhibit 2.5

WARRANT AGREEMENT

This Warrant Agreement (the "**Agreement**"), is made as of the 9 day of February, 2020 (the "**Effective Date**") by and between:

(1) Itamar Medical Ltd. (the "**Company**"), an Israeli public company (Company No. 51-243421-8), whose shares are traded on the Tel-Aviv Stock Exchange ("**TASE**"); and

(2) Mizrahi Tefahot Bank Ltd. (the "**Bank**"), an Israeli Company formed under the laws of the State of Israel.

In connection with the Credit Facility Agreement between the Company and the Bank dated February 9, 2020 (the "**Credit Agreement**"), the Company agrees to grant the Bank an additional Warrant (the "**Warrant**") to purchase up to 359,140 ordinary shares with a nominal value NIS 0.01 each of the Company ("**Ordinary Shares**").

In consideration of the foregoing and for the purpose of defining the terms and provisions of the Warrant and the respective rights and obligations thereunder, the Company and the Bank hereby agree as follows:

1. Issue of Warrant

1.1. General. The Company hereby grants to the Bank an assignable (only to Permitted Transferees (as defined below) Warrant to purchase 359,140 Ordinary Shares (the "**Warrant Shares**"). The Warrant may only be assigned to a Permitted Transferee in the event that the Bank makes a corporate decision to sell a portfolio of its holdings in startup companies (comprising of at least two companies), or in the event that the Bank is required by law (including instructions by the Israeli Banking Supervision authorities) to sell and/or transfer this Warrant and/or the Warrant Shares.

"**Permitted Transferee**" shall mean any entity in which the Bank has an equity interest of at least 5% or to any other reputable financial institution, bank or venture capital fund.

1.2. Registration. The Warrant shall be registered on the books of the Company when issued. Upon issuance of this Warrant, the Company shall provide the Bank with a confirmation from the Tel Aviv Stock Exchange Ltd. (the "**TASE**"), that the Warrants Shares will be registered for trading upon exercise hereof in accordance with its terms and the applicable TASE rules.

1.3. Limited Rights of Warrant-Holder. Nothing contained in this Agreement or in the Warrant shall, prior to an exercise thereof, be construed as conferring upon the Bank or any Permitted Transferee of the Bank (collectively, the "**Warrant-Holder**") any rights as a shareholder of the Company, including (without limitation) the right to vote, receive dividends, consent or receive notices as a shareholder.

1.4. NEITHER THE SECURITIES REPRESENTED BY THIS WARRANT NOR THE SECURITIES INTO WHICH THIS WARRANT IS EXERCISABLE HAVE BEEN REGISTERED WITH THE SECURITIES AND EXCHANGE COMMISSION OR THE SECURITIES COMMISSION OF ANY STATE IN RELIANCE UPON AN EXEMPTION FROM REGISTRATION UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"), AND, ACCORDINGLY, MAY NOT BE OFFERED OR SOLD, EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT OR PURSUANT TO AN AVAILABLE EXEMPTION FROM, OR IN A TRANSACTION NOT SUBJECT TO, THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT AND IN ACCORDANCE WITH APPLICABLE STATE SECURITIES LAWS AS EVIDENCED BY A LEGAL OPINION OF COUNSEL REASONABLY ACCEPTABLE TO THE COMPANY TO SUCH EFFECT, THE SUBSTANCE OF WHICH SHALL BE REASONABLY ACCEPTABLE TO THE COMPANY.

2. Exercise; Exercise Price

2.1. The exercise price per each Warrant Share shall be NIS 1.044 (One New Israeli Shekel, and 4.4 Agorot) *[average closing price over last 30 trading days prior to November 25, 2019 (Date of Board Resolution)]* per Warrant Share (the "**Exercise Price**"). The Exercise Price shall be adjusted from time to time pursuant to the terms set forth below.

2.2. Exercise on a Net-Issuance Basis. In lieu of payment to the Company of the Exercise Price per Warrant Share, as set forth in Subsection 2.1 above, a Warrant-Holder may exercise the Warrant (or any portion thereof), into the number of Ordinary Shares calculated pursuant to the following formula, by delivering the Warrant to the Company, accompanied by a written notice of exercise, specifying the number of shares for which the Warrant-Holder desires to exercise the Warrant:

$$X = \frac{Y(A - B)}{A}$$

Where:

X = the number of Warrant Shares to be issued to the Warrant-Holder;

Y = the number of Warrant Shares with respect to which the Warrant Holder desires to exercise the Warrant;

A = the Fair Market Value (as defined below) of one Warrant Share; and

B = the Exercise Price of a Warrant Share, as adjusted.

"**Fair Market Value**" of a Warrant Share shall mean:

(i) the closing price of an Ordinary Share, as reported on the principal stock exchange on which the Company's shares are traded at such time one (1) trading day immediately preceding the delivery of the Purchase Form / exercise notice; or

(ii) If the Fair Market Value for the Warrant Shares cannot be determined in the manner set forth in sub section (i) above, then such Fair Market Value shall be as determined in good faith by the Company and the Warrant-Holder or, if the Company and the Warrant-Holder fail to reach an agreement, by any third party mutually agreed to by the Company and the Warrant-Holder who shall bear the cost of such third party in equal parts.

3. Exercise Period

3.1. The Warrant-Holder may exercise part or all of the Warrant at any time, and from time to time, in accordance with the provisions of this Agreement, during the period commencing on the Effective Date and terminating on the fourth anniversary thereof (i.e. at 23:59 Israel time on November 30, 2023) (the "**Exercise Period**"). The Warrant-Holder shall not exercise part or all of the Warrant on the record date of a Company Event (as defined hereunder); provided that if the last day of the Exercise Period occurs on such record date of a Company Event, then the Exercise Period will be automatically extended, without the need for any further approval of the Company, until the 7^{th} day following such record date. The Company shall inform the Holder of the extension of the Exercise Period as aforesaid.

Notwithstanding the foregoing, if the last day of the Exercise Period occurs during a period that was determined by the Company as a blackout period due to the existence or potential for the existence of inside information (as defined under the Israeli Securities Law, 1968) including due to a Company Event (hereinafter the: **"Blackout Period"),** then the Exercise Period will be automatically extended, without the need for any further approval of the Company, until the 30th day following the end of the Blackout Period. The Company shall inform the Holder of the extension of the Exercise Period as aforesaid.

"Company Event" means - (a) publication of a prospectus or shelf offering report in connection with the raising of capital from the public; (b) signing of a merger agreement; (c) signing of an agreement for the acquisition of the Company's business; (d) distribution of dividend; (e) distribution of bonus shares; (f) publication of a prospectus or shelf offering report in connection with raising capital from existing shareholders of the Company; (g) signing an investment agreement or a loan agreement to the Company.

3.2. Upon the earlier of: (i) the expiry of the Exercise Period; or (ii) the exercise of this Warrant in full; the Warrant shall become null and void and shall no longer remain outstanding or exercisable.

3.3. Automatic Exercise. If at the time of expiry of the Warrant Period for any portion of the Warrant, a portion of the Warrant has not been exercised, such portion of the Warrant will be deemed to have been exercised in accordance with the provisions of Section 2.2 at the date of expiry of the Warrant Period.

4. Warrant Shares

4.1. Reservation of Warrant Shares. The Company represents that it has reserved and shall at all times keep reserved, for so long as any Warrant remains outstanding, out of its authorized share capital, such number of Ordinary Shares as may be subject to purchase under the outstanding Warrant.

4.2. Exercise of Warrants; Issue of Warrant Shares.

4.2.1. The Warrant Holder shall exercise the Warrant (or any portion thereof) by delivering to the Company a duly executed Purchase Form, a form of which is attached to this Agreement, provided, however, that in each single exercise of a portion of the Warrant (except for the last portion), the Warrant Holder will exercise such portion in an exercise amount of at least NIS 200,000.

4.2.2. Within three (3) business days following surrender of this Warrant and (unless the Warrant Holder elects to exercise the Warrant on a net-issuance basis) payment of the Exercise Price as set forth herein, the Company shall issue and cause to be delivered to the Nominee Company of Mizrachi Tefahot Bank Ltd. (the "**Nominee Company**") a certificate or certificates (the "**Warrant Share Certificate**") representing the number of Warrant Shares so purchased upon the exercise of the Warrant in the name of the Nominee Company. The Warrant Share Certificate shall be credited to the bank account/TASE member account of the Warrant-Holder, details of which shall be provided by the Warrant-Holder to the Company within the Purchase Form.

4.2.3. Subject to applicable laws, rules and regulations (including stock exchange rules), such Warrant Share Certificate or Certificates shall be deemed to have been issued and any person so designated to be named therein shall be deemed to have become a holder of such Warrant Shares as of the date of surrender of the Warrant being exercised and payment of the Exercise Price, to the extent applicable, notwithstanding that the Warrant Share Certificate or Certificates representing such shares shall not actually have been delivered or that the shareholders register of the Company has yet to be updated.

4.2.4. Each Warrant shall be exercisable, at the election of the Warrant-Holder, either in full or from time to time in part and, in the event of a partial exercise of the Warrant at any time prior to the expiry of the Exercise Period, a new certificate evidencing the remaining amount applicable to the Warrant will be issued to the Warrant Holder by the Company.

4.2.5. Notwithstanding anything to the contrary, any or all of the Warrants may not be exercised on the record date with respect to the distribution of bonus shares, offer by way of rights issue, distribution of dividends, consolidation of share capital, consolidation of shares, reduction or split in share capital (each hereinafter referred to as a "**Corporate Event**"). In addition, if the ex-date with respect to a Corporate Event occurs before the record date relating to such Corporate Event, then the exercise of Warrants shall not occur on such ex-date.

5. Adjustment of Exercise Price and Number of Warrant Shares

Subject to applicable laws, rules and regulations (including stock exchange rules), the Exercise Price and/or the number and type of securities purchasable upon the exercise of the Warrant, as applicable, shall be subject to adjustment from time to time (at any time during the Exercise Period and prior to the exercise of the Warrant in full) upon the happening of certain events, as follows:

5.1. Bonus Shares. In the event the Company distributes bonus shares, the Warrant-Holder upon exercising the Warrant shall be issued by the Company (for the exercise price payable upon such exercise, if any), the Ordinary Shares as to which he is exercising the Warrant and, in addition thereto (at no additional cost), such number of shares of the class or classes in which such bonus shares were distributed, on the same terms and conditions as offered to the other shareholders, which he would have received if he had been the holder of the Ordinary Shares as to which he is exercising the Warrant at all times between the date of issuance of the Warrant and the date of its exercise.

In the event that the Warrant Holder will exercise the Warrant on a Net-Issuance Basis (in accordance with Section 2.2 above) immediately following a distributions of bonus shares, then the Exercise Price per Warrant Share will be reduced by the ratio of the bonus shares distribution (*i.e.*, the number of bonus shares distributed divided by the total number of Ordinary Shares immediately following the said distribution of bonus shares), and the number of Warrant Shares to be issued to Warrant Holder on a Net-Issuance Basis shall be calculated based on the following formula:

Y= R*X *(MP- (EP/R))/MP	
Y	The number of shares issued upon the exercise of the Warrant following the issuance of bonus shares.
X	Number of Ordinary Shares exercised by the Warrant Holder.
R	The result of: (i) the total number of Ordinary Shares immediately following the distribution of bonus shares; divided by (ii) the total number of Ordinary Shares immediately prior to the distribution of bonus shares.
MP	The price of an Ordinary Share on the stock exchange immediately following the distribution of bonus shares.
EP	Exercise Price

For illustration purposes only, in the event the Company granted the Bank a Warrant to 100 Ordinary Shares at an Exercise Price of NIS55 per Warrant Share, and following that the Company distributed bonus shares at a 1:1 ratio while the price of an Ordinary Share on the TASE prior to the distribution of the bonus shares was NIS 80 and immediately following such distribution of bonus shares was NIS 40, then upon the cashless exercise of such Warrant immediately following the distribution of bonus shares, the number of Warrant Shares issued to the Participant would be 62 Ordinary Shares pursuant to the following calculation:

[200 x (40-27.5)/40] = 62.5

The number of Warrant Shares resulting as of the said distribution shall be 62 Ordinary Shares only as no fractional shares will be issued.

5.2. Rights Offering**.** In the event of a rights offering conducted by the Company, the number of Warrant Shares issued as a result of the exercise of the Warrant shall be adjusted to the benefit component (מרכיב ההטבה) in the rights offering as reflected in the ratio between the closing price of an Ordinary Share on the stock exchange on the last trading prior to the ex-day and the basis price of an Ordinary Share on the stock exchange ex-rights. Notwithstanding the above, the Exercise Price shall not be reduced in any event to less than the higher of: (i) nominal value of an Ordinary Shares; (ii) minimum exercise price according to the stock exchange by laws (if and to the extent that the stock exchange by laws indeed imposes such a limitation on such an issuance of Warrant Shares).

5.3. Dividend. In the event the Company distributes cash dividends, then the Exercise Price for each Ordinary Share underlying such Warrant, not exercised prior to such record date, shall be reduced, as of the record date determining the right to receive such dividend, by the gross dividend amount so distributed per Warrant Share.

However, in any event, the Exercise Price shall not be reduced to less than the higher of: (i) the par value of an Ordinary Share; (ii) minimum exercise price according to the stock exchange by laws (if and to the extent that the stock exchange by laws indeed imposes such a limitation on such an issuance of Warrant Shares).

5.4. Adjustment Upon a Consolidation or Merger. In the event that the Company shall consolidate or merge with or into another corporation or convey all or substantially all of its assets to another corporation or other entity, then, in each such case, the Warrant Holder shall, upon any exercise of the Warrant, at any time after the consummation of such consolidation, merger, or conveyance, be entitled to receive, in lieu of the Warrant Shares or other securities and property receivable upon the exercise of the Warrant prior to such consummation, the shares or other securities or property to which the Warrant-Holder would have been entitled upon the consummation of such consolidation, merger or conveyance if the Warrant Holder had exercised the Warrant immediately prior thereto, all subject to further adjustment as provided in this Section; and in each such case, the terms of the Warrant (including exercisability, transfer and adjustment provisions of the Warrant) shall be applicable to the shares or other securities or property receivable upon the exercise of the Warrant after the consummation of such consolidation, merger or conveyance.

5.5. Adjustment Upon Reorganization**.** If the Company shall subdivide or combine its Ordinary Shares, the Exercise Price shall be proportionately reduced in case of subdivision of shares (and the number of Ordinary Shares purchasable upon the exercise of the Warrant shall be proportionately increased), as at the effective date of such subdivision, or if the Company shall fix a record date for the purpose of so subdividing, as at such record date, whichever is earlier, or shall be proportionately increased in the case of combination of shares (and the number of Ordinary Shares purchasable upon the exercise of the Warrant shall be proportionately reduced), as at the effective date of such combination, or, if the Company shall fix a record date for the purpose of so combining, as at such record date, whichever is earlier.

5.6. Adjustment Upon spin-off**.** In the event that the Company shall issue securities of a subsidiary to its shareholders (as a result of a split-off, spin-off or the like) then the Exercise Price for each Ordinary Share underlying the Warrant (not exercised prior to such record date) shall be adjusted by multiplying the Exercise Price in the ratio between: (1) the basis price of an Ordinary Share on the stock exchange ex- split-off, spin-off or the like; and (2) the closing price of an Ordinary Share on the stock exchange on the last trading prior to the ex-day for such a split-off, spin-off or the like.

Notwithstanding the above, the Exercise Price shall not be reduced in any event to less than the higher of: (i) nominal value of an Ordinary Shares; (ii) minimum exercise price according to the stock exchange by laws (if and to the extent that the stock exchange by laws indeed imposes such a limitation on such an issuance of Warrant Shares).

5.7. No Impairment. The Company will not, through any reorganization, recapitalization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities, amendment of its memorandum or articles of association or any other organizational document, or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms to be observed or performed hereunder by the Company, but will at all times in good faith assist in the carrying out of all the provisions of the Warrant and in the taking of all such action as may be reasonably necessary or appropriate in order to protect the rights of the Warrant-Holder against impairment.

5.8. Notice of Adjustments. Upon the occurrence of each adjustment or readjustment of the Exercise Price pursuant to the provisions contained herein, the Company, at its expense, shall promptly compute such adjustment or readjustment in accordance with the terms hereof and prepare and furnish to the Warrant-Holder a certificate setting forth each adjustment or readjustment and showing in detail the facts upon which such adjustment or readjustment is based.

5.9. Notice of Record Date. In the event of any taking by the Company of a record of the holders of any class of securities for the purpose of determining the holders thereof who are entitled to receive any dividend (including a cash dividend) or other distribution, any right to subscribe for, purchase or otherwise acquire any shares of any class or any other securities or property, or to receive any other right, the Company shall provide to the Warrant-Holder a notice (including through public filings), which shall be sent simultaneously with the notice sent to other shareholders of the Company, specifying the date on which any such record is to be taken for the purpose of such dividend, distribution or right, and the amount and character of such dividend, distribution or right.

5.10. No Fractional Shares. No fractional shares shall be issued upon exercise of all or any portion of the Warrant, and the number of Warrant Shares to be issued shall be rounded to the nearest whole share (with cash being paid by the Company for any unissued fractional shares).

6. Notice of Events

In the event that the Company files an immediate report regarding: (i) issuance of bonus shares (according to Section 5(i) above); or (ii) issuance of rights (according to Section 5(ii) above); or (iii) distribution of dividend (according to Section 5(iii) above); or (iv) a merger transaction (according to Section 5(iv) above); or (v) a reorganization (according to Section 5(v) above); or (vi) a spin off (according to Section 5(vi) above); or (vii) issuance of any securities of the Company other than: (i) issuance of securities under any of the Company's Employee Stock Options Plan; (ii) securities issued following an exercise of any of the securities mentioned in sub section (i); or (viii) the sale of all or substantially all of the Company assets to another person; or (ix) a voluntary or involuntary dissolution, liquidation or winding-up of the Company ("**Special Event**") the Company shall, on the same day it files such an immediate report, provide a copy of such immediate report to the Warrant-Holder (the "**Company Notice**").

7. Representations, Warranties and Covenants of the Company

The Company hereby represents and warrants to the Bank that as of the Effective Date:

7.1. This Warrant has been duly authorized and executed by the Company and is a valid and binding obligation of the Company enforceable in accordance with its terms. The grant of this Warrant and the issuance of the Warrant Shares in accordance herewith shall not entitle any third party, including any shareholders of the Company, to any pre-emptive rights, anti-dilution rights, or other benefits.

7.2. The Warrant Shares when issued in accordance with the terms hereof shall be duly authorized, will be validly issued, fully paid and non-assessable, not subject to any preemptive rights, and issued free and clear of all debts, liens, encumbrances, taxes, charges, equities, claims, any rights of third parties and any other liabilities.

7.3. The execution and delivery of this Warrant are not, and the issuance of the Warrant Shares upon exercise of this Warrant in accordance with the terms hereof will not, conflict with the Articles of Association of the Company, and do not contravene any law, governmental rule or regulation, judgment or order applicable to the Company, and do not and will not conflict with or contravene any provision of, or constitute a default under, any indenture, mortgage, contract or other instrument of which the Company is a party or by which it is bound or require any waiver or the consent or approval of, the giving of notice to, the registration with or the taking of any action in respect of or by, any government authority or agency or other person known to the Company other than the need to file an immediate report regarding the issuance of the Warrant Shares (if and when they are issued).

7.4. Without derogating from the generality of the aforesaid, the Company has fulfilled all requirements of the Articles of Association and any other agreement and/or document by which the Company is bound in respect of any limitations on: (i) the issuance of this Warrant; or (ii) the right of the Warrant-Holder to exercise the Warrant and purchase Warrant Shares.

7.5. The Company's: (i) authorized share capital; and (ii) issued and outstanding share capital; and (iii) securities convertible into Company's shares; are as set in the Company's public report a copy of which is attached in Exhibit 7.5 hereto. Except as set forth in Exhibit 7.5, there are no outstanding options, warrants and/or convertible instruments.

7.6. The Financial Statements (as defined below), as were provided to the Bank prior to the date hereof, (a) were prepared in accordance with International Financial Reporting Standards ("IFRS"); (b) fairly present the Company's financial condition and the results of its operations as of the relevant dates thereof and for the periods covered thereby.

"**Financial Statement**" – the Company's audited consolidated financial statements for the period of 12 month that ended on December 31, 2018 that were published on the Israeli Securities Authority web site on April 11, 2019.

7.7. There has been no claim or proceeding against the Company seeking bankruptcy, reorganization or other relief with respect to it or its debts under any foreign or domestic, federal, state or local bankruptcy, insolvency or other similar law, or any petition filed against any part of the property of the Company.

7.8. The Articles of Association of the Company, as in force at the date hereof, is attached hereto as Exhibit 7.8.

7.9. Subject to the Bank representation in Section 8.3 below, the offer and issuance of the Warrant and the Warrant Shares by the Company is not subject to obtaining an exemption from the Israeli Securities Authority from the requirement to publish a prospectus in Israel. The Warrant Shares will be listed for trading on the TASE promptly following the exercise of this Warrant.

7.10. Immediately following the exercise of this Warrant, Company shall (i) file an immediate report with the Israeli Securities Authority regarding such exercise, and (ii) deposit the Warrant Shares (immediately upon an exercise) with the Nominee Company together with instructions to transfer the Warrant Shares to the TASE Clearing House and deposit the Warrant Shares in MTB's bank account.

8. Representations and Warranties of the Bank.

The Bank hereby represents and warrants to the Company as follows:

8.1. The Bank has been given access to information regarding the Company and its Subsidiaries, and has had the opportunity to ask such questions as it has deemed necessary and to receive answers from representatives of the Company regarding the terms of the Warrant and the business of the Company and its Subsidiaries.

8.2. The Bank is an investor as defined in Section 15A(b)(1) of the Israeli Securities Law, 1967 and is aware of the implications of being qualified as such an investor, and is acquiring the Warrant for its own account and not with a view to distributing or reselling.

8.3. The Bank is experienced in investing in companies that are similar in nature to the Company, and is capable of evaluating the merits and risks involved in an investment of the type of the investment in the Company contemplated hereunder and in the purchase of the Warrants. The Bank is able to bear the economic risk of an investment in the Warrants.

9. **Miscellaneous**

9.1. Notices. Any notice pursuant to this Agreement by the Company or by a Warrant-Holder shall be in writing and shall be deemed to have been duly given (i) if given by facsimile transmission or electronic mail on the business day on which such transmission is sent and confirmed, (ii) if given by air courier, two business days following the date it was sent, or (iii) if mailed by registered mail, return receipt requested, five business days following the date it was mailed, to the following addresses:

If to the Warrant Holder:
Mizrahi Tefahot Bank Ltd.
Jabotinsky Street.
Ramat Gan, Israel
E-mail: dani_maor@umtb.co.il
Attn: Dani Maor

with a copy to:
Shlomo Farkas, Adv.,
Gross, Kleinhendler, Hodak, Halevy, Greenberg & Shenhav Co., Law Offices
One Azrieli Center, Circular Tower
Tel Aviv 6701101, Israel
Email: shlomo@gkh-law.com

If to the Company:
Itamar Medical Ltd.
9 Halamish Street, Caesarea, Israel
Attn: Chief Financial Officer
Tel: 046177000
Fax: 046275598
Email: bshy@Itamar-Medical.com

Each party may from time to time change the addresses or fax number to which notices to it are to be delivered or mailed hereunder by notice in accordance herewith to the other party.

9.2. Successors. All the covenants and provisions of this Agreement by or for the benefit of the Company or the Warrant-Holder shall, subject to applicable law, bind and inure to the benefit of their respective successors and assigns.

9.3. Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of Israel. The parties hereto irrevocably submit to the exclusive jurisdiction of the courts of Tel Aviv, Israel in any action connected with this Agreement.

9.4. Benefits of this Agreement. Nothing in this Agreement shall be construed to give to any person or corporation other than the Company and the Warrant-Holder any legal or equitable right, remedy or claim under this Agreement. This Agreement shall be for the sole and exclusive benefit of the Company and the Warrant-Holder.

9.5. Form of Warrant. The text of the Warrant Certificate evidencing the Warrant (the "**Warrant Certificate**") and of the form of election to purchase Warrant Shares shall be as set forth in **Exhibit 1** attached hereto. The Exercise Price and, accordingly, number of Warrant Shares issuable upon exercise of the Warrant are subject to adjustment upon the occurrence of certain events, all as herein provided.

9.6. Warrant Certificate.

9.6.1. **Exchange of Certificate**. Any Warrant Certificate may be exchanged for Warrant Certificates entitling a Warrant-Holder, in the aggregate, to purchase the same number of Warrant Shares as the Warrant Certificate or Certificates surrendered then entitled such Warrant-Holder to purchase. Any Warrant-Holder desiring to exchange a Warrant Certificate shall make such request in writing delivered to the Company, and shall surrender the certificate evidencing the Warrant to be so exchanged. Thereupon, the Company shall execute and deliver to the person entitled thereto a new Warrant Certificate as so requested.

9.6.2. **Mutilated or Missing Warrant**. In case any Warrant Certificate or Certificates shall be mutilated, lost, stolen or destroyed, the Company shall, at the request of the affected Warrant-Holder, issue and deliver in exchange and substitution for and upon cancellation of the mutilated certificate or certificates, or in lieu of and substitution for the certificate or certificates lost, stolen or destroyed, a new Warrant Certificate or Certificate representing an equivalent right or interest, but only upon receipt of evidence reasonably satisfactory to the Company of such loss, theft or destruction of such Warrant Certificate.

9.7. Severability. If any term or other provision of this Agreement is invalid, illegal, or incapable of being enforced by any law or public policy, all other terms or provisions of this Agreement shall nevertheless remain in full force and effect so long as the economic or legal substance of the transactions contemplated hereby is not affected in any manner materially adverse to any party. Upon such determination that any term or other provision is invalid, illegal, or incapable of being enforced, the parties hereto shall act in good faith to modify this Agreement so as to effect the original intent of the parties as closely as possible in an acceptable manner in order that the transactions contemplated hereby are consummated as originally contemplated to the greatest extent possible.

[Signature Page Follows]

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first above written.

Mizrahi Tefahot Bank Ltd.	Itamar Medical Ltd.
By: _____	By: _____
Name: _____	Name: _____
Title: _____	Title: _____
Date: _____	Date: _____

EXHIBIT 1

Warrant Certificate No. _____
WARRANT TO PURCHASE ORDINARY SHARES
VOID AFTER 23:59 ISRAEL TIME ON THE LAST DAY OF THE EXERCISE PERIOD (AS DEFINED IN THE WARRANT AGREEMENT).
ITAMAR MEDICAL LTD. ("**ITAMAR**")
INCORPORATED UNDER THE LAWS OF THE STATE OF ISRAEL

This certifies that, for value received, Mizrahi Tefahot Bank Ltd. the registered holder hereof or its Permitted Transferee (the "**Warrant-Holder**"), is entitled to purchase from Itamar, at any time during the Exercise Period (as defined in the Warrant Agreement entered into by and between the Warrant-Holder and Itamar on February 9, 2020 (the "**Warrant Agreement**"; capitalized terms used and not otherwise defined herein shall have the meanings ascribed to them in the Warrant Agreement)) commencing at 9.00 a.m., Israel Time, on the first day of the Exercise Period and ending at 11.59 p.m., Israel Time, on the last day of the Exercise Period, 359,140 ordinary shares with a nominal value NIS 0.01 each of the Company (the "**Warrant Shares**") at a purchase price per share equal to the Exercise Price, as such may be from time to time. The number and type of Warrant Shares evidenced hereby and the Exercise Price shall be subject to adjustment from time to time as set forth in the Warrant Agreement. The terms of this Warrant are subject to the terms and provisions contained in the Warrant Agreement. The Warrant evidenced hereby may be exercised in whole or in part in accordance with the provisions of the Warrant Agreement.
Upon any partial exercise of the Warrant evidenced hereby, there shall be signed and issued, to the Warrant-Holder effecting such partial exercise, a new Warrant Certificate in respect of the balance of the Warrant Shares as to which the Warrant evidenced hereby shall not have been exercised. This Warrant may be exchanged by delivery to the office of Itamar of this Warrant Certificate properly endorsed for one or more new Warrants of the same aggregate number of Ordinary Shares as hereby evidenced by the Warrant or Warrants exchanged. No fractional shares will be issued upon the exercise of rights to purchase hereunder, but Itamar shall pay the cash value of any fraction upon the exercise of any part of this Warrant. This Warrant is assignable only to Permitted Transferees.

Itamar Medical Ltd.

By: _____

Name: _____

Title: _____

ITAMAR MEDICAL LTD.
PURCHASE FORM

[Insert Details]

The undersigned hereby irrevocably elects to exercise the right of purchase represented by the Warrant Certificate with respect to ____ Ordinary Shares of Itamar Medical Ltd. ("**Ordinary Shares**"), at the Exercise Price per Ordinary Share set forth in the Warrant Agreement [on a net-exercise basis], and requests that certificates for the Ordinary Shares be issued and registered in Itamar's shareholders register, in the name of:

(name and address must be printed or typewritten)

_____
Name and I.D. number

_____
Address

_____

and, if the number of Ordinary Shares shall be less than the total number of Ordinary Shares that the Warrant-Holder is entitled to purchase pursuant to this Warrant, a new Warrant Certificate shall be registered for the balance of the Ordinary Shares in the name of the undersigned Warrant-Holder as below indicated and delivered to the address stated below.

Dated: _____

Name of Warrant-Holder: _____
Address: _____
_____
Signature: _____

Note: The above signature must correspond with the name as written upon the face of this Warrant Certificate in every particular, without alteration or enlargement or any change whatever, unless this Warrant has been assigned.

Signature Witnessed: _____

ASSIGNMENT

(To be signed only upon assignment of Warrants to Permitted Transferees)

FOR VALUE RECEIVED, the undersigned hereby sells, assigns and transfers this Warrant unto

(name and I.D. number and address of assignee must be printed or typewritten)

_____

_____

_____

which is a Permitted Transferee of the Bank under the terms of the Warrant, hereby irrevocably constituting and appointing _____ as Attorney-in-Fact to transfer said Warrant on the books of Itamar Medical Ltd., with full power of substitution in the premises.

Dated: _____ _____

Signature of Registered Holder

Note: The signature of this assignment must correspond with the name as it appears upon the face of the Warrant Certificate in every particular, without alteration or enlargement or any charge whatever.

Signature Witnessed: _____

Exhibit 2.6

DESCRIPTION OF THE RIGHTS OF EACH CLASS OF SECURITIES REGISTERED UNDER SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

As of December 31, 2019, Itamar Medical Ltd. had two classes of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended, or Exchange Act: our ordinary shares and our American Depositary Shares, or ADSs. References herein to "we," "us," "our" and the "Company" refer to Itamar Medical Ltd. and not to any of its subsidiaries.

Description of Share Capital and Memorandum and Articles of Association

Set out below is a description of our share capital and certain provisions of our memorandum of association, or memorandum, and articles of association and the Companies Law (as currently in effect) related to such provisions. This description is only a summary and does not purport to be complete and is qualified by reference to the full text of the memorandum and articles of association, which are incorporated by reference as exhibits to the annual report of which this Exhibit 2.6 is part, or the Annual Report, and to the applicable sections of the Companies Law.

General

We were incorporated under the laws of the State of Israel under the name "Itamar Medical (CM) 1997 Ltd." on January 15, 1997 as a company limited by shares. We changed our name to our current name in July 2000. Our registered office is 9 Halamish Street, Caesarea 3088900, Israel. Our registration number with the Israeli Registrar of Companies is 51-243421-8.

Pursuant to Section 2 of our memorandum and Section 4 of our articles of association, our objectives are to engage in any lawful activity as determined from time to time by our Board of Directors.

Authorized Share Capital

Our authorized share capital consists of 750,000,000 ordinary shares, par value NIS 0.01 per ordinary share.

Ordinary Shares

The following summarizes the rights of holders of our ordinary shares:

- Holders of ordinary shares have one vote for each ordinary share held on all matters submitted to a vote of shareholders. Such voting rights may be affected by the grant of any special voting rights to the holders of a class of shares with preferential rights that may be authorized in the future.

- Our shareholders have the right to share in our profits distributed as a dividend and any other permitted distribution.

- In the event of our liquidation, after satisfaction of liabilities to creditors, our assets will be distributed to the holders of ordinary shares in proportion to the par value of their holdings. This right may be affected by the grant of preferential dividend or distribution rights to the holders of a class of shares with preferential rights that may be authorized in the future.

- Under our memorandum and articles of association as well as the Companies Law, the liability of our shareholders is limited to the unpaid amount of the purchase price (i.e., the par value of the shares and the premium thereon, if any) that such shareholder (or its predecessor) initially undertook to pay for the shares issued thereto.

- Our ordinary shares are not redeemable and do not have any preemptive rights.

- All of our outstanding ordinary shares are validly issued, fully paid and non assessable.

For more information about our ordinary shares, see below.

Shares and Rights Attaching to Them

Voting Rights

Holders of ordinary shares have one vote for each ordinary share held on all matters submitted to a vote of shareholders. Such voting rights may be affected by the grant of any special voting rights to the holders of a class of shares with preferential rights that may be authorized in the future.

ADS holders generally have the right under the deposit agreement to instruct the depositary to exercise the voting rights for the ordinary shares represented by your ADSs. See “Description of American Depositary Shares” below.

Dividends

Subject to any preferential, deferred or other rights or restrictions attached to any special class of shares with regard to dividends, the profits of the Company available for dividend and resolved to be distributed by the Board of Directors shall be applied in payment of dividends upon the shares of the Company in the same manner with respect to all of the shares granting a right to receive dividends on the date that resolution is adopted (or on later date, as determined by the Board of Directors).

Our Board of Directors may declare dividends in accordance with the provisions of the Companies Law. The Companies Law imposes restrictions on our ability to declare and pay dividends. According to the Companies Law, a company may distribute dividends only out of its “profits,” as such term is defined in the Companies Law and provided that there is no reasonable concern that payment of the dividend will prevent such company from satisfying its existing and foreseeable obligations as they become due. Notwithstanding the foregoing, dividends may be paid with the approval of a court, provided that there is no reasonable concern that payment of the dividend will prevent us from satisfying our existing and foreseeable obligations as they become due. “Profits”, for purposes of the Companies Law, means the greater of retained earnings or earnings accumulated during the preceding two years, after deduction of previous distributions that were not already deducted from the surpluses, as evidenced by the most recent audited or reviewed financial statements of the company prepared no more than six months prior to the date of distribution. Our articles of association provide that dividends will be declared and paid at the discretion of, and upon resolution by, our Board of Directors, subject to the provisions of the Companies Law.

Our Board of Directors is entitled to invest or utilize any unclaimed amount of dividend in any manner to our benefit until it is claimed. We are not obligated to pay interest or linkage on an unclaimed dividend.

Payment of dividends may be subject to Israeli withholding taxes. See in Item 10.C of the Annual Report under “Material Tax Considerations — Israeli Tax Considerations” for additional information.

Change of Control

Except for requiring a special majority voting in order to amend our articles of association, there are no specific provisions of our memorandum, articles of association or other constituent documents that would have an effect of delaying, deferring or preventing a change in control of the Company or that would operate only with respect to a merger, acquisition or corporate restructuring involving us (or any of our subsidiaries). However, as described below, certain provisions of the Companies Law may have such effect.

The Companies Law includes provisions that allow a merger transaction and requires that each company that is a party to the merger have the transaction approved by its board of directors and a vote of the majority of its shares. For purposes of the shareholder vote of each party, unless a court rules otherwise, the merger will not be deemed approved if shares representing a majority of the voting power present at the shareholders meeting and which are not held by the other party to the merger (or by any person who holds 25% or more of the voting power or the right to appoint 25% or more of the directors of the other party) vote against the merger. Upon the request of a creditor of either party to the proposed merger, the court may delay or prevent the merger if it concludes that there exists a reasonable concern that as a result of the merger the surviving company will be unable to satisfy the obligations of any of the parties to the merger. In addition, a merger may not be completed unless at least (i) 50 days have passed from the time that the requisite proposals for approval of the merger were filed with the Israeli Registrar of Companies by each merging company and (ii) 30 days have passed since the merger was approved by the shareholders of each merging company.

The Companies Law also provides that an acquisition of shares in a public company must be made by means of a "special" tender offer if as a result of the acquisition (i) the purchaser would become a 25% or greater holder of the voting rights in the company, unless there is already another 25% or greater holder of voting rights in the company or (ii) the purchaser would become a 45% or greater holder of the voting rights in the company, unless there is already a 45% or greater holder of the voting rights in the company. These requirements do not apply if, in general, the acquisition (a) was made in a private placement that received shareholder approval, (b) was from a 25% or greater holder of the voting rights in the company which resulted in the acquirer becoming a 25% or greater holder of voting rights in the company, or (c) was from a 45% or greater holder of voting rights in the company which resulted in the acquirer becoming a 45% or greater holder of voting rights in the company. A "special" tender offer must be extended to all shareholders, but the offeror is not required to purchase more than 5% of the company's outstanding shares, regardless of how many shares are tendered by shareholders. In general, the special tender offer may be consummated only if (i) at least 5% of the company's outstanding shares will be acquired by the offeror and (ii) the number of shares tendered in the offer exceeds the number of shares whose holders objected to the offer. If a special tender offer is accepted, then the purchaser or any person or entity controlling it or under common control with the purchaser or such controlling person or entity may not make a subsequent tender offer for the purchase of shares of the target company and may not enter into a merger with the target company for a period of one year from the date of the offer, unless the purchaser or such person or entity undertook to effect such an offer or merger in the initial special tender offer. Shares purchased in contradiction to the special tender offer rules under the Companies Law will have no rights and will become dormant shares.

If, as a result of an acquisition of shares, the acquirer will hold more than 90% of a company's outstanding shares, the acquisition must be made by means of a "full" tender offer for all of the outstanding shares. In general, if less than 5% of the outstanding shares are not tendered in the tender offer and more than half of the offerees who have no personal interest in the offer tendered their shares, all the shares that the acquirer offered to purchase will be transferred to it. However, a full tender offer will also be accepted if the shareholders who do not accept the offer hold less than 2% of the issued and outstanding shares of the company. Shareholders may request appraisal rights in connection with a full tender offer for a period of six months following the consummation of the tender offer, but the acquirer is entitled to stipulate that tendering shareholders will forfeit such appraisal rights. If (i) the shareholders who did not respond or accept the tender offer hold at least 5% of the issued and outstanding shares of the company or the shareholders who accept the offer constitute less than a majority of the offerees that do not have a personal interest in the acceptance of the tender offer, or (ii) the shareholders who do not accept the offer hold 2% or more of the outstanding shares of the company, then the acquirer may not acquire shares that will cause its shareholdings to exceed 90% of the outstanding shares. Shares purchased in contradiction to the full tender offer rules under the Companies Law will have no rights and will become dormant shares.

Lastly, Israeli tax law treats some acquisitions, such as stock-for-stock exchanges between an Israeli company and a foreign company, less favorably than U.S. tax laws. For example, Israeli tax law may, under certain circumstances, subject a shareholder who exchanges his ordinary shares for shares in another corporation to taxation prior to the sale of the shares received in such stock-for-stock swap.

Distributions on Winding Up

In the event of our liquidation, after satisfaction of liabilities to creditors, our assets will be distributed to the holders of ordinary shares in proportion to the par value of their holdings. This right may be affected by the grant of preferential dividend or distribution rights to the holders of a class of shares with preferential rights that may be authorized in the future.

Variation of Rights

The rights attached to any class of shares (unless otherwise provided by the terms of issuance of the shares of that class) may be varied with the consent in writing of the holders of all the issued shares of that class, or with the sanction of a vote at a meeting of the shareholders passed at a separate meeting of the holders of the shares of the class by a majority of the voting rights of such class represented at the meeting in person or by proxy and voting thereon.

Under our articles of association, unless otherwise provided by the conditions of issuance, the enlargement of an existing class of shares, or the issuance of additional shares thereof, shall not be deemed to modify or abrogate the rights attached to the previously issued shares of such class or of any other class.

Alteration to Share Capital

Changes in our capital, such as increase of authorized share capital or creation of another class of shares, are subject to the approval of the shareholders by a special majority of 75% or more of the voting power represented at the meeting in person or by proxy and voting thereon.

Preemption Rights

Holders of our ordinary shares are not entitled to preemptive rights.

Transfer of Shares

Our fully paid ordinary shares are issued in registered form and may be freely transferred under our articles of association, unless the transfer is restricted or prohibited by another instrument, applicable law or the rules of a stock exchange on which the shares are listed for trade. The ownership or voting of our ordinary shares by non-residents of Israel is not restricted in any way by our articles of association or the laws of the State of Israel, except for ownership by nationals of some countries that are, or have been, in a state of war with Israel.

Shareholder Meetings

The Board of Directors must convene an annual meeting of shareholders at least once every calendar year, within fifteen months of the last annual meeting. A special meeting of shareholders may be convened by the Board of Directors, as it decides.

The Companies Law provides that the board of directors must, in general, convene a special meeting of shareholders upon the written demand of: (i) two of the directors or such number of directors equal to one fourth of the nominated directors, (ii) one or more shareholders having, in the aggregate, (a) at least 5% of the outstanding share capital and at least 1% of the voting power in the company, or (b) at least 5% of the voting power in the company. The Companies Law further provides that one or more shareholders holding 1% or more of the outstanding voting power in the company may ask the board of directors to add an item to the agenda of the shareholders' meeting. Our articles of association contain procedural guidelines and disclosure items with respect to the submission of shareholder proposals for shareholders meetings.

In accordance with our articles of association, shareholders meetings require notice in the manner prescribed by the Companies Law. Under the Companies Law, shareholders meetings generally require prior notice of not less than 21 days or, with respect to certain matters, such as election of directors and affiliated party transactions, not less than 35 days. Subject to the provisions of the Companies Law and the regulations promulgated thereunder, shareholders entitled to participate and vote at general meetings are the shareholders of record on a date to be decided by the board of directors, which may be between four days and 40 days prior to the date of the meeting.

The quorum required at any meeting of shareholders consists of at least two shareholders present in person or represented by proxy, within half an hour from the time appointed for holding the meeting, who hold or represent, in the aggregate, at least 33 1/3% of the total voting rights in the Company. A meeting adjourned for lack of a quorum generally is adjourned to the same day in the following week at the same time and place or any time and place as the directors designate in a notice to the shareholders. If, at such adjourned meeting, a quorum is not present within half an hour from the time appointed for holding the meeting, any two shareholders present in person or by proxy who hold or represent, in the aggregate, at least 10% of the outstanding share capital of the Company, shall constitute a quorum.

Under our articles of association, all shareholder resolutions require approval of no less than a majority of the voting rights represented at the meeting in person or by proxy and voting thereon, except that (i) amendments to our articles of association (including any change to provisions relating to the composition of our Board of Directors) and (ii) removal of directors (who are not external directors or "independent directors" as such term is defined by the Companies Law) by our shareholders, require a special majority of 75% or more of the voting power represented at the meeting in person or by proxy and voting thereon.

Pursuant to our articles of association, our directors (except external directors) are elected at our annual general meeting of shareholders by a vote of the holders of a majority of the voting power represented and voting at such meeting.

Access to Corporate Records

Under the Companies Law, shareholders generally have the right to review minutes of our general meetings, our shareholders register and principal shareholders register, our articles of association, our annual audited financial statements and any document that we are required by law to file publicly with the Israeli Registrar of Companies or the Israel Securities Authority. In addition, shareholders may request to be provided with any document related to an action or transaction requiring shareholder approval under the related party transaction provisions of the Companies Law. We may deny this request if we believe it has not been made in good faith or if such denial is necessary to protect our interests or protect a trade secret or patent.

Board of Directors

Introduction

According to the Companies Law and our articles of association, the management of our business is vested in our Board of Directors. Pursuant to the Companies Law and our articles of association, our board of directors may exercise all powers and take all actions that are not required under law or under our articles of association to be exercised or taken by our shareholders, including the power to borrow money for company purposes. As such, the Board of Directors is primarily responsible for outlining our policies and supervising our chief executive officer.

Under our articles of association, retirement of directors from office is not subject to any age limitation and our directors are not required to own shares in our Company in order to qualify to serve as directors.

Number of Directors

Under our articles of association, our Board of Directors must consist of not less than five and not more than nine members, including two external directors as required by the Companies Law.

Election of Directors

Pursuant to our articles of association, other than the external directors, for whom special election and removal requirements apply under the Companies Law (as further described below), the vote required to elect a director is a simple majority vote of holders of our ordinary shares participating and voting at the relevant shareholders meeting. Our articles of association provide that, unless otherwise provided by law, our directors (other than external directors and "independent directors" as such term is defined by the Companies Law) may be elected solely at our shareholders annual general meetings, which are required to be held at least once during every calendar year and not more than fifteen months after the last preceding annual general meeting. However, our articles of association allow our Board of Directors to appoint directors to fill vacancies on our Board of Directors, which occur for any reason, or as additional directors, provided that the number of board members shall not exceed the maximum number of directors, as mentioned above. The appointment of a director by the Board of Directors shall remain in effect until the annual general meeting of our shareholders following the appointment or until the end of his tenure, in accordance with our articles of association.

Except for our external directors (as further described below), our directors hold office until the next annual meeting of shareholders following the annual meeting at which they were appointed.

Under our articles of association and the Companies Law, (i) directors (other than external directors and "independent directors" as such term is defined by the Companies Law) may be removed by our shareholders before the expiration of their term by a special majority vote of at least 75% of the votes of shareholders present and voting at the meeting, not taking into account abstentions; (ii) external directors may be removed by our shareholders before the expiration of their term only in limited circumstances as described under the section titled "External Directors" below; and (iii) "independent directors" (as such term is defined by the Companies Law) may be removed before the expiration of their term only by a simple majority of the shareholders, or by a court, and then only if the independent directors cease to meet the statutory qualifications with respect to their appointment or if they violate their duty of loyalty to the Company. In addition, under the Companies Law, directors may be removed upon the occurrence of disqualifying events, such as bankruptcy or conviction of the director in certain criminal offenses. Under the Companies Law, our Board of Directors is required to determine the minimum number of directors who must have "accounting and financial expertise" (as such term is defined in regulations promulgated under the Companies Law). Our Board of Directors determined that the Board of Directors should consist of at least two directors who have "accounting and financial expertise".

Meetings of the Board of Directors are generally held at least once each quarter, with additional special meetings scheduled when required.

Alternate directors

Our articles of association provide, as allowed by the Companies Law, that any director may, by written notice to us, appoint another person who is qualified to serve as a director to serve as an alternate director. See in Item 6.C of the Annual Report under "Board Practices — Alternate Directors" for additional information.

External Directors

The Companies Law requires Israeli companies with shares that have been offered to the public, such as the Company, to appoint at least two external directors. See in Item 6.C of the Annual Report under "Board Practices — External Directors" for additional information.

Independent Directors

See in Item 6.C of the Annual Report under "Board Practices — Independent Directors" for additional information.

Directors' Interests

Under the provisions of the Companies Law and our articles of association, a director generally cannot participate in a meeting of the board of directors nor vote on a proposal, arrangement or contract in which he or she is personally interested, unless the transaction is not an "extraordinary transaction" or a majority of the other directors have a personal interest in such matter.

In addition, our directors generally cannot vote on proposals related to their own compensation. See also under "Approval of Office Holder Compensation" below.

Fees and Remuneration

Each of the directors (i) is entitled to remuneration for their service as directors and other services undertaken for the Company, subject to, in general, approval of our Compensation Committee, Board of Directors and our shareholders at a general meeting and (ii) may be paid his expenses in connection with the exercise of powers and the discharge of responsibilities in relation to the Company. See also under "Approval of Office Holder Compensation" below.

Exculpation, Indemnification and Insurance of Directors and Officers

See in Item 6.C of the Annual Report under "Board Practices — Exculpation, Indemnification and Insurance of Directors and Officers" for additional information.

Other Israeli Law Considerations

Approval of Related Party Transactions under Israeli Law

General

Under the Companies Law, a company may approve an action by an office holder from which the office holder would otherwise have to refrain, as described above, if:

- the office holder acts in good faith and the act or its approval does not cause harm to the company; and
- the office holder disclosed the nature of his or her interest in the transaction (including any significant fact or document) to the company at a reasonable time before the company's approval of such matter.

Disclosure of Personal Interests of an Office Holder

The Companies Law requires that an office holder disclose to the company, promptly, and, in any event, not later than the board meeting at which the transaction is first discussed, any direct or indirect personal interest that he or she may have and all related material information known to him or her relating to any existing or proposed transaction by the company. If the transaction is an extraordinary transaction, the office holder must also disclose any personal interest held by:

- the office holder's relatives. Relatives are defined to include the spouse, siblings, parents, grandparents, descendants, spouse's descendants and the spouses of any of these people; or
- any corporation in which the office holder or his or her relatives holds 5% or more of the shares or voting rights, serves as a director or general manager or has the right to appoint at least one director or the general manager.

Under the Companies Law, an extraordinary transaction is a transaction:

- not in the ordinary course of business;
- not on market terms; or
- that is likely to have a material impact on the company's profitability, assets or liabilities.

The Companies Law does not specify to whom within the company nor the manner in which required disclosures are to be made. We require our office holders to make such disclosures to our Board of Directors. Under the Companies Law, once an office holder complies with the above disclosure requirement, the Board of Directors may approve a transaction between the company and an office holder, or a third party in which an office holder has a personal interest, unless the articles of association provide otherwise and provided that the transaction is not detrimental to the company's interest. If the transaction is an extraordinary transaction, first the audit committee and then the board of directors of the company, in that order, must approve the transaction. Under specific circumstances, shareholder approval may also be required. A director who has a personal interest in an extraordinary transaction, which is considered at a meeting of the board of directors or the audit committee, may not be present at this meeting or vote on this matter, unless a majority of the board of directors or the audit committee, as the case may be, has a personal interest. If a majority of the board of directors or the audit committee has a personal interest, then shareholder approval is generally also required.

Approval of Office Holder Compensation

Pursuant to the Companies Law, every Israeli public company, such as the Company, must adopt a compensation policy, recommended by the compensation committee, and approved by the Board of Directors and the shareholders, in that order. The shareholder approval must be by a simple majority of all votes cast, provided that (i) such majority includes a simple majority of the votes cast by non-controlling shareholders having no personal interest in the matter or (ii) the total number of votes of shareholders mentioned in clause (i) above who voted against the approval of the policy does not exceed 2% of the total voting rights in the company. Even if the shareholders do not approve the compensation policy, the board of directors may resolve to approve the compensation policy, subject to certain conditions. In general, all office holders' terms of compensation — including fixed remuneration, bonuses, equity compensation, retirement or termination payments, indemnification, liability insurance and the grant of an exemption from liability — must comply with the company's compensation policy. The compensation policy must take into account certain factors, including advancement of the company's objectives, the company's business plan and its long-term strategy, and creation of appropriate incentives. It must also consider, among other things, the company's risk management, size and the nature of its operations. The compensation policy must include certain principles, such as: a link between variable compensation and long-term performance and measurable criteria; the relationship between variable and fixed compensation; and the minimum holding or vesting period for variable, equity-based compensation.

In addition, the compensation terms of directors, the chief executive officer, and any employee or service provider who is considered a controlling shareholder, must be approved separately by the compensation committee, the board of directors and, subject to certain exceptions, the shareholders of the company (by the same majority noted above), in that order. The compensation terms of other officers require the approval of the compensation committee and the board of directors.

Duties of Shareholders

Disclosure by Controlling Shareholders

Under the Companies Law, the disclosure requirements that apply to an office holder also apply to a controlling shareholder of a public company. A controlling shareholder is a shareholder who has the ability to direct the activities of a company, including a shareholder that owns 25% or more of the voting rights if no other shareholder owns more than 50% of the voting rights, but excluding a shareholder whose power derives solely from his or her position on the board of directors or any other position with the company. Two or more shareholders with a personal interest in the approval of the same transaction are deemed to be holding the shares together.

Approval of Certain Transactions

Extraordinary transactions with a controlling shareholder or (i) in which a controlling shareholder has a personal interest (including a private placement in which a controlling shareholder has a personal interest); (ii) transactions for the provision of services, whether directly or indirectly, by a controlling shareholder or his or her relative, or a company such controlling shareholder controls; and (iii) the engagement of a controlling shareholder or his or her relative as an office holder or employee (including compensation therefor), generally require the approval of the audit committee (or compensation committee with respect to engagement as an office holder or employee), the Board of Directors and the shareholders, in that order. The shareholder approval must include at least a majority of the shares of non-interested shareholders voted on the matter. However, the transaction can be approved by shareholders without this special approval if the total shares of non-interested shareholders that voted against the transaction do not represent more than 2% of the voting rights in the company. In addition, any such extraordinary transaction whose term is longer than three years may require further shareholder approval every three years, unless, where permissible under the Companies Law, the audit committee approves that a longer term is reasonable under the circumstances. Pursuant to regulations promulgated under the Companies Law, certain transactions with a controlling shareholder or his or her relative, or with directors or other office holders, that would otherwise require approval of a company's shareholders may be exempt from shareholder approval under certain conditions.

Duties of Shareholders

Under the Companies Law, each shareholder has a duty to act in good faith toward the company and other shareholders and to refrain from abusing his or her power in the company, such as in shareholder votes. In addition, specified shareholders have a duty of fairness toward the company. These shareholders include any controlling shareholder, any shareholder who knows that it possesses the power to determine the outcome of a shareholder vote and any shareholder who, pursuant to the provisions of the articles of association, has the power to appoint or prevent the appointment of an office holder or any other power with respect to the company. However, the Companies Law does not define the substance of this duty of fairness.

Private Placements

Under the Companies Law, if (i) as a result of a private placement a person would become a controlling shareholder (as defined under the Companies Law) or (ii) a private placement will entitle investors to receive 20% or more of the voting rights of a company as calculated before the private placement, and all or part of the private placement consideration is not in cash or in public traded securities or is not in market terms and if as a result of the private placement the holdings of a substantial shareholder shall increase or as a result of it a person shall become a substantial shareholder, then in either case, the private placement must be approved by the board of directors and by the shareholders of the company. A "substantial shareholder" is defined as a shareholder who holds five percent or more of the company's outstanding share capital or voting power, assuming the exercise of all of the securities convertible into shares held by that person. In order for the private placement to be considered on "market terms," the board of directors has to determine, on the base of detailed explanation, that the private placement is on market terms, unless proven otherwise.

Exchange Controls

Israeli law and regulations do not impose any material foreign exchange restrictions on non-Israeli holders of our ordinary shares. There are currently no Israeli currency control restrictions on payments of dividends or other distributions with respect to our ordinary shares or the proceeds from the sale of the shares, except for the obligation of Israeli residents to file reports with the Bank of Israel regarding certain transactions. However, legislation remains in effect pursuant to which currency controls can be imposed by administrative action at any time.

The ownership or voting of our ordinary shares by non-residents of Israel, except with respect to citizens of countries which are in a state of war with Israel, is not restricted in any way by our memorandum or articles of association or by the laws of the State of Israel.

Description of American Depositary Shares

American Depositary Shares

The Bank of New York Mellon, as depositary, will register and deliver American Depositary Shares, also referred to as ADSs. Each ADS will represent 30 shares (or a right to receive 30 shares) deposited with either of Bank Leumi or Bank Hapoalim, as custodian for the depositary in Israel. Each ADS will also represent any other securities, cash or other property that may be held by the depositary. The deposited shares together with any other securities, cash or other property held by the depositary are referred to as the deposited securities. The depositary's office at which the ADSs will be administered and its principal executive office are located at 240 Greenwich Street, New York, New York 10286.

You may hold ADSs either (A) directly (i) by having an American Depositary Receipt, also referred to as an ADR, which is a certificate evidencing a specific number of ADSs, registered in your name, or (ii) by having uncertificated ADSs registered in your name, or (B) indirectly by holding a security entitlement in ADSs through your broker or other financial institution that is a direct or indirect participant in The Depository Trust Company, also called DTC. If you hold ADSs directly, you are a registered ADS holder, also referred to as an ADS holder. This description assumes you are an ADS holder. If you hold the ADSs indirectly, you must rely on the procedures of your broker or other financial institution to assert the rights of ADS holders described in this section. You should consult with your broker or financial institution to find out what those procedures are.

Registered holders of uncertificated ADSs will receive statements from the depositary confirming their holdings.

As an ADS holder, we will not treat you as one of our shareholders and you will not have shareholder rights. Israeli law governs shareholder rights. The depositary will be the holder of the shares underlying your ADSs. As a registered holder of ADSs, you will have ADS holder rights. A deposit agreement among us, the depositary, ADS holders and all other persons indirectly or beneficially holding ADSs sets out ADS holder rights as well as the rights and obligations of the depositary. New York law governs the deposit agreement and the ADSs.

The following is a summary of the material provisions of the deposit agreement. This description is only a summary and does not purport to be complete and is qualified by reference to the full text of the deposit agreement and the form of ADR, which are incorporated by reference as exhibits to the Annual Report.

Dividends and Other Distributions

How will you receive dividends and other distributions on the shares?

The depositary has agreed to pay or distribute to ADS holders the cash dividends or other distributions it or the custodian receives on shares or other deposited securities, upon payment or deduction of its fees and expenses. You will receive these distributions in proportion to the number of shares your ADSs represent.

Cash. The depositary will convert any cash dividend or other cash distribution we pay on the shares into U.S. dollars, if it can do so on a reasonable basis and can transfer the U.S. dollars to the United States. If that is not possible or if any government approval is needed and cannot be obtained, the deposit agreement allows the depositary to distribute the foreign currency only to those ADS holders to whom it is possible to do so. It will hold the foreign currency it cannot convert for the account of the ADS holders who have not been paid. It will not invest the foreign currency and it will not be liable for any interest.

Before making a distribution, any withholding taxes, or other governmental charges that must be paid will be deducted. See Item 10.C of the Annual Report under “Material Tax Considerations” for additional information. The depositary will distribute only whole U.S. dollars and cents and will round fractional cents to the nearest whole cent. *If the exchange rates fluctuate during a time when the depositary cannot convert the foreign currency, you may lose some of the value of the distribution.*

Shares. The depositary may distribute additional ADSs representing any shares we distribute as a dividend or free distribution. The depositary will only distribute whole ADSs. It will sell shares which would require it to deliver a fraction of an ADS (or ADSs representing those shares) and distribute the net proceeds in the same way as it does with cash. If the depositary does not distribute additional ADSs, the outstanding ADSs will also represent the new shares. The depositary may sell a portion of the distributed shares (or ADSs representing those shares) sufficient to pay its fees and expenses in connection with that distribution.

Rights to purchase additional shares. If we offer holders of our securities any rights to subscribe for additional shares or any other rights, the depositary may (i) exercise those rights on behalf of ADS holders, (ii) distribute those rights to ADS holders or (iii) sell those rights and distribute the net proceeds to ADS holders, in each case after deduction or upon payment of its fees and expenses. To the extent the depositary does not do any of those things, it will allow the rights to lapse. *In that case, you will receive no value for them.* The depositary will exercise or distribute rights only if we ask it to and provide satisfactory assurances to the depositary that it is legal to do so. If the depositary will exercise rights, it will purchase the securities to which the rights relate and distribute those securities or, in the case of shares, new ADSs representing the new shares, to subscribing ADS holders, but only if ADS holders have paid the exercise price to the depositary. United States securities laws may restrict the ability of the depositary to distribute rights or ADSs or other securities issued on exercise of rights to all or certain ADS holders, and the securities distributed may be subject to restrictions on transfer.

Other Distributions. The depositary will send to ADS holders anything else we distribute on deposited securities by any means it thinks is legal, fair and practical. If it cannot make the distribution in that way, the depositary has a choice. It may decide to sell what we distributed and distribute the net proceeds, in the same way as it does with cash. Or, it may decide to hold what we distributed, in which case ADSs will also represent the newly distributed property. However, the depositary is not required to distribute any securities (other than ADSs) to ADS holders unless it receives satisfactory evidence from us that it is legal to make that distribution. The depositary may sell a portion of the distributed securities or property sufficient to pay its fees and expenses in connection with that distribution. United States securities laws may restrict the ability of the depositary to distribute securities to all or certain ADS holders, and the securities distributed may be subject to restrictions on transfer.

The depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any ADS holders. We have no obligation to register ADSs, shares, rights or other securities under the Securities Act. We also have no obligation to take any other action to permit the distribution of ADSs, shares, rights or anything else to ADS holders. *This means that you may not receive the distributions we make on our shares or any value for them if it is illegal or impractical for us to make them available to you.*

Deposit, Withdrawal and Cancellation

How are ADSs issued?

The depositary will deliver ADSs if you or your broker deposits shares or evidence of rights to receive shares with the custodian. Upon payment of its fees and expenses and of any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will register the appropriate number of ADSs in the names you request and will deliver the ADSs to or upon the order of the person or persons that made the deposit.

How can ADS holders withdraw the deposited securities?

You may surrender your ADSs to the depositary for the purpose of withdrawal. Upon payment of its fees and expenses and of any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will deliver the shares and any other deposited securities underlying the ADSs to the ADS holder or a person the ADS holder designates at the office of the custodian. Or, at your request, risk and expense, the depositary will deliver the deposited securities at its office, if feasible. However, the depositary is not required to accept surrender of ADSs to the extent it would require delivery of a fraction of a deposited share or other security. The depositary may charge you a fee and its expenses for instructing the custodian regarding delivery of deposited securities.

How do ADS holders interchange between certificated ADSs and uncertificated ADSs?

You may surrender your ADR to the depositary for the purpose of exchanging your ADR for uncertificated ADSs. The depositary will cancel that ADR and will send to the ADS holder a statement confirming that the ADS holder is the registered holder of uncertificated ADSs. Upon receipt by the depositary of a proper instruction from a registered holder of uncertificated ADSs requesting the exchange of uncertificated ADSs for certificated ADSs, the depositary will execute and deliver to the ADS holder an ADR evidencing those ADSs.

Voting Rights

How do you vote?

ADS holders may instruct the depositary how to vote the number of deposited shares their ADSs represent. If we request the depositary to solicit your voting instructions (and we are not required to do so), the depositary will notify you of a shareholders' meeting and send or make voting materials available to you. Those materials will describe the matters to be voted on and explain how ADS holders may instruct the depositary how to vote. For instructions to be valid, they must reach the depositary by a date set by the depositary. The depositary will try, as far as practical, subject to the laws of the State of Israel and the provisions of our articles of association or similar documents, to vote or to have its agents vote the shares or other deposited securities as instructed by ADS holders. If we do not request the depositary to solicit your voting instructions, you can still send voting instructions, and, in that case, the depositary may try to vote as you instruct, but it is not required to do so.
Except by instructing the depositary as described above, you won't be able to exercise voting rights unless you surrender your ADSs and withdraw the shares. However, you may not know about the meeting enough in advance to withdraw the shares. In any event, the depositary will not exercise any discretion in voting deposited securities and it will only vote or attempt to vote as instructed or as described in the following sentence. If (i) we asked the depositary to solicit your instructions at least 30 days before the meeting date, (ii) the depositary does not receive voting instructions from you by the specified date and (iii) we confirm to the depositary that:

- we wish to receive a proxy to vote uninstructed shares;
- we reasonably do not know of any substantial shareholder opposition to a particular question; and
- the particular question is not materially adverse to the interests of shareholders.

the depositary will consider you to have authorized and directed it to give, and it will give, a discretionary proxy to a person designated by us to vote the number of deposited securities represented by your ADSs as to that question.

We cannot assure you that you will receive the voting materials in time to ensure that you can instruct the depositary to vote your shares. In addition, the depositary and its agents are not responsible for failing to carry out voting instructions or for the manner of carrying out voting instructions. *This means that you may not be able to exercise voting rights and there may be nothing you can do if your shares are not voted as you requested.*
In order to give you a reasonable opportunity to instruct the depositary as to the exercise of voting rights relating to Deposited Securities, if we request the Depositary to act, we agree to give the depositary notice of any such meeting and details concerning the matters to be voted upon at least 30 days in advance of the meeting date.

Fees and Expenses

See in Item 12.D of the Annual Report under “American Depositary Shares — Fees and Expenses” for additional information.

Payment of Taxes

See in Item 12.D of the Annual Report under “American Depositary Shares — Payment of Taxes” for additional information.

Tender and Exchange Offers; Redemption, Replacement or Cancellation of Deposited Securities

The depositary will not tender deposited securities in any voluntary tender or exchange offer unless instructed to do so by an ADS holder surrendering ADSs and subject to any conditions or procedures the depositary may establish.

If deposited securities are redeemed for cash in a transaction that is mandatory for the depositary as a holder of deposited securities, the depositary will call for surrender of a corresponding number of ADSs and distribute the net redemption money to the holders of called ADSs upon surrender of those ADSs.

If there is any change in the deposited securities such as a sub-division, combination or other reclassification, or any merger, consolidation, recapitalization or reorganization affecting the issuer of deposited securities in which the depositary receives new securities in exchange for or in lieu of the old deposited securities, the depositary will hold those replacement securities as deposited securities under the deposit agreement. However, if the depositary decides it would not be lawful or practical to hold the replacement securities because those securities could not be distributed to ADS holders or for any other reason, the depositary may instead sell the replacement securities and distribute the net proceeds upon surrender of the ADSs.

If there is a replacement of the deposited securities and the depositary will continue to hold the replacement securities, the depositary may distribute new ADSs representing the new deposited securities or ask you to surrender your outstanding ADRs in exchange for new ADRs identifying the new deposited securities.

If there are no deposited securities underlying ADSs, including if the deposited securities are cancelled, or if the deposited securities underlying ADSs have become apparently worthless, the depositary may call for surrender of those ADSs or cancel those ADSs upon notice to the ADS holders.

Amendment and Termination

How may the deposit agreement be amended?

We may agree with the depositary to amend the deposit agreement and the ADRs without your consent for any reason. If an amendment adds or increases fees or charges, except for taxes and other governmental charges or expenses of the depositary for registration fees, facsimile costs, delivery charges or similar items, or prejudices a substantial right of ADS holders, it will not become effective for outstanding ADSs until 30 days after the depositary notifies ADS holders of the amendment. *At the time an amendment becomes effective, you are considered, by continuing to hold your ADSs, to agree to the amendment and to be bound by the ADRs and the deposit agreement as amended.*

How may the deposit agreement be terminated?

The depositary will initiate termination of the deposit agreement if we instruct it to do so. The depositary may initiate termination of the deposit agreement if:

- 90 days have passed since the depositary told us it wants to resign but a successor depositary has not been appointed and accepted its appointment;
- we delist the ADSs from an exchange on which they were listed and do not list the ADSs on another exchange;
- we appear to be insolvent or enter insolvency proceedings;
- all or substantially all the value of the deposited securities has been distributed either in cash or in the form of securities;
- there are no deposited securities underlying the ADSs or the underlying deposited securities have become apparently worthless; or
- there has been a replacement of deposited securities.

If the deposit agreement will terminate, the depositary will notify ADS holders at least 90 days before the termination date. At any time after the termination date, the depositary may sell the deposited securities. After that, the depositary will hold the money it received on the sale, as well as any other cash it is holding under the deposit agreement, unsegregated and without liability for interest, for the pro rata benefit of the ADS holders that have not surrendered their ADSs. Normally, the depositary will sell as soon as practicable after the termination date.

After the termination date and before the depositary sells, ADS holders can still surrender their ADSs and receive delivery of deposited securities, except that the depositary may refuse to accept a surrender for the purpose of withdrawing deposited securities or reverse previously accepted surrenders of that kind that have not settled if it would interfere with the selling process. The depositary may refuse to accept a surrender for the purpose of withdrawing sale proceeds until all the deposited securities have been sold. The depositary will continue to collect distributions on deposited securities, but, after the termination date, the depositary is not required to register any transfer of ADSs or distribute any dividends or other distributions on deposited securities to the ADSs holder (until they surrender their ADSs) or give any notices or perform any other duties under the deposit agreement except as described in this paragraph.

Limitations on Obligations and Liability

Limits on our Obligations and the Obligations of the Depositary; Limits on Liability to Holders of ADSs

The deposit agreement expressly limits our obligations and the obligations of the depositary. It also limits our liability and the liability of the depositary. We and the depositary:

- are only obligated to take the actions specifically set forth in the deposit agreement without negligence or bad faith, and the depositary will not be a fiduciary or have any fiduciary duty to holders of ADSs;
- are not liable if we are or it is prevented or delayed by law or by events or circumstances beyond our or its ability to prevent or counteract with reasonable care or effort from performing our or its obligations under the deposit agreement;
- are not liable if we or it exercises discretion permitted under the deposit agreement;

- are not liable for the inability of any holder of ADSs to benefit from any distribution on deposited securities that is not made available to holders of ADSs under the terms of the deposit agreement, or for any special, consequential or punitive damages for any breach of the terms of the deposit agreement;

- have no obligation to become involved in a lawsuit or other proceeding related to the ADSs or the deposit agreement on your behalf or on behalf of any other person;

- may rely upon any documents we believe or it believes in good faith to be genuine and to have been signed or presented by the proper person;

- are not liable for the acts or omissions of any securities depository, clearing agency or settlement system; and

- the depositary has no duty to make any determination or provide any information as to our tax status, or any liability for any tax consequences that may be incurred by ADS holders as a result of owning or holding ADSs or be liable for the inability or failure of an ADS holder to obtain the benefit of a foreign tax credit, reduced rate of withholding or refund of amounts withheld in respect of tax or any other tax benefit.

In the deposit agreement, we and the depositary agree to indemnify each other under certain circumstances.

Requirements for Depositary Actions

Before the depositary will deliver or register a transfer of ADSs, make a distribution on ADSs, or permit withdrawal of shares, the depositary may require:

- payment of stock transfer or other taxes or other governmental charges and transfer or registration fees charged by third parties for the transfer of any shares or other deposited securities;

- satisfactory proof of the identity and genuineness of any signature or other information it deems necessary; and

- compliance with regulations it may establish, from time to time, consistent with the deposit agreement, including presentation of transfer documents.

The depositary may refuse to deliver ADSs or register transfers of ADSs when the transfer books of the depositary or our transfer books are closed or at any time if the depositary or we think it advisable to do so.

Your Right to Receive the Shares Underlying your ADSs

ADS holders have the right to cancel their ADSs and withdraw the underlying shares at any time except:

- when temporary delays arise because: (i) the depositary has closed its transfer books or we have closed our transfer books; (ii) the transfer of shares is blocked to permit voting at a shareholders' meeting; or (iii) we are paying a dividend on our shares;

- when you owe money to pay fees, taxes and similar charges; or

- when it is necessary to prohibit withdrawals in order to comply with any laws or governmental regulations that apply to ADSs or to the withdrawal of shares or other deposited securities.

This right of withdrawal may not be limited by any other provision of the deposit agreement.

Direct Registration System

In the deposit agreement, all parties to the deposit agreement acknowledge that the Direct Registration System, also referred to as DRS, and Profile Modification System, also referred to as Profile, will apply to the ADSs. DRS is a system administered by DTC that facilitates interchange between registered holding of uncertificated ADSs and holding of security entitlements in ADSs through DTC and a DTC participant. Profile is a feature of DRS that allows a DTC participant, claiming to act on behalf of a registered holder of uncertificated ADSs, to direct the depositary to register a transfer of those ADSs to DTC or its nominee and to deliver those ADSs to the DTC account of that DTC participant without receipt by the depositary of prior authorization from the ADS holder to register that transfer.

In connection with and in accordance with the arrangements and procedures relating to DRS/Profile, the parties to the deposit agreement understand that the depositary will not determine whether the DTC participant that is claiming to be acting on behalf of an ADS holder in requesting registration of transfer and delivery as described in the paragraph above has the actual authority to act on behalf of the ADS holder (notwithstanding any requirements under the Uniform Commercial Code). In the deposit agreement, the parties agree that the depositary's reliance on and compliance with instructions received by the depositary through the DRS/Profile system and in accordance with the deposit agreement will not constitute negligence or bad faith on the part of the depositary.

Shareholder communications; inspection of register of holders of ADSs

The depositary will make available for your inspection at its office all communications that it receives from us as a holder of deposited securities that we make generally available to holders of deposited securities. The depositary will send you copies of those communications or otherwise make those communications available to you if we ask it to. You have a right to inspect the register of holders of ADSs, but not for the purpose of contacting those holders about a matter unrelated to our business or the ADSs.

Jury Trial Waiver

The deposit agreement provides that, to the extent permitted by law, ADS holders waive the right to a jury trial of any claim they may have against us or the depositary arising out of or relating to our shares, the ADSs or the deposit agreement, including any claim under the United States federal securities laws. If we or the depositary opposed a jury trial demand based on the waiver, the court would determine whether the waiver was enforceable in the facts and circumstances of that case in accordance with applicable case law.

You will not, by agreeing to the terms of the deposit agreement, be deemed to have waived our or the depositary's compliance with United States federal securities laws or the rules and regulations promulgated thereunder.

Exhibit 4.12

[INFORMAL ENGLISH TRANSLATION]

Date: February 9, 2020

Name of the customer: **Itamar Medical Ltd.** (hereinafter: the "**Borrower**" or the "**Company**" or the "**Customer**")

Company No. 512434218

Address: **9 Halamish Street, Caesarea 3088900**

Account number: **250888 in the Orot Mall Branch** (hereinafter: the "**Account**")

To: **Mizrahi Tefahot Bank Ltd.** (hereinafter: the "**Bank**")

To Whom It May Concern:

Re: Credit Agreement

We are setting forth in writing the agreements reached between us in connection with the Credit Line and the loans made available to the Company, from time to time, in reliance on this Agreement and in reliance of a specific credit agreement and/or specific loan agreement that will be submitted to you in the future, from time to time, in reliance on this Credit Agreement. In addition to the provisions of this Agreement, the terms of the Line of Credit and all of the loans that will be provided to the Company, under any of the credit frameworks (hereinafter: the "**Credit**"), shall be in accordance with and subject to the "Account Opening Application" and/or "Account Changes" and "Account Management Packet" and "Credit Packet for a Business Customer," and all of the appendices and amendments in which we have engaged with the Bank, as well as subject to any specific credit / loan agreement or otherwise, between the Company and the Bank (hereinafter: the "**Credit Documents**"), and all of the provisions of the Credit Documents and all of the terms thereof shall apply and be binding with respect to the credit that will be provided to the Company by you. This Credit Agreement hereby replaces the line of credit agreements dated March 29, 2017 (including its amendments) and March 12, 2019 (hereinafter: the **"Former Agreement"**). It is hereby clarified that the provisions of this Agreement shall apply to credit lines which were provided under the credit frameworks pursuant to the Former Agreement, mutatis mutandis.

1. Types of credit:

The amount of the credit that will be provided pursuant to this Agreement: a sum of USD 17,000,000, and subject to the provisions of section 4.1.1. hereunder, the amount of the credit shall be USD 20,000,000 (hereinafter: the "**Credit Amount**").

The Line of Credit and the Credit will be provided and may be utilized by the Company as of the date on which all of the preconditions and general terms as set forth in Section 5 below are satisfied (hereinafter: the "**Preconditions**") and subject to the Bank's signature on this Agreement.

All of the Credit Amounts that were provided and/or will be provided to the Company shall be repaid in full pursuant to the agreements set forth in the documents signed and/or that will be signed by the Company in connection with the provision of the same Credit, and subject to the terms of this Agreement.

2. **The Lender - Mizrahi Tefahot Bank Ltd.** (hereinafter: the "**Bank**")

3. **The Borrower - Itamar Medical Ltd.**, Company No. 512434218 (hereinafter: the "**Borrower**" or the "**Company**")

4. Types of credit:

4.1. Long-term loans framework -

4.1.1. The Bank shall provide a long-term loans framework (hereinafter: "**Loans framework**") in a cumulative amount of USD 10,000,000. It is hereby agreed that upon the fulfillment of the following terms, the Loans Framework shall be increased to the sum of USD 13,000,000 (the "**Increase**"):

A. There has been no adverse change in the borrower's state.
B. The borrowers' revenues in the months January – June 2020, were no less than USD 15,000,000.

The Borrower shall provide the bank with documents evidencing the foregoing, to the bank's satisfaction.

The Loans Framework shall be valid and may be taken, until 25.10.2020. It is hereby agreed that the sum of the loan shall be no less than USD 2,000,000. It is hereby agreed that the Borrower may also elect to utilize the Long-term Loans Framework in order to obtain short term loans.

The Borrower's notice of its intent to withdraw any loan as stated above will be provided to the Bank in writing no later than two (2) business days prior to the date of the execution of the loan and will include the date requested for the provision thereof as well as the amount of the loan. The Bank will prepare the relevant loan agreement for the Borrower's signatures, including all of the details of the Loan and the relevant interest, as well as the other documents customary at the Bank.

4.1.2 The annual interest rate for each long-term loan or short-term loan that will be drawn from the Line of Credit - Quarterly Libor Rate + 5.5%, however, if the Line of Credit is increased as noted above, then loans made from the Line of Credit after the Increase will bear annual interest at the Quarterly Libor Rate + 7%.

4.1.3. Repayment –
The principal of the long-term loan and the interest for the same will be repaid in 12 consecutive quarterly payments, as of the end of three months from the date on which each long-term loan was provided, all as shall be set forth in the amortization table which shall be provide to the Borrower upon the provision of the Loan. The method of repayment of the short-term loans shall be agreed by the parties in writing prior to the provision of the short-term loans.

4.1.4. The execution fee provision of each loan - shall be payable on the date of the provision of each loan, with a 50% discount compared to the Bank's fee schedule at the time.

For avoidance of doubt, it is hereby clarified that all of the foregoing loans are part of the Credit, as defined in this Agreement and all the provisions of this Credit Agreement with respect to the Credit shall apply to said loans.

4.2. Credit limit to finance customer debt -

4.2.1 The Loans Framework for financing customer debt in the amount of up to USD 7,000,000 (hereinafter: the "**Line of Credit for Financing Customer Debt**" or the "**Loan for Financing Customer Debt**") will be in force and may be utilized subject to the provisions of Section 1 above, by 25.10.2020 (hereinafter: the "**Expiration of the Line of Credit**"). Any loan from the aforesaid framework will be calculated and provided pursuant to the following aggregate rules and conditions:

1) Invoices for payment that are not yet paid, which are issued by the Borrower and/or the US Subsidiary Itamar Medical Inc. (hereinafter: the "**US Subsidiary**") and/or **I.M.E. 2016 B.V.** (hereinafter: the "**Dutch Subsidiary**") to their customers, will be financed at a rate between **80%** and 85% of the amount of the same invoices (for each invoice), subject to the bank's sole discretion.

2) Invoices will be financed that are payable no later than 90 days from the Reporting Date, as set forth in Section 4.2.3 below, and in any case no later than the Expiration of the Line of Credit. Invoices in arrears shall not be financed, excluding invoices that are in arrears of up to 60 days on the date of the provision of the loan (hereinafter: "**Invoices in Arrears**"), and provided that the rate of the Invoices in Arrears does not exceed 10% of the total Loans for Financing Customer Debt. It is clarified that in transactions in installments, the payment date is the payment date of each payment. Additionally, deferred income as well as doubtful debts will be offset from the balance of the invoices.

Notwithstanding the foregoing, it is hereby agreed that the bank shall provide the Borrower financing against invoices which were issued as set forth above, for transactions which were paid by means of credit card and their repayment date exceeds 90 days, subject to the following terms;

A. Transaction whose final repayment date does not exceed 12 months of the date of their execution, shall be financed.
B. The total credit out of the Line of Credit for Financing Customer Debt, to be provided against such invoices shall not exceed USD 1,050,000.

3) The exposure vis-a-vis each individual customer (as calculated pursuant to this section) will not exceed 20% of the total Credit Limit for Financing Customer Debt.

Notwithstanding the foregoing, the exposure vis-à-vis the following customers shall not exceed 305 of the of the total Credit Limit for Financing Customer Debt. –

Kaiser Foundation Health Plan, Inc. and its affiliates
Department of Veterans Affairs and its affiliates
Phillips Respironics GK, Japan

The amount of the loan calculated in accordance with the rules above will be hereinafter: the "**Derived Amount**."

4.2.2 Payment date of the Loans for Financing Customer Debt - the payment date of each Loan for Financing Customer Debt will not exceed 3 months from the date on which it is provided, with the final and absolute payment date of the loans provided being the expiration of the framework.

4.2.3 Reporting - The Borrower will provide the Bank, no later than 12 days from the end of each calendar month, with a report including the details of the invoices as of the last day of the previous calendar month, which is not yet paid by the reporting date, as well as the calculation of the Derived Amount. The reporting will be made in the form customary at the Bank as agreed upon by the parties in writing (hereinafter: the "**Monthly Invoices Report**").

Additionally, together with the transfer of the unpaid invoices report, the Borrower will also provide a collection report regarding all of the invoices that were financed, which details the amounts collected in the previous month and the invoices that were paid.

The reports will be signed by the CEO of the Company or its CFO.

It is agreed that the Bank may, at its sole discretion, demand the presentation of the invoices set forth in the Report, in whole or in part.

The Bank may examine the calculation of the Derived Amount as well as disqualify any of the customers and/or invoices set forth in the report.

4.2.4 The adjustment of the balance amount of the Loans for Financing Customer Debt to the Derived Amount will be made within five days from the date of the provision of the report. The adjustment of the balance of the Loans for Financing Customer Debt will take place by the provision of Loans for Financing Customer Debt or the early repayment thereof. It is clarified that the Bank will not be required to provide Loans for Financing Customer Debt from the Line of Credit unless it has approved the debtor customers and the calculation of the Derived Amount, at its discretion.

4.2.5 The Borrower shall sign all of the documents required by the Bank for the execution of the provisions of this section.

4.2.6 The interest rate for the Loans for Financing Customer Debt - for each Loan for Financing Customer Debt, the Borrower will pay the Bank variable annual interest at a rate of monthly Libor + **4.25%.** The interest for the Loan for Financing Customer Debt will be repaid on a monthly basis (or based on the term of the Loan for Financing Customer Debt, as the case may be).

4.3 Fees

4.3.1. For the Credit Limit for Financing Customer Debt and the Line of Credit, the account will be charged a credit allocation fee at a rate of 0.75% per year, for the entire Credit Amount, as defined above, as of the signing date of this Agreement. The credit allocation fee shall be calculated daily and collected on a quarterly basis, at the beginning of each calendar quarter, for the preceding quarter.

For the same part of the framework that was actually utilized by the Borrower, the Borrower will receive a full reduction from the credit allocation fee set forth above. The calculation will take place regarding any credit provided, as of the date on which it is actually provided, for the unused balance.

The credit allocation fee as set forth above does not constitute a substitute for the ordinary fees customary at the Bank.

4.4 All of the additional conditions in connection with the credit that will be provided to the Borrower, insofar as they are not provided in this Agreement, including interest rates, payment dates, fees and other payments, will be as agreed upon and/or will be agreed upon in writing by the Bank and the Borrower.

5. Preliminary and general terms:

Any provision of any credit and/or its continued provision will be subject to the fulfillment of all of the following conditions:

5.1 The Borrower has opened account number 250888 at the Orot Mall branch (438) of the Bank (hereinafter: the "**Account**").

The Borrower above has executed the customary Credit Documents at the Bank as well as the relevant documents required for the requested activity and/or credit and provided all of the minutes and attorney verifications as customary at the Bank.

5.2 The Borrower has provided the Bank with all of the following sureties, signed a bond or pledge deed for the same in the form customary in the Bank, and provided all of the documents, minutes, and attorney verifications as customary at the Bank:

5.2.1 A first-ranked floating charge, unlimited in amount, on all of the property, funds, rights and assets of any type or kind of the Borrower, and a first-ranked fixed charge, unlimited in amount, on the intellectual property of the Borrower, on the goodwill, documents and negotiable papers, on its bank account, and its holdings in the US Subsidiary and the Dutch Subsidiary, all as set forth in the bond, dated 28.5.17, which was registered on 13.6.17 as Lien No. 13 with the Registrar of Companies.

A first-ranked fixed pledge, unlimited in amount, on all of the rights to receive funds from customers of the Borrower, as set forth in the list that will be attached to the bond.

5.2.2 A first-ranked pledge for the benefit of the Bank, unlimited in amount, on all of the assets and property of the US Subsidiary (including its customers debts). The Borrower will provide the Bank, at the time of the execution of this agreement, with a consent of the US Subsidiary's attorney that the charge on the assets of the US Subsidiary and its shares which was registered with the UCC on 12.3.19 also secures the credit made available under this agreement. The Borrower and the US Subsidiary will make efforts to update the registered charge, such that it will remain in force until the absolute and final clearance of the debts and liabilities of the Borrower to the Bank.

5.2.3 The Dutch Subsidiary has signed on May 29, 2017, a "negative charge" document in the form agreed upon by the parties.

5.2.4 The lists of intellectual property and customers of the Borrower and the US Subsidiary as set forth above include the intellectual property of the companies as well as the lists of their customers on the signing date of the charge documents above. The companies undertake to update the lists on a biannual basis, to provide the updated lists to the Bank, and, to the extent required by the bank in writing, to update the pledge documents accordingly.

The Borrower shall provide to the bank upon the execution of this Agreement, updated lists of equipment, intellectual property rights and customers' debts, and shall further sign an amending warrant agreement, in the form attached hereto as exhibit 5.2.4.

5.3 The Borrower and the US Subsidiary will sign and provide the Bank with any document required by the competent authorities for the fulfillment of their undertakings in accordance with the provisions of this section.

5.4 The Borrower will deposit in the Account, funds as set forth in Section 8 below.

5.5 The Borrower signed on 07.09.2017 an undertaking with respect to various changes in the Borrower, including in its equity.

5.6 The borrower granted the bank on 05.14.2017 and March 12, 2019, warrant agreements (as amended from time to time). The Borrower signed at the time of the execution of this agreement a document for the extension of the expiration dates of the existing warrants **until November 30, 2023**.

Additionally, the Borrower signed a warrant agreement for an additional 359,140 warrants with the bank, attached hereto as exhibit 5.6 of the agreement. The listing of the securities underlying the said warrant agreement an options agreement for trading on the Tel Aviv Securities Exchange (**"TASE"**) is subject to the TASE approval. The company shall take action as soon as practicable in order to obtain such approval.

6. The Borrower and the US Subsidiary hereby assign to the Bank all of their rights, existing and future, for the receipt of funds from their customers, existing and future. Additionally, the Borrower undertakes to act in order for all of the direct payments of its customers, as well as all of the payments owed thereto from the subsidiaries, will be made solely to the bank account set forth in Section 5.1 above, and the same Account will be listed in all of the accounts for payment provided thereby.

7. The subsidiaries undertake to transfer funds to the Borrower's Account, at the first request of the Bank, to cover the credit provided in the Credit Limit for Financing Customer Debt.

The Borrower hereby undertakes to employ its means of control over such subsidiaries in order for the funds to be transferred to its account as aforementioned.

8. The Borrower undertakes that as of the date of the withdrawal of the credit, in whole or in part (whether a withdrawal of a loan from the Credit Limit for Financing Customer Debt or a withdrawal from the loans framework), the balance of the cash in the Bank's Account will not be less at any time than the following:

Amount of Utilized Credit in USD	Total Cash in Account
Up to 10,000,000	30% of the utilized credit
Above 10,000,000	40% of the utilized credit

(hereinafter: the "**Required Deposited Amount**").

It is agreed that a temporary reduction in the amount, at a rate of up to 10% of the Required Deposited Amount, , will not constitute grounds to call the credit due for repayment, subject to the fulfillment of the following terms: (1) the temporary reductions was coordinated with the Bank in advance and in writing; and (2) the Borrower has deposited, within 30 days, in its Account, the amount required such that the Borrower's cash balance in the Account is at least the required Deposited Amount.

9. The Borrower undertakes to ensure that no charges are created on the assets of the subsidiaries (other than as set forth in this Agreement), unless agreed to in advance and in writing by the Bank, and the Borrower further undertakes that it will not change the pricing of the transactions between it and the subsidiaries, as it may be, on the signing date of this Agreement without obtaining the Bank's prior written consent, unless such a pricing change is required under applicable law.

10. Without derogating from the undertaking of the Borrower to provide information and documents, as agreed upon by the Bank and the Borrower, the Borrower undertakes to provide the Bank, on a quarterly basis, with its consolidated financial statements and those of its subsidiaries, audited (regarding the annual financial statements) and reviewed (regarding the quarterly financial statements) by an accountant, as the case may be, as well as any business and financial information, at the request of the Bank. It is emphasized that the reporting on MAGNA and/or on EDGAR (in the event that the securities of the company are listed for trading in the U.S.A) of the annual or quarterly financial statements shall be considered to be the delivery of the information to the Bank. In the event that the company's securities are listed for trading I the U.S.A, an Earnings Release shall be deemed a quarterly financial statement.

11. It is hereby explicitly clarified that the actual provision of the loans and/or credit, pursuant to this Agreement, is contingent on the fulfillment of all of the conditions set forth in this Agreement above, and that the loans and/or credit will be provided based on the agreements set forth in the terms of the Credit Documents, subject to the provisions of this Agreement. The provision of the credit is also contingent on there being no legal impediment for the same, and that the same does not conflict with the provisions of the law and/or the instructions of the Supervisor of Banks (including the provisions of Proper Banking Procedure No. 311 "Minimum Capital Ratio" and Procedure no. 313 - "Restrictions on Companies of a Borrower and Group of Borrowers" and/or any other provisions that shall replace them) and provided that the granting of the credit does not cause a deviation from the liability restrictions of a borrower / group of borrowers. As of the date of the execution of this Agreement, the Bank is not aware of any such impediment or limitation.

12. A breach of any of the undertakings set forth in this document shall be deemed grounds to call for immediate repayment of the credit in its entirety and will not permit the provision of loans from the Credit Limit for Financing Customer Debt and/or the provision of the long-term loan, as the case may be. For the avoidance of doubt, the above shall be in addition to the grounds for calling the credit for immediate repayment, as set forth in the other documents signed and/or that will be signed by the Borrower.

13. The Bank may, at any time and from time to time, in any case in which the Bank may perceive an inability to collect the credit and/or if an adverse change occurs to the Borrower's solvency and/or a materially adverse change to the financial or business state thereof and/or if there are grounds to call the credit for immediate repayment and/or in the event that any of the other conditions occur as a result of changes of the law, or its interpretation which require a reduction and/or cancellation and/or delay of the Line of Credit immediately, while providing notice to the Borrower to reduce and/or cancel the Lines of Credit that are not utilized and/or postpone the provision of any loan, in whole or in part, and/or to delay it.

14. For the avoidance of doubt, the above was not intended to grant rights to any third party, and the same will not constitute a representation on which any third party may rely.

15. All of the appendices to this Agreement constitute integral parts hereof and all of the provisions of the appendices will supplement and be in addition to the provisions of this Agreement. In any case of a conflict between the provisions of this Agreement and the provisions of the Credit Documents or the appendices, the provisions of this Agreement shall prevail, unless expressly agreed otherwise in any of the appendices or Credit Documents. In any other case, the provisions of this Agreement and the provisions of the Credit Documents and the appendices thereto shall be deemed supplementary to each other.

16. The Borrower will pay the Bank, upon the signing of this Agreement, a sum of USD 14,000, for the drafting of the documents. This fee is in addition to the fees customary in the Account.

Respectfully,

Itamar Medical Ltd.
By: Gilad Glick; Shy Basson
Date: 2/9/2020

To Bank Mizrahi Tefahot Ltd.
Dear Sir, madam

We confirm that we have read the foregoing document and we agree to its contents and undertake to act accordingly.

Itamar Medical Inc.

I.M.E. 2016 B.V.

We confirm the above

Mizrahi Tefahot Bank Ltd.

[INFORMAL ENGLISH TRANSLATION]

Mizrahi Tefahot Bank Ltd.

Deed of Pledge Legal Amendment

Company Number
512434218

Pledge number 13

Name of the Company/borrower – **Itamar Medical Ltd.**

Amendment Code: 40
Replacement of Appendix A, A2 and B of the attached appendixes to the amending Deed.

List of codes:

01 Assignment of rights to another
02 Change in the loan agreement
03 Decrease of the secured amount
04 Change in special terms
05 Change in the degree of the pledge
11 Addition of collateral
12 Changes in collateral
13 Release of a collateral
14 Addition of identification for a collateral (include vehicle license number)
21 Partial repayment
40 Other Changes

February 9, 2020
Date

signature of the Borrower

Signature of the Bank

Date: February 9, 2020

Amendment to Deed of Debenture dated 28.5.2017

Whereas: on 28.5.17 Itamar Medical Ltd. company number 512434218 (hereinafter, the **"Company"**) signed a debenture in favor of Mizrahi Tefahot Bank Ltd. (hereinafter, the **"Bank"**), pursuant to which it pledged by floating charge of a first degree its manufacturing facility and all the reminder of assets and rights of any kind what so ever, in its possession now or in the future and by fixed pledge of a first degree its reputation, its fixed assets as detailed in **Appendix A** of the debenture, the intellectual property as detailed in **Appendixes A1 and A2**, of the debenture, the Company's rights to receive funds as detailed in **Appendix B** of the debenture, all the Company's holdings in Itamar Medical Inc, and I.M.E B.V (2016), its bills of lading and certificates, securities, documents and deeds as well as the Company's account with the Bank, all as detailed in the debenture; the said debenture was registered by the Companies Registrar on 13.6.17 as certificate number 13;

Whereas: the company and the Bank agreed that the debenture shall be amended as detailed in this amending deed and that the reminder of the provisions of the debenture shall remain unchanged, all as detailed hereunder;

Now therefore it is hereby agreed by the parties as follows;

1. It is hereby agreed that:
- Appendix A (list of the fixed assets) shall be replaced with Appendix A attached to this amending deed.
- Appendix A2 (list of intellectual property rights) shall be replaced with Appendix A2 attached to this amending deed.
- Appendix B (list of customers) shall be replaced with Appendix B attached to this amending deed.

2. The reminder of the provisions of the debenture shall remain unchanged.

3. The respectable registrar is hereby requested to register in his records the amendment of the debenture as set forth above.

In witness thereof the parties have thereunto signed today February 9, 2020

signature of the Borrower

Signature of the Bank

Appendix A
to the Secured Debenture

[Omitted. The registrant agrees to furnish supplementally a copy of such omitted appendix to the U.S. Securities and Exchange Commission upon request.]

Appendix A1
to the Secured Debenture

[Omitted. The registrant agrees to furnish supplementally a copy of such omitted appendix to the U.S. Securities and Exchange Commission upon request.]

Appendix A2
to the Secured Debenture

[Omitted. The registrant agrees to furnish supplementally a copy of such omitted appendix to the U.S. Securities and Exchange Commission upon request.]

Appendix B
to the Secured Debenture

[Omitted. The registrant agrees to furnish supplementally a copy of such omitted appendix to the U.S. Securities and Exchange Commission upon request.]

Name of Customer: Itamar Medical, Inc.
Address: c/o Itamar Medical Ltd. Halamish 9, Caesarea, Israel
I.D./Company No: 3213646

MIZRAHI TEFAHOT BANK LTD

Kenyon Orot Branch

CONTINUING GUARANTEE IN AN UNLIMITED AMOUNT TO SECURE ALL DEBTS

PREAMBLE

WHEREAS Mizrahi Tefahot Bank Ltd (hereinafter referred to as the "Bank") has granted or from time to time shall grant to Itamar Medical Ltd. (hereinafter referred to as the "Customer") credit under such terms as from time to time were and/or shall be agreed upon between the Bank and the Customer in respect of each credit;

AND WHEREAS we, the undersigned, are willing to guarantee to the Bank the repayment of debts of any kind owing now and / or hereafter from the Customer to the Bank;

NOW THEREFORE WE CONFIRM, GUARANTEE AND UNDERTAKE AS FOLLOWS:-

DEFINITIONS

1. In this Guarantee:-
   (a) "Credit", whether in Israeli currency or in any foreign currency, includes every revolving credit, single credit, loan, discount, purchase and or brokerage of bills, overdraft, granting of guarantee and/or letter of indemnity, opening of documentary credit, grant of extension of time, and of various banking facilities, handling of bills of lading transactions in securities services, or any other payments granted or to be granted now or hereafter by the Bank to the Customer or to his order, whether in Israel or abroad, as well as every and any other transaction or other action whereby or as a result of which debts or obligations are or may be incurred or undertaken by the Customer towards the Bank, whether as debtor, guarantor or endorser and/or in any other manner whether the said debts be owing from the Customer jointly or severally, whether owing presently or hereafter, whether maturing prior to the execution hereof or hereafter, whether certain or contingent, whether owing directly or indirectly, whether express or implied.
   (b) Words importing the singular shall include the plural and vice versa.
   (c) Words importing the masculine gender shall include the feminine gender and vice versa.
   (d) "Bank" means Mizrahi Tefahot Bank Ltd and includes all branches and/or offices and/or subsidiaries and/or affiliates of the Bank existing on the date of this Guarantee, whether in Israel or abroad, and/or any such branch and/or office and/or subsidiary and/or affiliate of the Bank that shall at any future date be established in any place whether in Israel or abroad, its assigns and any person or legal entity duly authorized to act on behalf of the Bank and its duly appointed representatives.
   (e) The "Customer" includes the heirs, estates, successors, executors and administrators of their wills and estates and their appointees and substitutes, guardians, liquidators, directors, partners, shareholders, trustees and assigns of the Customer or power of attorney acting in the Customer's stead.
   (f) "Bills" include promissory notes, cheques, bills of exchange, commitments, guarantees, bills of securities, drafts, bills of lading and any other negotiable and any other negotiable instruments.
   (g) "Consumer Price Index" means the price index known as "the Consumer Price Index" (cost of living index) including fruits and vegetables, published by the Central Bureau of Statistics of the State of Israel, and including such index if published by another official body or institute, and also any official index replacing it, irrespective of whether based on the same data.
   (h) The expression "Representative Rate of the US Dollar" or "Representative Rate" means the representative of the US dollar determined by the Bank of Israel. In the event that the Bank of Israel ceases to determine the Representative Rate either temporarily or permanently, the Representative Rate shall be determined by the Bank.
   (i) The expression "Dollar" means the US dollar.
   (j) "Exchange Rate" means the selling price for cheques and transfers and/or bank notes of any denomination whatsoever in foreign currency, all as shall be determined by the Bank. In the event that at any such time two or more exchange rates as aforesaid are prevailing at the Bank, the Exchange Rate shall be the highest such rate then prevailing. In the event that at the time of such conversion of foreign currency additional payments, including commissions, levies, taxes, fees and other costs, etc. shall apply, the Exchange Rate shall be deemed to include any such additional payments.
   (k) The preamble to this Guarantee shall constitute an integral part hereof.

GUARANTEE 2. We hereby irrevocably guarantee to the Bank and its assigns absolutely, unequivocally and unconditionally the full and prompt repayment of any sums owing now and/or hereafter from the Customer to the Bank, *inter alia*, in connection with the granting of the Credit by the Bank to the Customer, whether the said debts be owing from the Customer singly or jointly with another or others, whether incurred by the Customer in the past or are to be incurred by the Customer in the future, whether owing from the Customer as debtor, guarantor or endorser, whether owing now or hereafter, whether certain or contingent, whether owing directly or indirectly, with the addition of interest, commissions, damages, linkage differentials, exchange rate differentials and any other reasonable and actual charges and costs (all the aforesaid sums hereby guaranteed by us shall hereinafter be referred to as the "Said Sums"). For the avoidance of any doubt, it is hereby agreed and confirmed that we hereby guarantee all linkage differentials and/or exchange rate differentials of any kind whatsoever owing now and/or hereafter by the Customer to the Bank in respect of linked principal and/or linked interest constituting part of the Said Sums. Accordingly, the expression the "Said Sums" shall also be deemed to include the aforesaid linkage differentials and exchange rate differentials.

OBLIGATION AMOUNT. 3. The aggregate amount which we shall be obliged to pay the Bank under the present Guarantee (hereinafter referred to as the "Guaranteed Amount") shall be an **unlimited amount.**

PAYMENTS DATES 4. We undertake to pay the Bank any amount it may demand from us from time to time, within 7 (seven) days of the date of the dispatch of its first demand notice on account of the Guaranteed Amount as the Customer shall owe the Bank, up to the full actual repayment thereof.

WAIVER OF PRIOR DEMAND NOTICE FOR REPAYMENT TO CUSTOMER 5. Except for the notices required pursuant to this Guarantee and as required by applicable law, the undersigned waives notice of acceptance of this Guaranty and notice of any liability to which it may apply, and waives presentment, demand of payment, protest, notice of dishonor or nonpayment of any such liabilities, suit or taking other action by the Bank against, and any other notice to, any party liable thereon (including the undersigned). Notwithstanding the foregoing, the Bank shall provide notice of default to the Customer concurrently with providing a demand for payment to us. We shall pay the Bank all such sums as the Bank may demand from us as aforesaid, without imposing upon the Bank any duty to provide us with any accounts or proof whatsoever of the non-performance by the Customer of his obligations, and we hereby waive any requirement that the Bank make prior demand for payment of any such sums from the Customer. The Bank shall be entitled to demand from us the performance of this Guarantee, without the Bank being obliged to institute any proceedings for the collection of any such sums from the Customer, or from any liquidator or trustee thereof or from other guarantors or to realize other collateral. The institution of any proceedings by the Bank in order to collect any such sums shall not derogate from our obligations to pay any such sums immediately and we shall not be entitled to delay the payment of any such sums until the finalization of any other proceedings instituted by the Bank.

FOREIGN CURRENCY TRANSACTION 6. In every instance that Credit is granted or is to be granted to the Customer in any foreign currency (hereinafter referred to as a "Foreign Currency Transaction"), we hereby undertake to pay to the Bank or to its order in that same foreign currency all the Said Sums which are due and which shall become due from the Customer with respect to that Foreign Currency Transaction, including principal, interest and linkage differentials, if they occur, as well as commissions and reasonable and actual expenses resulting from the linkage of the principal and the interest or any one of them, to the Exchange Rate.

In the event that the Bank shall be compelled to take legal action against us (on the basis of this Guarantee) in order to recover Said Sums in respect of a Foreign Currency Transaction and the court and/or the execution office shall order us to pay any sums in respect of the Foreign Exchange Transaction, in Israeli currency or in consideration of Israeli currency, we hereby undertake to pay the Bank the amount, in New Israeli Shekel, or the proceeds thereof, which shall be sufficient for the conversion into foreign currency of the said amount in accordance with the Exchange Rate prevailing on the date of actual payment.

LIABILITY IN EVENT OF ARRANGMENT, LIQUIDATION OR BANKRUPTCY 7. In the event of any arrangement made with respect to the debts of the Customer, (including an arrangement by the court) or the liquidation or bankruptcy thereof, such arrangement shall not derogate from our obligations pursuant to this Guarantee and the Bank shall be entitled to demand from us the Guaranteed Amount in full in accordance with the amount of the Said Sums as would have been due from the Customer to the Bank if it were not for such arrangement, liquidation or bankruptcy. The Bank shall be entitled to consent to any compromise settlement, and such compromise shall not to derogate from our guarantee for the entire Guaranteed Amount. We undertake not to submit evidence of a debt to a receiver, trustee, etc., without the prior written approval of the Bank which shall not be unreasonably withheld. Notwithstanding the foregoing, we may submit to the receiver, trustee, etc., proof of a debt (or claims of a debt or claims of a similar nature), only if it is emphasized that such claims are subordinate and junior to the rights of the Bank at the time of the receivership or dissolution.

UNCONDITIONAL GUARANTEE

8. The Bank is not bound to accept any additional collateral or guarantee from Customer in respect of the payment of the Said Sums. If it was known to us at the time of or prior to our signing this Guarantee that the Bank was about to obtain other collateral from the Customer or further guarantees, including any instance in which names of additional guarantors were to be supplemented to this Guarantee and the Bank shall not have received such additional collateral and/or the additional guarantors shall not have signed any other guarantee, the validity of this Guarantee shall not thereby be derogated from and we shall perform all our obligations hereunder.

PRESERVATION OF GUARANTEE

9. The Bank may from time to time, whether with or without our consent and with or without any notice to us:-

(a) Discontinue, vary, decrease, increase, or renew any Credit to the Customer;

(b) extend the time for payment or grant other similar accommodations to the Customer and/or to any other person and/or to the Guarantor or to any one of us;

(c) exchange, renew, modify, release, terminate, enforce or refrain from enforcing any collaterals or guarantees held or which shall be held by the Bank, whether obtained from the Customer and/or from other persons and/or from the Guarantors and/or from any one or more of us;

(d) compromise, waive, release or make any other arrangement with the Customer and/or with any other person and/or with the Guarantors and/or with any one of us, of his obligations;

(e) procure the non-discharge of any indebtedness incurred by the Customer in respect of the granting of the Credit, or procure the release of any collateral given in connection with the granting of the Credit;

(f) refrain from notifying us of the non-performance of any obligations whatsoever by the Customer and/or postpone or suspend the submission of demands against us hereunder, without the same being deemed to constitute a precedent, waiver, limitation of action or negligence on the part of the Bank.

Upon the occurrence of any of the aforesaid events, even if as a consequence thereof a loss shall be incurred by the Bank, this Guarantee shall remain fully valid and effective and shall not be affected or altered or reduced as to the amount thereof and all our obligations shall remain unaffected and shall not be reduced. In order to avoid all doubt, it is hereby stipulated that if the Bank perform any of the aforesaid acts, we shall not be entitled to any right of option, right of cancellation or any other right stipulated in the Guarantee Law, 5727-1967, in respect of the said acts and we hereby expressly waive all our said rights thereunder.

WAIVER OF DEFENCE CLAIMS

10. This Guarantee shall not be derogated from, reduced or altered and shall remain valid and effective:-

(a) in the event that the Customer's indebtedness to the Bank is impaired or invalid for any reason whatsoever including, inter alia, by reason of the capacity or representation of the Customer;

(b) in the event that the Bank's right to claim the payment of the Guaranteed Amount from the Customer has terminated due to prescription;

(c) in the event that the Customer denies his liability towards the Bank or in the event that the Customer has or raises any claims against the Bank.

(d) In the event that the Customer is a corporation that has passed a resolution to merge with another corporation, whether as an absorbing company or as a target company, as defined in the Companies Law, 5759-1999.

In each of the aforesaid instances, the abovementioned indebtedness shall, for the purposes of this Guarantee, be deemed to be valid, unimpaired, fully effective, non-appealable and unable to be responded to for the purposes of this Guarantee and we hereby declare that we shall not raise any claim against the Bank and that all our obligations pursuant to this Guarantee shall remain fully effective and we hereby waive, in advance, any rights or claims that the Guarantee Law, 5727-1967, confers or allows in such circumstances.

PRESERVATION OF OBLIGATIONS

11. In the event that we or any one of us or the Customer is a legal entity, whether incorporated or unincorporated, or a trustee, executor or administrator, or joint account holder at the Bank, or any type of organization or entity constituting an affiliation of entities, our obligations hereunder shall not be derogated from by reason of any change in our name, constitution or composition or in that of the Customer.

CONSIDERATION

12. Without deeming consideration to be a precondition to the validity of this Guarantee in whole or in part, we hereby confirm that the Bank's consent to advance Credit from time to time to the Customer or any party constituting the Customer shall be deemed to be full consideration for our obligations hereunder, in whole or in part.

COLLATERAL

13. All present and future collateral and guarantees for our obligations held or to be held by the Bank including those stipulated hereunder, shall constitute collateral for the performance of all our obligations hereunder: The bills of our customers or other parties, or securities or other negotiable instruments as shall be held by the Bank from time to time. Such bills, securities or other negotiable instruments shall be deemed to be pledged and charged to the Bank from the moment of their delivery to the Bank as collateral. We hereby exempt the Bank from all obligations as holder of a bill, such as, presentation for acceptance or for payment, protest and notice of dishonor and the signatures, endorsements and guarantees on bills and any other negotiable instruments shall remain valid until their discharge, without any formal requirements whatsoever having to be met and we hereby waive the right to raise the defense of prescription.

BANKER'S LIEN PLEDGE AND SET-OFF

14. Without prejudice to any other right of the Bank, the Bank shall have a right of pledge, charge, possession, bankers' lien and set-off on all amounts that are or shall be held by the Bank at any time to our credit in a current or any other account whatsoever, whether held jointly or severally, whether with another or others and/or with respect to any and all assets (including, without derogation from the generality thereof, diamonds, gold, securities, bills, coins, banknote, goods, documents relating to goods, insurance policies, assignments of debts, any negotiable instruments, deposits, collateral, mortgages and other rights) that are and/or shall be held and/or credited to or on our behalf at the Bank, in any form or manner whatsoever, including those that have been or shall be delivered to the Bank for collection and/or as security and/or for custody and/or in any other manner whatsoever and on the proceeds thereof. The Bank shall be entitled at any time and from time to time to utilize any asset to which the said lien, pledge, charge or set-off shall apply, in any way or manner, including by realization, collection and sale, at any price and in accordance with any terms as the Bank shall deem proper, and from time to time, to utilize the proceeds (in part or fully) that shall be received as a result of or in relation to such realization and/or collection or sale for the partial and/or full repayment of the Said Sums. At any time that we shall owe, or might owe, or only conditionally owe the Bank any monies pursuant to this Guarantee, the Bank shall be entitled to utilize its rights to fully realize the said pledge, charge, possession, lien and set-off or any of them, in order to discharge the amounts that are or shall be owed by us to the Bank or as security for their repayment. We do not have and shall not have any claim or plea of any type whatsoever against the Bank for taking any action stipulated in this Clause. In order to effect any of the said actions, the Bank shall be entitled to take all legal and other proceedings as it shall deem necessary.

All costs related to the realization and/or sale and/or taking any legal proceedings both against Customer and us, shall be borne by us, and the Bank shall be entitled to debit our account accordingly. In every instance of the collection of bills, the Bank shall be entitled to negotiate and discount the bills to other persons in a reasonable amount, take all legal and other proceedings for the collection of the bills, debit our account with the collection charges, compromise with the makers, endorsers or guarantors thereof or grant any reasonable concessions whatsoever, accept partial payment and from time to time, apply the proceeds of the bills in full or partial payment of the Said Sums.

DEBITING AND CREDITING OF PAYMENTS

15. The Bank may at any time at its reasonable discretion:-

(a) Debit any account in our name with any amount owing now or hereafter to the Bank pursuant to this Guarantee.

(b) Credit any amount paid by us or on our account in any manner and form to such account as the Bank shall deem proper.

(c) Transfer any amount standing to our credit in any account in our name to any other account maintained in our name.

(d) Credit any amount received from the Customer or on his behalf or on account thereof or upon the realization of any collateral held by the Bank to such account as the Bank shall deem proper.

CONTINUING GUARANTEE

16. This Guarantee shall be continuing and revolving security and shall continue to be effective notwithstanding any settlement of accounts with the Customer and shall bind us and our assigns (which expression shall be interpreted as including guardians, custodians, heirs, administrators and executors of wills, trustees, receivers, liquidators and successors and any party acting in their stead) until the expiration of thirty (30) days from the day on which the Bank, through the branch at which we executed the present Guarantee, receives written notice from us of the termination of the Guarantee. The said notice shall not derogate from our Guarantee and our liability for the debts, transactions and obligations that the Customer has effected or undertook to effect prior to the termination of the said period of 30 (Thirty) days, even though their maturity dates may occur after the expiration of the said period.

SUBORDINATIOM OF INDEBTEDNESS OF CUSTOMER

17. We hereby agree that any indebtedness of the Customer, now or in the future owed to us and outstanding at the time of enforcement of, or collection under, this Guarantee, is hereby subordinated to the Said Sums. If the Bank so request, any such indebtedness shall be collected, enforced and received by the Guarantor as trustee for the Bank, and shall be paid over to the Bank in kind on account of the Said Sums, provided that the Bank is then entitled to collect an amount equal to, or greater than, such indebtedness from the Customer pursuant to any agreement and/or Credit provided by Bank to Customer.

SUBROGATION 18. We hereby agree that, until the payment and satisfaction in full of all of the Said Sums, we shall not exercise any right, remedy, power or privilege, such as any right of subrogation, contribution or indemnity or related remedy, power or privilege, arising to us (whether by contract or operation of law) against the Customer in respect of all or any part of the Said Sums or any collateral for all or any part of the Said Sums by reason of any payment or other performance pursuant to the provisions of this Guarantee and, if any amount shall be paid to us on account of such rights, remedies, powers or privileges, we shall hold such amount in trust for the benefit of, and pay the same over to, the Bank, on account of the Said Sums. We understand that the exercise by the Bank of any right, remedy, power or privilege that it may have under any agreement with Customer and/or with us relative to all or any part of the Said Sums may affect or eliminate our right of subrogation or similar recovery against the Customer, any other guarantors or any collateral, and that we may therefore incur partially or totally non-reimbursable liability under this Guarantee. Nevertheless, we hereby authorize and empower the Bank to exercise, in its sole discretion, any combination of such rights, remedies, powers and privileges, provided however, that such exercise of rights is in accordance with the terms of its agreements with Customer or with us.

CONDITIONAL RELEASE 19. In the event that our obligation to the Bank pursuant to this Guarantee is for any reason whatsoever revoked or terminated or the Bank shall confirm that our obligation as herein stipulated has terminated, we hereby agree that in any event of the Bank being ordered by any court to repay to any person or body whatsoever any amount whatsoever paid to the Bank in discharge of the Said Sums or on account thereof (whether such amount was paid to the Bank by mistake or in fraudulent preference or for any other reason whatsoever) we hereby undertake to compensate and indemnify the Bank in respect of any sum which the Bank is ordered to pay and/or incurs in relation thereto, with the addition of all the expenses and payments incurred with respect thereto and with the addition of interest accrued on such sums, charged at the highest rate of interest then prevailing, until we fully repay all the amounts stipulated in this paragraph to the Bank.

AUTONOMOUS NATURE OF COLLATERAL 20. This Guarantee shall be deemed to be autonomous of any other collateral or guarantees and shall not be prejudiced or affected by any such other collateral or by reason of the Bank receiving impaired or invalid collateral or guarantees.

We hereby waive any right to receive by way of transfer to us or to participate in any other collateral which the Bank holds in respect of the repayment of the Said Sums and we shall not perform any act with the purpose of obtaining any rights in the said collateral, notwithstanding payment by us of the full Guaranteed Amount.

INDEMNITY 21. In addition to our guarantee provided herein, the present document shall constitute an undertaking of indemnity and we hereby undertake to indemnify the Bank, within the limits of the Guaranteed Amount, for any damages, costs and losses caused to the Bank in any action or legal proceeding brought by third parties, with the exclusion of lost-profit damages only, as result of granting credit to the Customer, subject to the relevant conditions stipulated herein.

BANK ENTRIES 22. All entries recorded in the books of the Bank shall be deemed to be accurate and shall serve as sufficient evidence against us with respect to all their details, regarding all the accounts of the Customer unless disputed by Customer within thirty (30) days of entry being provided to Customer. Copies of such entries and/or, at the discretion of the Bank, every item in such entry or such page or in separate document or any part of such entry or the last page of the said entry or any part thereof that shall be approved by an officer of the Bank, shall serve as sufficient evidence as to the existence of such entry and as to the accuracy of the details appearing thereon.

The term “the books of the Bank” shall be deemed to also include any book, ledger, statement, copy of statement, loan agreement, deed of undertaking, bill signed by the Customer, index card, page, roll or any other means or by electronic data storage and computerization and other means of data storage.

The term “entry” shall be deemed to also include any entry or copy of an entry whether written or copied by hand or typewriter or whether recorded by printing, stenciling, duplicating, photostating (including microfilming) or any other mechanical, electrical or electronic means or by electronic computer recording means or any other means of recording or presenting words or presenting words or number or any other symbols whatsoever which exist and/or are utilized at the Bank.

For avoidance of doubt, in no event shall the Bank provide us with any books and records with respect to Customer if doing so is prohibited by any applicable law or regulation.

TAX GROSS UP AND SETOFF 23. We shall make all payments to be made by us under this Guarantee without any deduction or withholding for or on account of any tax (together, a ”Tax Witholding") unless a Tax Withholding is required by law. We shall promptly upon becoming aware that we must make a Tax Withholding (or that there is any change in the rate or the basis of a Tax Withholding) notify the Bank accordingly. If a Tax Withholding is required by law to be made by us, the amount of the payment due from us shall be increased to an amount which (after making any Tax Withholding) leaves an amount equal to the payment which would have been due if no Tax Withholding had been required. If we are required to make a Tax Withholding, we shall make that Tax Withholding and any payment required in connection with that Tax Withholding within the time allowed and in the minimum amount required by law. Within 30 days of making either a Tax Withholding or any payment required in connection with that Tax Withholding, we shall deliver to the Bank evidence satisfactory to the Bank that the Tax Withholding has been made or (as applicable) any appropriate payment has been paid to the relevant taxing authority. All payments made by us to the Bank under this Guarantee shall (save insofar as required by law to the contrary) be paid in full without set-off or counterclaim.

TECHNICAL CHANGES	24.	For the avoidance of any doubt and for the purposes of clarification, it is hereby stated that: in the event that for any bureaucratic, administrative or technical reasons, a change shall occur in the number of any account (as such account is included in the definition of "Credit" in this document) or the account is transferred to another branch of the Bank, all the provisions of this Guarantee shall be deemed to relate to the said account pursuant to the new number so given or at the other branch to which the account has been transferred, even in the event that it shall be stated in this document that our Guarantee relates to Credit which the Customer has received in a particular account or at a particular branch.
ASSIGNMENT OF RIGHTS	25.	This Guarantee may be assigned by the Bank without the need to obtain our prior consent.
MUTUALLY DEPENDENT, JOINT AND SEVERAL LIABILITY	26.	In the event that the Customer shall have a number of Guarantors, the liability hereunder shall be mutually dependent, jointly and severally, and the Bank shall at its sole discretion, be entitled to collect from any one or more of the Guarantors, the full Guaranteed Amount or any part thereof. The liability of each one of the Guarantors shall not be affected by reason of any of the other Guarantors not having the capacity to be bound as Guarantors, or as a consequence of the Bank releasing them from their liability or returning to them the collateral that they delivered to the Bank.
STATUTE OF LIMITATIONS	27.	We hereby waive all our rights to plead prescription under any law in force at such time in all matters relating to this Guarantee and we hereby agree that the fact that the Bank does not immediately exercise its rights hereunder or in connection herewith in any given event shall not be deemed a waiver of such rights, nor a consent or acknowledgment by the Bank, nor shall it be deemed to create any precedent and the Bank shall be entitled to exercise the rights deriving from this document and/or in connection herewith and/or the law at such time as it may deem fit.
RATIFICATION	28.	We hereby undertake to sign all such documents and forms as the Bank may require, if and insofar as under any or some of the laws of the State of Israel, our signing of any such document or form is or shall be deemed to be required, at the Bank's sole discretion, in order to make the present document fully valid and effective. In compliance with the provisions of this Clause, we hereby appoint the Bank as our principal attorney, either itself or through such person to whom the Bank may delegate its powers, to sign all such documents and forms as may be requested by the Bank, and the Bank or any party acting on its behalf shall in no way be liable to us in respect of any act or omission whatsoever made thereby under or by virtue of this Clause. The said appointment shall be irrevocable as the rights of the Bank are dependent thereon and full consideration has been given by the Bank therefor by the Bank advancing the Credit to the Customer.
NOTICES	29.	Any notice, demand, request, consent, approval, declaration, or other communication hereunder shall be deemed to have been duly given or served on the date on which personally delivered, or - if mailed to us by the Bank through the post by registered or ordinary mail to the addresses set out below or to such other address in Israel of which we shall notify the Bank in writing shall be deemed to have been duly received by the addressee five (5) business days after the date of delivery of the letter for dispatch. A written statement by the Bank shall constitute sufficient proof of the time and posting of the notice.
STAMPING AND EXPENSES	30.	Stamp duty payable in respect of this Guarantee and all such other expenses as relate to the enforcement hereof or the realization of any collateral delivered in connection herewith, including the Bank's advocate's fees, shall be borne by us and secured by this Guarantee.
WAIVER OF PRIOR NOTICE	31.	We hereby waive the need for dispatching any notarial or other warnings in all matters in connection with this Guarantee.
GOVERNING LAW AND JURISDICTION	32.	The laws of the State of Israel shall govern this Guarantee and we hereby agree that the city of Tel Aviv-Jaffa, State of Israel, shall be the place of jurisdiction for the purposes of this Guarantee, provided that the Bank shall be entitled to institute proceedings against us in any such other competent court as it may deem fit.
MARGINAL NOTES	33.	The marginal notes in this Guarantee have been inserted for ease of reference only and shall not be utilized as a means of interpreting the intentions of the parties or the interpretation of this Guarantee.

ADDENDA 34. **SPECIAL CONDITIONS:**

IN WITNESS WHEREOF THE PARTIES HERETO HAVE HEREUNTO EXECUTED THIS GUARANTEE ON THIS 12 DAY OF March 2019

NAME OF GUARANTORS

Date	Name of Guarantor	Address (in Israel only)	Company/Id. No.	Signature
Ma March 12, 2019	Itamar Medical, Inc.	c/o Itamar Medical Ltd. Halamish 9, Caesarea, Israel	3213646	

VERIFICATION OF GUARANTORS SIGNATURES

I, the undersigned, hereby verify that the Guarantor/s whose names appear hereunder, have signed before me on the dates stipulated above next to their names/signatures on this Guarantee and have been identified by me in accordance with an identification document and I have explained to them the contents and significance of this Guarantee after they have confirmed to me that they have read it.

Name of Guarantor*	Bank Officer's Full Name	Position	Bank Officer's Signature	Date of Bank Officer of Signature 03.12.2019

* First and Surname/Corporate Name (In case of corporate Guarantor – in addition, the name of the authorized signatory signing on behalf of the Corporation must be completed

Execution Copy

UNLIMITED SECURITY AGREEMENT

THIS SECURITY AGREEMENT ("**Security Agreement**") is made and entered into as of the 12th day of March, 2019 (the "**Execution Date**") by and between Itamar Medical Inc., a *Delaware* Corporation, c/o Itamar Medical Ltd., 9 Halamish St., Caesarea, Israel USA ("**Guarantor**"), and Mizrahi Tefahot Bank Ltd., Israel (the "**Bank**").

WHEREAS Itamar Medical Ltd., the parent company of Guarantor (**"Affiliated Company"**) has, or may have, obtained in the past, pursuant to previous agreements and transactions with the Bank, and intends to obtain – in the future - additional credit lines, loans, banking facilities, credit and other miscellaneous banking services from the Bank (hereinafter jointly and severally referred to as the "**Banking Service**(s)") on such terms as have been and/or are in future from time to time agreed in respect of each Banking Service; and

WHEREAS in order to induce the Bank to provide the Banking Services to the Affiliated Company, and in consideration of the Bank's agreement to extend such Banking Services to the Affiliated Company, it has been agreed between the Guarantor and the Bank that the Guarantor will guarantee all of the Affiliated Company's debts and liabilities to the Bank of any kind whatsoever related to the Banking Services, whether in Israeli currency, in United States Dollars, or in any other currency whatsoever, all as set forth in the Guarantee Agreement entered into between the parties hereto, dated March 12, 2019 (the "**Guarantee Agreement**"), and will secure all of its undertakings and obligations, all as set out in this Security Agreement below;

NOW, THEREFORE, in consideration of the premises and of the mutual covenants herein contained and for other good and valuable consideration, the receipt of which is hereby acknowledged, the parties hereto agree as follows:

1. Defined Terms. The following terms shall have the following meanings (such meanings being equally applicable to both the singular and plural forms of the terms defined):

"**Accounts**" shall mean any "account," as such term is defined in section 9-102(a)(2) of the UCC, now owned or hereafter acquired by the Guarantor and, in any event, shall include, without limitation, all accounts receivable, book debts, and other forms of obligations now owned or hereafter received or acquired by or belonging or owing to the Guarantor (including, without limitation, under any trade names, styles, or divisions thereof) whether arising out of goods sold or services rendered by the Guarantor or from any other transaction, whether or not the same involves the sale of goods or services by the Guarantor (including, without limitation, any such obligation that might be characterized as an account or contract right under the UCC) and all of the Guarantor's rights in, to, and under all purchase orders or receipts now owned or hereafter acquired by it for goods or services, and all of the Guarantor's rights to any goods represented by any of the foregoing (including, without limitation, unpaid seller's rights of rescission, replevin, reclamation, and stoppage in transit, and rights to returned, reclaimed, or repossessed goods), and all moneys due or to become due to the Guarantor under all contracts for the sale of goods or the performance of services or both by the Guarantor (whether or not yet earned by performance on the part of the Guarantor or in connection with any other transaction), now in existence or hereafter occurring, including, without limitation, the right to receive the proceeds of such purchase orders and contracts, and all collateral security and guaranties of any kind given by any person or entity with respect to any of the foregoing.

"**Chattel Paper**" shall mean any "chattel paper," as such term is defined in section 9-102(a)(11) of the UCC, now owned or hereafter acquired by the Guarantor.

"**Collateral**" shall have the meaning assigned to such term in Section 5 of this Security Agreement.

"**Contracts**" shall mean all contracts, undertakings, or other agreements (other than rights evidenced by Chattel Paper, Documents, or Instruments) under which the Guarantor may now or hereafter have any right, title or interest, including, without limitation, with respect to an Account, any agreement relating to the terms of payment or the terms of performance thereof.

"**Copyrights**" shall mean all of the following now or hereafter acquired by the Guarantor: (i) all copyrights, registrations, and applications therefor; (ii) all renewals and extensions thereof; (iii) all income, royalties, damages, and payments now and hereafter due or payable or both with respect thereto, including, without limitation, damages and payments for past or future infringements or misappropriations thereof; (iv) all rights to sue for past, present, and future infringements or misappropriations thereof; and (v) all other rights corresponding thereto throughout the world.

"**Deposit Accounts**" shall mean any "deposit account" as such term is defined in section 9-102(a)(29) of the UCC, now owned or hereafter acquired by the Guarantor.

"**Documents**" shall mean any "documents," as such term is defined in section 9-102(a)(30) of the UCC, now owned or hereafter acquired by the Guarantor.

"**Equipment**" shall mean any "equipment," as such term is defined in section 9-102(a)(33) of the UCC, now owned or hereafter acquired by the Guarantor and, in any event, shall include, without limitation, all machinery, equipment, furnishings, fixtures, vehicles, computers, and other electronic data-processing and other office equipment now owned or hereafter acquired by the Guarantor and any and all additions, substitutions, and replacements of any of the foregoing, wherever located, together with all attachments, components, parts, equipment, and accessories installed thereon or affixed thereto.

"**Event of Default**" shall mean any Event of Default as defined in Section 10 herein.

"**General Intangibles**" shall mean any "general intangibles," as such term is defined in section 9-102(a)(42) of the UCC, now owned or hereafter acquired by the Guarantor and, in any event, shall include, without limitation, all right, title, and interest that the Guarantor may now or hereafter have in or under any Contract, all customer lists, Copyrights, Trademarks, Patents, rights in intellectual property, Licenses, permits, Trade Secrets, proprietary or confidential information, inventions (whether patented or patentable or not), technical information, procedures, designs, knowledge, know-how, software, data bases, data, skill, expertise, experience, processes, models, drawings, materials, and records now owned or hereafter acquired by the Guarantor, goodwill, and rights of indemnification.

"**Hereby**," "**herein**," "**hereof**," "**hereunder**" and words of similar import refer to this Security Agreement as a whole (including, without limitation, any schedules hereto) and not merely to the specific section, paragraph, or clause in which the respective word appears.

"**Instruments**" shall mean any "instrument," as such term is defined in section 9-102(a)(47) of the UCC, now owned or hereafter acquired by the Guarantor, other than instruments that constitute, or are a part of a group of writings that constitute, Chattel Paper.

"**Intellectual Property**" shall mean all of the Copyrights, Licenses, Patents, Trademarks, and Trade Secrets of Guarantor.

"**Inventory**" shall mean all "inventory," as such term is defined in section 9-102(a)(48) of the UCC, now owned or hereafter acquired by the Guarantor and, in any event, shall include, without limitation, all inventory, merchandise, goods, and other personal property now owned or hereafter acquired by the Guarantor which are held for sale or lease or are furnished or are to be furnished under a contract of service or which constitute raw materials, work in process, or materials used or consumed or to be used or consumed in the Guarantor's business, or the processing, packaging, delivery, or shipping of the same, and all finished goods.

"Investment Property" means (i) a security, whether certificated or uncertificated, (ii) a security entitlement, (iii) a securities account, (iv) a commodities contract, or (v) a commodities account, all as defined in Article 9 of the UCC.

"**License**" shall mean any Patent License, Trademark License, or other license as to which the Bank has been granted a security interest hereunder.

"**Liens**" shall mean, with respect to any asset, (a) any mortgage, deed of trust, lien, pledge, hypothecation, encumbrance, charge or security interest in, on or of such asset, (b) the interest of a vendor or a lessor under any conditional sale agreement, capital lease or title retention agreement (or any financing lease having substantially the same economic effect as any of the foregoing) relating to such asset and (c) in the case of securities, any purchase option, call or similar right of a third party with respect to such securities.

"**Patent License**" shall mean any written agreement granting any right to practice any invention on which a Patent is in existence, now owned or hereafter acquired by the Guarantor.

"**Patents**" shall mean all of the following now or hereafter acquired by the Guarantor: (i) all patents and patent applications throughout the world, whether arising under U.S. federal law, state law, common law or the law of any other jurisdiction; (ii) all inventions and improvements described and claimed therein; (iii) all reissues, divisions, continuations, renewals, extensions, and continuations-in-part thereof; (iv) all income, royalties, damages and payments now and hereafter due and/or payable to the Guarantor with respect thereto, including, without limitation, damages and payments for past, present or future infringements or misappropriations thereof; (v) all rights to sue for past, present, and future infringements or misappropriations thereof; and (vi) all other rights corresponding thereto throughout the world.

"**Proceeds**" shall mean "proceeds," as such term is defined in section 9-102(a)(64) of the UCC and, in any event, shall include, without limitation, (i) any and all proceeds of any insurance, indemnity, warranty or guaranty payable to the Guarantor from time to time with respect to any of the Collateral; (ii) any and all payments (in any form whatsoever) made or due and payable to the Guarantor from time to time in connection with any requisition, confiscation, condemnation, seizure, or forfeiture of all or any part of the Collateral by any governmental body, authority, bureau, or agency (or any person acting under color of governmental authority); and (iii) any and all other amounts from time to time paid or payable under or in connection with any of the Collateral.

"**Secured Sums**" shall have the meaning defined in Section 2 herein.

"**Security Agreement**" shall mean this Security Agreement, as the same may from time to time be amended, modified, or supplemented pursuant to Section 19 of this Security Agreement, and shall refer to this Security Agreement as in effect on the date such reference becomes operative.

"**Trade Secrets**" shall mean trade secrets, along with any and all (i) income, royalties, damages, and payments now and hereafter due and/or payable to the Guarantor with respect thereto, including, without limitation, damages and payments for past or future infringements or misappropriations thereof; (ii) rights to sue for past, present, and future infringements or misappropriations thereof; and (iii) all other rights corresponding thereto throughout the world.

"**Trademark License**" shall mean any written agreement granting any right to use any Trademark or Trademark registration, now owned or hereafter acquired by the Guarantor.

"**Trademarks**" shall mean all of the following now owned or hereafter acquired by the Guarantor: (i) all trademarks (including service marks and trade names, whether registered or at common law), registrations and applications therefor, and the entire product lines and goodwill of the Guarantor's business connected therewith and symbolized thereby; (ii) all renewals thereof; (iii) all income, royalties, damages, and payments now and hereafter due or payable or both with respect thereto, including, without limitation, damages and payments for past, present, or future infringements or misappropriations thereof; (iv) all rights to sue for past, present, and future infringements or misappropriations thereof; and (v) all other rights corresponding thereto throughout the world.

"**UCC**" shall mean the Uniform Commercial Code as the same may, from time to time, be in effect in the State of Delaware; provided, however, in the event that, by reason of mandatory provisions of law, any or all of the attachment, perfection or priority of security interest in any Collateral is governed by the Uniform Commercial Code as in effect in a jurisdiction other than the State of Delaware the term "UCC" shall mean the Uniform Commercial Code as in effect in such other jurisdiction for purposes of the provisions hereof relating to such attachment, perfection, or priority and for purposes of definitions related to such provisions.

2. Secured Obligations. This Unlimited Security Agreement has been executed to secure the full and punctual payment of all the amounts, whether in New Israeli Shekels, in United States Dollars or in any foreign currency, now and in future due to the Bank from the Guarantor and/or from the Affiliated Company, in any manner or way and for any reason, whether or not the amounts are due from the Affiliated Company in connection with the provision of the Banking Services, whether due from the Affiliated Company alone or together with others, whether the Affiliated Company has already become liable for them or becomes liable for them in the future, as debtor and/or guarantor and/or otherwise (including the Affiliated Company's liability in accordance with bills that have been or are in the future delivered to the Bank either by the Affiliated Company or by third parties for discounting or as security and/or pursuant to any other liability of the Affiliated Company to the Bank), that are now and/or in future due, payable prior to or after realization of the collateral hereby given, absolutely or contingently due, pursuant to the Affiliated Company's original obligation or formulated in a court judgment or otherwise, in an unlimited amount, plus any and all accrued interest, commissions and all expenses whatsoever, including the costs of realization, advocates' professional fees, insurance fees and other payments pursuant to this Security Agreement, with the addition of any sums of any type now or in the future due from the Affiliated Company to the Bank in any way in respect or as a result of linkage to any index or rate of exchange, including, without limitation, any such linked principal and linked interest (all the foregoing amounts being hereinafter referred to as the "**Secured Sums**").

3. Realization of Collateral. Upon the following, the Bank shall be entitled to exercise all rights and remedies of a secured party under the UCC, and may collect, receive, appropriate, and realize upon the Collateral, or any part thereof, and/or may forthwith sell, lease, assign, give an option or options to purchase, or sell or otherwise dispose of and deliver such Collateral (or contract to do so), or any part thereof, and all such proceeds shall be used to pay the Bank all of the Secured Sums:

(a) on the due date of the Secured Sums (or any part thereof), if it has been agreed between the Bank and the Affiliated Company that the particular amount is payable on a particular date (giving effect to any grace periods as agreed between the Bank and the Affiliated Company or the Guarantor in writing), and the Affiliated Company has not paid such Secured Sums;

(b) at the end of ten (10) days from the date of receipt by Guarantor of the Bank's first written demand to the Guarantor, if a due date has not been agreed as provided in paragraph (a) above, if such Secured Sums have not been paid by Affiliated Company;

(c) the occurrence of an Event of Default.

4. Interest.

(a) The Bank shall compute interest on the Secured Sums at such rate as has been or is in future from time to time agreed between it and the Affiliated Company. In cases in which the interest rate has not been agreed, the Bank may fix the interest rate for any part of the Secured Sums for which the Affiliated Company and Bank have not agreed on an interest rate, and give notice thereof to the Affiliated Company in accordance with interest rates customary at the Bank at such time. The Affiliated Company and/or Guarantor shall be charged such interest rates as aforesaid and the Bank may add them to principal at the end of each quarter or at the end of any other period, as determined by it.

(b) In an event of default in payment of all or any of the Secured Sums, they shall bear default interest at the rate agreed upon in the agreement for the provision of the Banking Services. In the absence of a provision with regard to default interest in those agreements, the Secured Sums shall bear interest at the maximum rate prevailing at the Bank in respect of unauthorized withdrawals and defaults on an approved overdraft account, but not less than 2% (two percent) more than the interest rate fixed in the agreement for the provision of any Banking Service.

(c) In the event that the Bank becomes entitled to realize the Collateral under this Security Agreement it may increase the interest rates of the Secured Sums, commencing at such time when the Bank becomes entitled to realize the Collateral to the maximum rate prevailing at the Bank in respect of unauthorized withdrawals and defaults on an approved overdraft account.

5. Grant of Security Interest.

(a) As collateral security for the punctual and full payment and performance when due (whether at stated maturity, by acceleration, or otherwise) of all the Secured Sums, and to induce the Bank to provide the Banking Services to the Affiliated Company, the Guarantor hereby grants to the Bank, a first priority lien on, and security interest in, to, and under the following property, now owned or hereafter acquired by the Guarantor (all of which being hereinafter collectively called the "**Collateral**"):

(i) all Accounts, including, without limitation, all accounts receivable set forth in **Schedule A** attached hereto;

(ii) all Chattel Paper;

(iii) all Contracts;

(iv) all Copyrights;

(v) all Deposit Accounts other than the Deposit Accounts identified on Schedule I attached hereto;

(vi) all Documents;

(vii) all Equipment;

(viii) all General Intangibles;

(ix) all Instruments;

(x) all Inventory;

(xi) all Investment Property;

(xii) all Patents;

(xiii) all Patent Licenses;

(xiv) all Trademarks;

(xv) all Trade Secrets;

(xvi) all Trademark Licenses;

(xvii) the Company's goodwill, as currently and at any time in future existing;

(xviii) all other goods and personal property of the Guarantor whether tangible or intangible or whether now owned or hereafter acquired by the Guarantor and wherever located; and

(xix) to the extent not otherwise included, all Proceeds of each of the foregoing and all accessions to, substitutions, and replacements for, and rents, profits and linkage thereon, and products of each of the foregoing.

(xx) any and all Intellectual Property owned or that shall be owned by the Guarantor, or to which it is or shall be entitled or that it possesses or shall possess any proprietary or other rights thereto, by virtue of any law, agreement or any other source whatsoever, including without limitation all Intellectual Property listed in **Schedule B**, including but not limited to all information or materials in any shape or form, relating to research, development, specifications, formulas, algorithms, prototypes, computer programs, records, data, designs, concepts, ideas, methods, techniques, processes, samples, trade secrets, analyses, materials, patents, pending patent applications, registered trademarks, pending trademark applications, and applications for registration, other data and information, as well as any improvements and derivatives thereof; and any and all Proceeds of the foregoing and all accessions to, substitutions, and replacements for, and rents, profits, and products of the foregoing.

The Guarantor hereby confirms that the list attached hereto as **Schedule B**, constitutes all of the Guarantor's Intellectual Property, including all patents, pending patent applications, registered trademarks, pending trademark applications, and applications for registration, to this date.

(b) The Guarantor agrees to deliver promptly or cause to be delivered to the Bank all Pledged Shares, and any and all certificates or other instruments or documents representing any of the Collateral (together with any necessary endorsement). All Pledged Shares delivered to the Bank shall be accompanied by undated stock powers duly executed in blank (in form as attached in **Schedule C**) or other instruments of transfer satisfactory to the Bank and by such other instruments and documents as the Bank may reasonably request. Such stock powers and other documents and instruments shall be held by the Bank in escrow and may be executed by the Bank - at its sole and absolute discretion - only upon the occurrence of an Event of Default.

(c) Upon signing this Agreement, and each time Schedule A is updated, Guarantor shall execute and deliver to bank, in a form as attached hereto in **Schedule D**, a specific assignment of such accounts of borrower listed in Schedule A.

(d) The security interest that has been given to the Bank pursuant to this Security Agreement is of perpetual character notwithstanding settlement of all or any of the Affiliated Company's accounts and it shall remain in force until this Security Agreement is terminated pursuant to the provisions of Section 14 below.

(e) Should the Bank have or in future be given collateral or guarantees for payment of the Secured Sums, all the collateral and guarantees shall be independent of each other.

(f) Should the Bank compromise with or grant forbearance or a concession to the Affiliated Company, or should the Bank alter the Affiliated Company’s obligations in connection with the Secured Sums or release or waive other collateral or guarantees, the same shall not alter the nature of the collateral created pursuant to this Security Agreement and all the collateral and obligations of the Guarantor pursuant to this Security Agreement shall remain in full force and effect in accordance with the terms of the Security Agreement.

(g) The Bank shall have rights of possession, lien and set-off over all the amounts, assets and rights, including securities, currency, gold, bank notes and documents for goods, insurance policies, bills, checks, obligations, deposits, collateral and the proceeds thereof, that are at the Bank at any time to or for the credit of the Guarantor, including those given for collection, security, safe keeping or otherwise. The Bank may withhold the said assets until full discharge of the Secured Sums or sell them and apply all of the proceeds of sale to the discharge of the Secured Sums, in accordance with the terms of this Security Agreement.

(h) The Bank may at any time charge any of Guarantor's accounts held with it with any outstanding amount now or in future due to it from the Guarantor and apply the entire amount that it receives from or for the Guarantor to the credit of such amount as it deems fit, and transfer any amount standing to the Guarantor's credit in any account with it to any other account with it as the Bank deems fit.

6. Rights of the Bank; Limitations on the Bank's Obligations.

(a) The Bank shall have no obligation or liability under any contract by reason of or arising out of this Security Agreement or the granting to the Bank of a security interest therein or the receipt by the Bank of any payment relating to any contract pursuant hereto, nor shall the Bank be required or obligated in any manner to perform or fulfill any of the obligations of the Guarantor under or pursuant to any contract, or to make any payment, or to make any inquiry as to the nature or the sufficiency of any payment received by it or the sufficiency of any performance by any party under any contract, or to present or file any claim, or to take any action to collect or enforce any performance or the payment of any amounts which may have been assigned to it or to which it may be entitled at any time or times.

(b) So long as no Event of Default shall have occurred, the Guarantor shall be entitled to exercise all voting rights pertaining to the Pledged Shares and to give consents, waivers and ratifications in respect thereof, provided however that the Guarantor shall not vote or give any consent, waiver, or ratification if the effect thereof would in the reasonable judgment of the Bank impair the stock secured or pledged hereby or be inconsistent with or result in any violation of the provisions of this Security Agreement, and Guarantor shall notify the Bank regarding any shareholder action that may impair the Bank's rights under this Security Agreement and the Bank shall have the exclusive right to vote any and all of the Pledged Shares and to give consents, waivers and ratifications in respect thereof, and the Guarantor shall deliver to the Bank such proxies or other documents and instruments as the Bank may request to further effectuate the foregoing. After the occurrence and during the continuance of an Event of Default, the Bank shall have the exclusive right to vote any and all of the Pledged Shares and to give consents, waivers and ratifications in respect thereof, and the Guarantor shall deliver to the Bank such proxies or other documents and instruments as the Bank may request to further effectuate the foregoing. For these purposes, the Guarantor designates and appoints the Bank as the Guarantor's agent and attorney-in-fact for purposes of executing such documents and instruments as the Bank may consider necessary or appropriate for purposes of implementing this Agreement. The foregoing designation and appointment is irrevocable and coupled with an interest.

(c) The Bank shall not be liable for failure to collect or realize upon the Collateral, or for any delay in so doing, nor shall it be under any obligation to take any action whatsoever with regard thereto. If an Event of Default has occurred and had not been cured during the applicable cure period, the Bank may thereafter, without notice, exercise all rights, privileges or options pertaining to any Pledged Shares and/ or to the Collateral as if it were the absolute owner thereof, upon such terms and conditions as it may determine, all without liability except to account for property actually received by it, but the Bank shall have no duty to exercise any of the aforesaid rights, privileges or options and shall not be responsible for any failure to do so or delay in so doing.

7. Representations and Warranties. The Guarantor hereby represents and warrants that:

(a) Except for the security interest granted to the Bank pursuant to this Security Agreement, the Guarantor is the sole owner of each item of the Collateral in which it purports to grant any interest hereunder, having good and marketable title and unlimited rights thereto, free and clear of any and all Liens, assignments, restrictions, and any current or future rights whatsoever.

(b) No effective security agreement, financing statement, equivalent security or lien instrument, or continuation statement covering all or any part of the Collateral is on file or of record in any public office, except such as may have been filed by the Guarantor in favor of the Bank pursuant to this Security Agreement.

(c) The Affiliated Company is an Israeli Company. The Affiliated Company's registered office is at 9 Halamish Street, P.O. Box 3579, Caesarea 3088900, Israel. Guarantor is a fully-held subsidiary of the Affiliated Company, on a fully diluted and as-converted basis.

(d) Guarantor's exact legal name is as set forth in the preamble to this Agreement and Guarantor is not generally known by or using any fictitious or other name or trade name or style. Guarantor's address is at 3290 Cumberland Club Drive, Suite 100, Atlanta, GA 30339, USA. Guarantor's address in Israel, to which any and all documents could legally be delivered, is at 9 Halamish Street, P.O. Box 3579, Israel.

(e) There is no legal, contractual or other restraint or condition prohibiting the transfer, charge or pledge of the Collateral, or of any part thereof.

(f) Guarantor is entitled to pledge or charge the Collateral pursuant to this Security Agreement.

(g) No assignment of right or other transaction has been made that derogates from the value of the Collateral as in effect on the date of this Security Agreement.

(h) Guarantor has received the necessary consents and/or waivers (if any) from its directors and stockholders pursuant to the certificate of incorporation and by-laws of Guarantor or the various investment agreements. A copy of the resolutions of the Guarantor's board of directors and shareholders' meetings approving the execution of this agreement and the grant of a security interest under the terms and conditions herein are attached hereto as **Schedule E**. No additional consents or waivers are necessary.

(i) Upon the appropriate UCC Financing Statements having been filed in the State of Delaware, this Security Agreement is effective to create and perfect a valid and continuing first priority charge on, and first priority perfected security interest in, the Collateral, with respect to which a security interest may be perfected by filing pursuant to the UCC, in favor of the Bank, prior to all other Liens, and is enforceable as such against creditors.

(j) Upon the appropriate filings and/or statements having been filed with the United States Patent and Trademark Office ("USPTO") if and to the extent applicable, and upon the filings of the UCC Financing Statement in the state of [Delaware], this Security Agreement is effective to create and perfect a valid and continuing first priority security interest in, and/or floating charge on, the respective Intellectual Property that is pledged in favor of the Bank, if any, prior to all other Liens, and is enforceable as such against creditors. As of the date of Execution of this Agreement, the Guarantor hereby represents and warrants that it is not the owner of any Patents or Trademarks.

(k) Upon entering into the Account Control Agreement, attached hereto as **Schedule F**, and upon the filings of the UCC Financing Statement in the state of Delaware, this Security Agreement is effective to create and perfect a valid and continuing , first priority security interest in, and/or floating charge on the Deposit Accounts in favor of the Bank, prior to all other Liens, and is enforceable as such against creditors, all subject to applicable bankruptcy, insolvency, reorganization or other similar laws generally affecting the enforcement of the rights of creditors and equitable principles (regardless of whether enforcement is sought in equity or at law).

(l) Except for the filing of Financing Statements under the UCC and the filing of this Agreement with the USPTO, if and to the extent applicable, and entering into the attached Account Control Agreement no authorization, approval or other action by, and no notice to or filing with, any governmental or regulatory authority, agency or office is required for the grant by the Guarantor or the effectiveness of the first priority security interest granted hereby or for the execution, delivery and performance of this Agreement by the Guarantor.

(m) The Guarantor is the owner and/or holds the rights of use under license or agreement, of all the intellectual property currently used for the purpose of its business; and

(n) The Guarantor is not currently in breach and there are no proceedings against it in connection with any breach of any intellectual property rights of any third party

8. Covenants. The Guarantor covenants and agrees with the Bank that from and after the date of this Security Agreement and until this Security Agreement is terminated pursuant to Section 14 below, unless compliance is waived by the Bank in writing:

(a) Guarantor shall properly preserve the Collateral. On the date hereof and as of the date of any future delivery of Collateral to the Bank and at all times until the security interests granted by this Agreement are terminated pursuant to Section 14 hereof: (A) the Guarantor shall maintain ownership of such Collateral, unless conveyed during the ordinary course of business, subject to no adverse claim (including any lien, encumbrance or claim of legal or beneficial ownership), except the lien and security interest in favor of the Bank; (B) the Guarantor shall provide that at all times it will have full power, authority and legal right to pledge the Collateral to the Bank hereunder, and no consent, approval or other authorization of any person or governmental authority is required (except those which have been obtained) in connection therewith; and (C) the lien of this Agreement constitutes and will constitute a first priority perfected security interest in the Collateral in favor of the Bank.

(b) Guarantor shall notify the Bank forthwith of the imposition of an attachment over the Collateral and/or any of it, and forthwith notify the attacher of the charge in favor of the Bank and at the Guarantor's expense forthwith and without delay take all steps in order to remove the attachment. If the Guarantor does not take such steps as aforesaid the Bank may (but need not) take all steps to remove the attachment, and the Guarantor shall be liable immediately to pay the Bank all actual and reasonable expenses involved therein (including the professional fees of the Bank’s advocates);

(c) Guarantor shall not create any other lien or charge over the Collateral or any of it, and shall not assign and/or license (other than a limited license or similar type of commercial agreement entered into in the ordinary course of business) any right that the Guarantor has in the Collateral without obtaining the Bank’s prior written consent which shall not be unreasonably withheld;

(d) The Guarantor shall not issue shares in aggregate constituting more than 10% of the issued share capital to any other shareholder, without the Bank's prior written consent; provided, however, that any shares issued under such threshold shall not be superior to the Shares issued to the Affiliated Company, and shall only be of the classes of stock currently existing at the time of this Agreement.

(e) None of the tangible components of the Collateral shall be maintained at locations other than in the address as stated above or otherwise leased by Guarantor and/or by Affiliated Company. In the event that Guarantor, after the date hereof, intends to store or otherwise deliver any portion of the Collateral to a bailee, then Guarantor will first receive the written consent of the Bank, and such bailee must acknowledge in writing that the bailee is holding such Collateral for the benefit of the Bank. All inventory is in all material respects of good and marketable quality, free from material defects.

(f) Guarantor shall be responsible for the genuineness and accuracy of all signatures, endorsements and particulars on bills, documents and securities that have been and/or are in future given to the Bank by Guarantor as collateral;

(g) Guarantor shall pay on due date all the taxes, municipal rates, levies and other mandatory payments legally imposed over the Collateral and shall furnish the Bank, on demand, with all the receipts for such payments, and if the Guarantor does not duly make such payments, the Bank may make them at the Guarantor’s expense and charge it the payments, plus expenses and interest at the then maximum rate prevailing at the Bank in respect of unauthorized withdrawals and defaults on an approved overdraft account. Those payments are secured by this Security Agreement;

(h) Guarantor shall keep books of account and permit the Bank or its representative at any time, upon a reasonable prior notification to Guarantor, during normal business hours and subject to customary non-disclosure restrictions, to examine the Guarantor's books.

(i) Guarantor undertakes to assist the Bank or its representatives and to give them on demand balance sheets, documents and any information reasonably required by the Bank, including explanations in connection with the financial and operational state of the Guarantor, its subsidiaries, and/or its business;

(j) There shall be no material change to the business of the Guarantor or its subsidiaries (if any) without the Bank’s prior written consent.

(k) At the sole expense of the Guarantor, the Guarantor will promptly, but no later than 15 days after the Execution Date to file a UCC-1 Financing Statement in substantially the form of **Schedule G** (the "**UCC Financing Statement**") and any additional necessary and required financing statements under the UCC with respect to the Liens and security interests granted hereby. Guarantor will also promptly, following the request of the Bank, duly execute and deliver any and all such further instruments and documents and take such further action as the Bank may reasonably deem desirable to obtain the full benefits of this Security Agreement and of the rights and powers herein granted. The Guarantor shall file all necessary continuation statements from time to time under the applicable provisions of Article 9 of the UCC in order to maintain the perfection of the Collateral. The Guarantor also hereby authorizes the Bank to file any such financing statement or continuation statement (including a notice that any disposition of the Collateral, by either the Debtor or any other Person, shall be deemed to violate the rights of Lenders under the Code) without the signature of the Guarantor to the extent permitted by applicable law.

(l) At the sole expense of the Guarantor, the Guarantor will promptly, but no later than 30 days after the Execution Date, record a security interest with the USPTO, if and to the extent applicable, including, *inter alia*, file this Agreement and any additional necessary and required filings and/or statements with respect to the Liens and security interests granted hereby, with the USPTO. Guarantor will also promptly, following the request of the Bank, duly execute and deliver any and all such further instruments and documents and take such further action as the Bank may reasonably deem desirable to obtain the full benefits of this Security Agreement and of the rights and powers herein granted. The Guarantor also hereby authorizes the Bank to file any such documents without the signature of the Guarantor to the extent permitted by applicable law;

(m) The Guarantor will promptly, but no later than 3 business days from the Execution Date, enter into the attached Account Control Agreement;

(n) Guarantor undertakes not to enter into any account control agreement with respect to any of its existing or future Deposit Accounts, without the Bank's prior written consent.

(o) In any suit, proceeding, or action brought against the Bank by a third party, relating to any part of the Collateral, the Guarantor will save, indemnify, and keep the Bank harmless from and against all expense, loss, or damage suffered by reason of any defense, setoff, counterclaim, recoupment, or reduction of liability whatsoever of the obligor thereunder, arising out of a breach by the Guarantor of any obligation thereunder or arising out of any other agreement, indebtedness, or liability at any time owing to, or in favor of, such obligor or its successors from the Guarantor, and all such obligations of the Guarantor shall be and remain enforceable against and only against the Guarantor and shall not be enforceable against the Bank;

(p) Guarantor will not create, permit, or suffer to exist, any Lien on the Collateral, will defend the Collateral against, and take such other action as is necessary to remove any unauthorized Lien on the Collateral, and will defend the right, title, and interest of the Bank in and to any of the Guarantor's rights under the Collateral;

(q) Guarantor hereby agrees that if the Guarantor changes its name, its type of organization or its state of organization, the Guarantor will promptly thereafter notify the Bank in writing of the additions or changes. Guarantor will not change its state of incorporation or its name, identity, or corporate structure in any manner that might make any financing or continuation statement filed in connection herewith seriously misleading within the meaning of section 9-503 of the UCC (or any other then applicable provision of the UCC) unless the Guarantor shall have given the Bank at least thirty (30) days' prior written notice thereof and shall have taken all action (or made arrangements to take such action substantially simultaneously with such change if it is impossible to take such action in advance) necessary or reasonably requested by the Bank to amend such financing statement or continuation statement so that it is not seriously misleading;

(r) Throughout the subsistence of this Security Agreement, Guarantor undertakes: (i) not to pay its stockholders any loan or funds that the stockholders have lent or do in future lend to the Guarantor or any funds that they have invested and/or do in future invest in the Guarantor without the Bank's prior written consent; (ii) not to declare, pay or set aside dividends on shares of capital stock of itself without the Bank's prior written consent; (iii) not to enter into any related party transactions with Affiliated Company; and (iv) not to enter into any related party transactions with any of Guarantor's and/or Affiliated Company's office holders and/or directors (other than standard and arm's-length employment agreements and service agreements with Guarantor's office holders)*; provided, however,* that limitations (i), (ii) and (iii) shall not apply in the event that (and as long as) Affiliated Company remains the sole shareholder of Guarantor.

(s) Upon the execution of this Security Agreement by all parties hereto, the Guarantor shall provide the Bank with a written legal opinion of Guarantor's Counsel in the form attached hereto as **Schedule H**.

(t) No later than 45 days after the Execution Date, Guarantor shall provide the Bank with copies of the UCC Financing Statement certifying the filing of the first priority security interest granted herein;

(u) No later than 45 days after the registration of any Patents or Trademarks with the USPTO, Guarantor shall provide the Bank with an official document evidencing the filing of a copy of this Agreement with the USPTO, if and to the extent applicable, and certifying the filing of the first priority security interest in the Intellectual Property, granted herein;

(v) Guarantor shall file annual franchise tax report and pay annual franchise tax which it is required to file under the laws of the State of Delaware on a timely basis;

(w) Guarantor shall update the Bank of its accounts receivable every six months. Upon such notification, Guarantor shall update **Schedule A** accordingly, and have the updated schedule re-submitted and re-filed; and

(y) In each instance from time to time on a recurring basis in which the collective account balances of the bank accounts denoted with an asterisk on Schedule I attached hereto exceed $200,000 in the aggregate, the Guarantor shall no later than seven (7) days thereafter either reduce such collective balances below $50,000 or proceed to enter into a deposit account control agreement with such depository institution and the Bank on substantially similar terms to this Agreement.

(z) The account balance of the "Payroll Account" set forth on Schedule I attached hereto shall not exceed $500,000 in the aggregate, for a period of more than seven (7) consecutive days, and shall only be used for payroll purposes.

(aa) The account balance in the Certificate of Deposit account set forth on Schedule I attached hereto shall not exceed $110,000 + accruing interest, in the aggregate, and shall only be used to secure payments to the Atlanta offices landlord.

9. Exchange Rate. Having regard to the fact that the amounts that are now and in future due to the Bank from the Guarantor on account of the Secured Sums can be both in Israeli currency and in foreign currency, it is hereby agreed and declared that the Bank, may convert Israeli currency in their possession to foreign currency as necessary for the full or partial discharge of the Secured Sums that are due to the Bank in foreign currency and convert foreign currency in their possession to Israeli currency, at the rates of exchange existing at the time when any such conversions are actually made by either of them.

The expression "**rate of exchange**" means:

(a) in respect of the time when there is a restraint by Israeli law in respect of the free use of foreign currency in Israel - the highest amount of Israeli currency that an Israeli resident is required to pay for a unit of the currency of such debt to an entity duly licensed to trade in Israel in foreign currency, together with the bank commission for such transaction;

(b) in respect of the time when there is no such restraint - the highest price for the purchase of a unit of the currency of such debt existing at the Bank of Israel in respect of bank telegraphic withdrawals on a city for the time being known as one of the financial centers of the state in which the currency of the debt is legal tender or in New York, at the option of the Bank, together with the bank commission for such transaction.

10. Events of Default. Without prejudice to the generality of the provisions of this Security Agreement or any other written agreement between the parties with respect to the Bank's right to call for immediate payment of all or any of the Secured Sums, the Bank may in any of the under-mentioned cases ("**Events of Default**") call for the immediate payment by the Guarantor of all or any of the Secured Sums, without prior notice to the Guarantor and/or the Affiliated Company, unless otherwise stated below:

(a) if Affiliated Company and/or Guarantor fails to pay any payment pursuant to any agreement (including the principal amount, interest, linkage, expenses and/or related fees) to the Bank, when due.

(b) if a voluntary winding-up resolution is passed by the Guarantor and/or the Affiliated Company or if a winding-up order or a suspension of proceedings order is issued against either of the Guarantor and/or the Affiliated Company by the court or if the court calls a creditors meeting for the purpose of finding an arrangement with them or if the Guarantor's and/or the Affiliated Company's name has been removed or is about to be removed from any register operated by law;

(c) if a provisional or permanent receiver, receiver and manager or liquidator is appointed over Guarantor's and/or over any of its subsidiaries' and/or over Affiliated Company's material assets or any of them; or if a petition for the appointment of any of the above has been filed by any party against any asset of either of Guarantor and/or Affiliated Company.

(d) if an attachment (temporary or permanent) covering any obligation is imposed over all or any of the Guarantor's and/or Affiliated Company's assets or over any of the Collateral given by the Guarantor to the Bank or if any act of execution in respect of any obligation is taken against either of them; provided however that in the case of an attachment that was only registered (and which did not remove any assets), then only to the extent that the registered attachment has not been revoked or reversed within 60 days thereafter; Such 60 day period may be shortened by the Bank, if Bank is convinced, upon exercising reasonable judgment, that such delay may impair the Bank's rights, or its ability to collect any amounts owed thereto.

(e) if Guarantor and/or the Affiliated Company stops paying its debts to third parties for a period longer than two months;

(f) if the Affiliated Company's business or a substantial part of it is stopped for three or more weeks, or if Affiliated Company's business or a substantial part of it is shut down; Such time period may be shortened by the Bank, if Bank is convinced, upon exercising reasonable judgment, that such delay may impair the Bank's rights, or its ability to collect any amounts owed thereto.

(g) if Affiliated Company has been declared as a "Limited Customer" or as a "Severe Limited Customer", as such terms are defined in the Israeli Checks Without Cover (bad checks) Law, 1981.

(h) if all or a significant portion of the Affiliated Company's current assets (inventory) are burned, lost or otherwise damaged, and not replaced with insurance proceeds; or if all or a significant portion of the Affiliated Company's fixed assets (including, for avoidance of doubt, manufacturing lines) are burned, lost or otherwise damaged, and the Affiliated Company does not have sufficient inventory to enable continuous sales (at least at the same volume as existing prior to such event);

(i) if more than $50,000 of the Collateral value is burned, lost or otherwise damaged and not replaced with insurance proceeds;

(j) if there has been a change in the identity of the security holders and/or of the security - holdings of the Guarantor (except in the event of an initial public offering of the Guarantor) without the Bank's prior written approval, or if there has been a change of control in the Affiliated Company ("control" shall have the meaning ascribed to it in the Israeli Securities Law, 1968);

(k) if the Bank, at its reasonable discretion, takes the view that a material change in the Guarantor's financial situation has occurred, that may materially impair Guarantor's ability to dispose of its payment obligation relating to the Secured Sums;

(l) if, at the Bank's reasonable commercial opinion, there is a material deterioration in the value of the Collateral (excluding deterioration due to foreign currency exchange rates);

(m) if Guarantor and/or the Affiliated Company is required to accelerate the discharge of debts that it owes to other creditors;

(n) if Guarantor materially breaches or does not perform any of the covenants set forth in this Security Agreement and/or any of the material obligations that are contained in this Security Agreement and/or any agreement and/or instrument and/or contract made in the past and/or future between the Guarantor and the Bank and which breach or non-performance is not cured within thirty (30) days of receiving notice, except that Guarantor shall have an additional sixty (60) days if Guarantor has commenced performance and such performance will require more than thirty (30) days for compliance; provided, however, that such period may be shortened by the Bank, if Bank is convinced, upon exercising reasonable judgment, that such delay may impair the Bank’s rights, or its ability to collect any amounts owed thereto.

(o) if it transpires that any warranty of the Guarantor in this Security Agreement and/or any contract made in the past and/or future between Guarantor and the Bank is incorrect in a material respect and/or inaccurate or incomplete in any material respect;

(p) if Guarantor and/or the Affiliated Company alter any of their charter documents in such manner as to have a material adverse effect on the ability of Affiliated Company to comply with any of its obligations under the loan agreements, and /or on the ability of Guarantor to comply with any of its obligations under this Security Agreement;

(q) if Guarantor and/or the Affiliated Company pass a resolution to merge with another company, whether as absorbing or target company (including, for avoidance of doubt, any action as a result of which Guarantor and/or Affiliated Company purchase assets and/or obligation of another party, or transfers assets in consideration for securities of another party), without the Bank’s prior consent which shall not be unreasonably withheld;

(r) if any license, consent, approval or registration of any of the Intellectual Property or the intellectual property rights of the Guarantor and/or the Affiliated Company is denied, becomes void, suspended or is materially prejudiced, and has a material effect on such company.

(s) if Guarantor does not file the appropriate UCC Financing Statements in the State of Delaware; or if Guarantor does not file the necessary continuation statements from time to time under the applicable provisions of Article 9 of the UCC in order to maintain the perfection of the Collateral, or if any other security interest is perfected in the Collateral, having a higher priority over the Bank.

(t) if Guarantor does not file the appropriate filings with the USPTO in order to perfect the Guarantor's security interest in the Guarantor's future Intellectual Property; or if Guarantor does not file the necessary continuation filings, if such are required in order to maintain the perfection of the Intellectual Property Collateral, or if any other security interest is perfected relating to the Intellectual Property having a higher priority over the Bank. For avoidance of doubt, it is hereby explicitly stipulated, that as of the date hereof, Guarantor has no registered Patents, and thus no such filings are currently required.

(u) If the Guarantor shall issue any shares to any other shareholder, without the Bank's prior written consent.

(v) If the Guarantor shall not file annual franchise tax report and pay annual franchise tax which it is required to file under the laws of the State of Delaware on a timely basis.

(w) If an event of default shall be declared by the Bank pursuant to any agreement with either the Affiliated Company or the Guarantor.

11. The Bank's Appointment as Attorney-in-Fact.

(a) Upon any of the events set forth in section 3 above, the Bank may take all the steps it deems fit in order to collect all the Secured Sums, realize the Collateral in any way that the law permits and exercise all its rights pursuant to this Security Agreement, in whole or in part, and apply the proceeds thereof in discharge of the Secured Sums, without the Bank having to enforce or realize any other guarantees or collateral that it might have (whether against Guarantor or against any third party). Upon the giving of such notice (if any) as may be required by law, the Bank may, at its discretion, as the Guarantor's attorney, for which purpose the Guarantor irrevocably appoints the Bank as its attorney, sell the Collateral or any part of it by auction, public sale, private sale or otherwise, itself or through others and on conditions at the Bank's absolute discretion, and the Bank may itself or by the court or execution office realize the Collateral granted to it pursuant to this Security Agreement or otherwise by the appointment of a receiver or receiver and manager on behalf of the Bank (and the Guarantor agrees in advance to any person or legal entity that the Bank appoints or proposes as receiver and manager as aforesaid) at Guarantor's expense and amongst his other powers, he may:

(i) ask, demand, collect, receive, and give acquittances and receipts for any and all moneys due and to become due under any Collateral and, in the name of the Guarantor or its own name or otherwise, to take possession of and endorse and collect any checks, drafts, notes, acceptances, or other instruments for the payment of moneys due under any Collateral and to file any claim or to take any other action or proceeding in any court of law or equity or otherwise deemed appropriate by the Bank for the purpose of collecting any and all such moneys due under any Collateral whenever payable and to file any claim or to take any other action or proceeding in any court of law or equity or otherwise deemed reasonably appropriate by the Bank for the purpose of collecting any and all such moneys due under any Collateral whenever payable;

(ii) pay or discharge taxes, Liens, security interests, or other encumbrances levied or placed on or threatened against the Collateral, to effect any repairs or any insurance called for by the terms of this Security Agreement and to pay all or any part of the premiums therefor and the costs thereof; and

(iii) (A) direct any party liable for any payment under any of the Collateral to make payment of any and all moneys due, and to become due thereunder, directly to the Bank or as the Bank shall direct; (B) receive payment of and receipt for any and all moneys, claims and other amounts due, and to become due at any time, in respect of or arising out of any Collateral; (C) sign and endorse any invoices, freight or express bills, bills of lading, storage or warehouse receipts, drafts against debtors, assignments, verifications, and notices in connection with accounts and other documents constituting or relating to the Collateral; (D) commence and prosecute any suits, actions, or proceedings at law or in equity in any court of competent jurisdiction to collect the Collateral or any part thereof and to enforce any other right in respect of any Collateral; (E) defend any suit, action, or proceeding brought against the Guarantor with respect to any Collateral; and (F) settle, compromise, or adjust any suit, action, or proceeding described above and, in connection therewith, to give such discharges or releases as the Bank may deem appropriate.

(iv) (i) place a “hold” on any account maintained with Guarantor and/or (ii) deliver a notice of exclusive control, any entitlement order, or other directions or instructions pursuant to any Control Agreement or similar agreements providing control of any Collateral (including, without limitation, an Account Control Agreement);

(b) The Bank agrees that, except upon the occurrence and during the continuation of an Event of Default, it will forbear from exercising the power of attorney or any rights granted to the Bank pursuant to this Section 11. The Guarantor hereby ratifies, to the extent permitted by law, all that said attorneys shall lawfully do or cause to be done by virtue hereof. The power of attorney granted pursuant to this Section 11 is a power coupled with an interest and shall be irrevocable until this Security Agreement is terminated pursuant to Section 14 below.

(c) The powers conferred on the Bank hereunder are solely to protect the Bank's interests in the Collateral and shall not impose any duty upon it to exercise any such powers. The Bank shall be accountable only for amounts that it actually receives as a result of the exercise of such powers and neither it nor any of its representatives or agents shall be responsible to the Guarantor for any act or failure to act, except for its own gross negligence, bad faith, misrepresentation, fraud or willful misconduct.

(d) The Guarantor also authorizes the Bank, at any time and from time to time upon the occurrence and during the continuation of any Event of Default, to execute, in connection with the sale provided for in Section 13 hereof, any endorsements, assignments, or other instruments of conveyance or transfer with respect to the Collateral.

12. Performance by the Bank of Guarantor's Obligations. If the Guarantor materially fails to perform or comply with any of its material agreements contained herein and the Bank, as provided for by the terms of this Security Agreement, shall itself perform or comply, or otherwise cause performance or compliance, with such agreement, the reasonable expenses of the Bank incurred in connection with such performance or compliance, together with interest thereon, shall be payable by the Guarantor to the Bank on demand and shall constitute Secured Sums secured hereby.

13. Remedies, Rights Upon Default.

(a) Upon the occurrence of any of the events set forth in Section 3 above, and provided that the Secured Sums had not been fully paid, the Bank will be entitled to exercise in addition to all other rights and remedies granted to it in this Security Agreement and in any other instrument or agreement securing, evidencing, or relating to the Secured Sums, all rights and remedies of a secured party under the UCC. Without limiting the generality of the foregoing, the Guarantor expressly agrees that upon the occurrence of any such Event of Default (and provided that such Event of Default had not been cured during the applicable cure period), the Bank, without demand of performance or other demand, advertisement, or notice of any kind (except the notice specified below of time and place of public or private sale) or upon the Guarantor or any other person (all and each of which demands, advertisements, and/or notices are hereby expressly waived to the maximum extent permitted by the UCC and other applicable law), may forthwith collect, receive, appropriate, and realize upon the Collateral, or any part thereof, and/or may forthwith sell, lease, assign, give an option or options to purchase, or sell or otherwise dispose of and deliver such Collateral (or contract to do so), or any part thereof, in one or more parcels at public or private sale or sales, at any exchange or broker's board or at any of the Bank's offices or elsewhere at such prices on such terms as the Bank may deem commercially best, for cash or on credit or for future delivery without assumption of any credit risk. The Bank shall have the right upon any such public sale or sales, and, to the extent permitted by law, upon any such private sale or sales, to purchase the whole or any part of such Collateral so sold. The Guarantor further agrees, at the Bank's request, to assemble the Collateral and make it available to the Bank at places that the Bank shall reasonably select, whether at the Guarantor's premises or elsewhere. The Bank shall apply the net proceeds of any such collection, recovery, receipt, appropriation, realization, or sale, as provided in Section 13(d) hereof, the Guarantor remaining liable for any deficiency remaining unpaid after such application, and only after so paying over such net proceeds and after the payment by the Bank of any other amount required by any provision of law, including section 9-610 of the UCC, need the Bank account for the surplus, if any, to the Guarantor. To the maximum extent permitted by applicable law, the Guarantor waives all claims, damages, and demands against the Bank arising out of the repossession, retention, or sale of the Collateral except such as arise out of the gross negligence, fraud, misrepresentation, bad faith or willful misconduct of the Bank. The Guarantor agrees that the Bank need not give more than sixty (60) days' prior notice (which notification shall be deemed given when mailed or delivered on an overnight basis, postage prepaid, addressed to the Guarantor at its address referred to in Section 17 hereof with confirmation of receipt) of the time and place of any public sale or of the time after which a private sale may take place and that such notice is reasonable notification of such matters. The Guarantor shall remain liable for any deficiency if the proceeds of any sale or disposition of the Collateral are insufficient to pay all of the Secured Sums.

(b) The Guarantor also agrees to pay all costs of the Bank, including, without limitation, reasonable attorneys' fees, incurred in connection with the enforcement of any of its rights and remedies hereunder.

(c) Except as otherwise set forth in this Security Agreement, the Guarantor hereby waives presentment, demand, protest, or any notice (to the maximum extent permitted by applicable law) of any kind in connection with this Security Agreement or any Collateral.

(d) The Proceeds of any sale, disposition, or other realization upon all or any part of the Collateral shall be distributed by the Bank in the following order:

(a) first, in discharge of all expenses incurred in connection with collecting the Secured Sums, including the expenses and remuneration of any receiver and/or manager at such rate as reasonably fixed by the Bank;

(b) second, in discharge of the further amounts that are due to the Bank in consequence of the linkage conditions, the interest, damages, commission and expenses now and in future due to the Bank pursuant to this Security Agreement;

(c) third, in discharge of the principal of the Secured Sums; and

(d) fourth, to pay to the Guarantor, or its representatives or as a court of competent jurisdiction may direct, any surplus then remaining from such Proceeds.

(e) The Bank shall not be required to resort to or pursue any of its rights or remedies under or with respect to any other agreement or any other collateral or charge before pursuing any of its rights or remedies under this Security Agreement. The Bank may pursue its rights and remedies in such order as it determines, and the exercise by the Bank of any right or remedy will not preclude the Bank from exercising any other right or remedy.

(f) Until such time as any of the events set forth in Section 3 above have occurred, the Bank shall not exercise the rights set forth in subsection (a) above, including without limitation giving a Notice of Exclusive Control under the Deposit Account Control Agreement by and among the Bank, the Guarantor and Bank Leumi USA dated as of July 19th, 2017 (as such term is defined therein) or the giving of any similar notice under any other deposit account control agreement granting a security interest in any deposit account entered into pursuant to this Agreement or as a result of the Banking Services.

14. Termination. The Bank shall terminate this Security Agreement upon the Guarantor's request provided that there has been the full repayment of all outstanding Secured Sums, all credit lines of the Affiliated Company are cancelled, and there remain no obligations towards the Bank or any outstanding credit facilities either of Guarantor or of Affiliated Company. Upon termination of this Security Agreement the Bank will release the security interest hereunder and will provide the Guarantor with any required approval or executed documents to the Secretary of State of the State of Delaware to remove the security interest in favor of the Bank under this Security Agreement.

15. Appointment of the Bank; Limitation on the Bank's Duty in Respect of Collateral. The Bank shall be obligated and shall have the right hereunder to make demands, to give notices, to exercise or refrain from exercising any rights, and to take or refrain from taking action (including, without limitation, the release or substitution of Collateral) solely in accordance with this Security Agreement, and the Bank shall be bound thereby. So long as the Bank complies with reasonable banking practices, the Bank shall not have any duty as to any Collateral in its possession or control or in the possession or control of any agent or nominee of it or any income thereon or as to the preservation of rights against prior parties or any other rights pertaining thereto, except that the Bank shall use reasonable care with respect to the Collateral in its possession or under its control. Furthermore, neither the Bank nor any of its officers, directors, agents, or employees shall be liable for any action taken or omitted by any of them hereunder or in connection herewith or therewith, unless caused by it or their gross negligence, fraud, misrepresentation, bad faith or willful misconduct. Upon request of the Guarantor, the Bank shall account for any monies received by it in respect of any foreclosure on or disposition of the Collateral.

16. Reinstatement. Subject to the provisions of Section 14 above, this Security Agreement shall remain in full force and effect and continue to be effective should any petition be filed by or against the Guarantor for liquidation or reorganization, should the Guarantor become insolvent or make an assignment for the benefit of creditors, or should a receiver or trustee be appointed for all or any significant part of the Guarantor's assets, and shall continue to be effective or be reinstated, as the case may be, if at any time payment and performance of the Secured Sums, or any part thereof, is, pursuant to applicable law, rescinded or reduced in amount, or must otherwise be restored or returned by any obligee of the Secured Sums, whether as a "voidable preference", "fraudulent conveyance", or otherwise, all as though such payment or performance had not been made. In the event that any payment, or any part thereof, is rescinded, reduced, restored, or returned, the Secured Sums shall be reinstated and deemed reduced only by such amount paid and not so rescinded, reduced, restored, or returned.

17. Notices. Except as otherwise provided herein, whenever it is provided herein that any notice, demand, request, consent, approval, declaration, or other communication shall or may be given to or served upon any of the parties by any other party, or whenever any of the parties desires to give or serve upon any other communication with respect to this Security Agreement, each such notice, demand, request, consent, approval, declaration, or other communication shall be in writing and either shall be delivered in person with receipt acknowledged or sent by registered or certified mail, return receipt requested, postage prepaid, or by facsimile, and confirmed by answerback addressed as follows:

(a) **If to the Bank:**

Mizrahi Tefahot Bank Ltd.
7 Jabotinsky Street
Ramat Gan, Israel
Email: Dani_maor@umtb.co.il
Attention: Dani Maor

with a copy to: E. Landau Law Offices
7 Jabotinsky Street.
Ramat Gan, Israel
Facsimile: 972-2-561-8212
Attention: Shlomo Farkas, Adv.

(b) **If to the Guarantor:**
Itamar Medical Inc.
c/o Itamar Medical Ltd.
9 Halamish Street, P.O. Box 3579
Caesarea 3088900, Israel
Attn: Shy Basson, CFO

Itamar Medical Inc.
3290 Cumberland Club Drive
Suite 100, Atlanta, GA 30339
Attn: Shy Basson, CFO

with a copy to: Itamar Medical Ltd.
9 Halamish Street, P.O. Box 3579
Caesarea 3088900, Israel
Attn: Gil Ashkenazi, Legal Counsel

or at such other address in Israel, as may be substituted by notice given as herein provided. The giving of any notice required hereunder may be waived in writing by the party entitled to receive such notice. Every notice, demand, request, consent, approval, declaration, or other communication hereunder shall be deemed to have been duly given or served on the date on which personally delivered, with receipt acknowledged, telecopied, and confirmed by telecopy answerback, or five (5) Business Days after the same shall have been deposited in the local postal service in Israel or in the U.S. To the extent permitted under applicable law, failure or delay in delivering copies of any notice, demand, request, consent, approval, declaration, or other communication to the persons designated above to receive copies shall in no way adversely affect the effectiveness of such notice, demand, request, consent, approval, declaration, or other communication, unless the recipient thereof has been materially prejudiced by such failure or delay.

Guarantor hereby irrevocably designates, appoints and empowers Mr. Shy Basson, 9 Halamish Street, P.O. Box 3579, Caesarea 3088900, Israel to receive for and on behalf of the Guarantor, any and all notices and/or correspondence relating to this Agreement and/or to Guarantor‘s relations with the Bank, including without limitation, service of process issued out of the courts of the State of Israel or by or on behalf of the Bank or in any other manner in any legal action or proceedings arising out of or in connection with this Agreement. Any service of process to the above mentioned agent shall be deemed as service of process to the Guarantor itself. Guarantor hereby irrevocably agrees that if its agent ceases to have an address in Israel or ceases to act as its agent it shall appoint a new agent in Israel and will deliver to the Bank within 7 days a copy of a written acceptance of appointment by its agent. If at any time Guarantor appoints a new agent it shall give notice to the Bank of such appointment and until such time service on the agent last known to the other party shall be deemed to be effective service.

18. Severability. Any provision of this Security Agreement which is prohibited or unenforceable in any jurisdiction shall, as to such jurisdiction, be ineffective to the extent of such prohibition or unenforceability without invalidating the remaining provisions hereof, and any such prohibition or unenforceability in any jurisdiction shall not invalidate or render unenforceable such provision in any other jurisdiction.

19. No Waiver; Cumulative Remedies. Neither party shall, by any act, delay, omission, or otherwise, be deemed to have waived any of its rights or remedies hereunder, and no waiver shall be valid unless in writing, signed by the waiving party, and then only to the extent therein set forth. A waiver by either party of any right or remedy hereunder on any one occasion shall not be construed as a bar to any right or remedy which such party would otherwise have had on any future occasion. No failure to exercise, nor any delay in exercising on the part of a party hereunder, any right, power, or privilege hereunder, shall operate as a waiver thereof, nor shall any single or partial exercise of any right, power or privilege hereunder preclude any other or future exercise thereof or the exercise of any other right, power, or privilege. The rights and remedies hereunder provided are cumulative and may be exercised singly or concurrently, and are not exclusive of any rights and remedies provided by law. None of the terms or provisions of this Security Agreement may be waived, altered, modified, or amended except by an instrument in writing, duly executed by the Bank and the Guarantor.

20. Successors and Assigns; Governing Law.

(a) This Security Agreement and all obligations of the Guarantor hereunder shall be binding upon the successors and assigns of the Guarantor, and shall, together with the rights and remedies of the Bank hereunder, inure to the benefit of the Bank and its successors and assigns. No sales of participations, other sales, assignments, transfers, or other dispositions of any agreement governing or instrument evidencing the Secured Sums or any portion thereof or interest therein shall in any manner affect the security interest granted to the Bank, hereunder.

(b) This Security Agreement shall be governed by, and be construed and interpreted in accordance with, the laws of the State of Delaware.

(c) All parties to this Security Agreement hereby irrevocably consent to the jurisdiction of the courts in Tel Aviv, Israel, with respect to all matters related to and /or arising of this Agreement. The competent court in Tel Aviv is hereby vested with jurisdiction for the purpose of this Security Agreement, but the Bank may also take legal proceedings in any other competent court and/or jurisdiction. Subject to the provisions set forth in this section, all parties waive any objection to venue and any objection based on a more convenient forum in any action instituted under this Security Agreement.

21. Further Indemnification. The Guarantor agrees to pay, and to save the Bank harmless from, any and all liabilities with respect to, or resulting from any delay in paying, any and all excise, sales, or other similar taxes that may be payable or determined to be payable with respect to any of the Collateral or in connection with any of the transactions contemplated by this Security Agreement, except for losses caused by the Bank’s gross negligence, fraud, misrepresentation, bad faith or willful misconduct.

22. Books of Account. Guarantor confirms that the Bank's books and accounts are acceptable to it, shall be deemed correct and shall serve as prima facie evidence against it of all their particulars, including as regards the computation of the Secured Sums, the details of the bills and guarantees and the other collateral and every other matter relating to this Security Agreement.

23. Waiver of Jury Trial. Each of the parties to this Security Agreement waives all right to trial by jury in any action or proceeding to enforce or defend any rights or remedies hereunder. The parties acknowledge that the foregoing waiver is knowing and voluntary.

24. Section Titles. The section titles contained in this Security Agreement are and shall be without substantive meaning or content of any kind whatsoever and are not a part of the agreement between the parties hereto.

25. Counterparts. This Security Agreement may be executed in any number of counterparts, which shall, collectively and separately, constitute one agreement.

26. Transfer of Rights. The Bank may at any time, at its discretion, without needing the Guarantor's consent, transfer to a corporation under its control or to another banking institution or to any venture capital or secondary fund with whom the Bank has transferred warrants or security agreements relating to at least two (2) operating high-technology companies, this Security Agreement and the rights pursuant hereto, including the Collateral, in whole or parts, and any such transferee may transfer the said rights without requiring further consent from Guarantor to a corporation under its control or to another banking institution or to any venture capital or secondary fund. The transfer may be made by endorsement of the Security Agreement or in such other manner as the Bank deems fit.

Notwithstanding the above, in the event that the Bank declares an Event of Default under section 10 above, the Bank may freely transfer this Security Agreement and the rights pursuant hereto, including the Collateral, in whole or parts, to any third party it deems fit, and any such transferee may transfer the said rights without requiring any further consent.

[Signature page Follows]

[Security Agreement dated March 12th, 2019 - Signature Page]

IN WITNESS WHEREOF, each of the parties hereto has caused this Security Agreement to be executed and delivered by its duly authorized officer on the date first set forth above.

Mizrahi Tefahot Bank Ltd.	Guarantor
By: _____	By: _____

Schedule A:
List of Accounts

Schedule B:
List of IP.
None.

Schedule C:

Pledged Shares' Certificates + Undated stock powers duly executed in blank or other instruments of transfer satisfactory to the Bank and by such other instruments and documents as the Bank may reasonably request.

None.

Schedule D:

ASSIGNMENT OF FUNDS

In consideration of One Dollar cash in hand, the receipt and sufficiency of which are hereby acknowledged, Itamar Medical, Inc., a Delaware corporation ("Guarantor"), hereby irrevocably assigns to Mizrahi Tefahot Bank ("Bank") all accounts receivable due to it from all customers listed in Schedule A, and does hereby authorize and instruct them to pay to the Bank all amounts now due or which later become due to Guarantor, and authorizes the Bank to endorse any checks received in the name of Guarantor.

Itamar Medical, Inc.	Guarantor
By: _____	By: _____

Schedule E:

A copy of the resolutions of the Guarantor's board of directors or to be done by unanimous consent of shareholders approving the execution of this agreement and the grant of a security interest under the terms and conditions herein.

[Omitted. The registrant agrees to furnish supplementally a copy of such omitted schedule to the U.S. Securities and Exchange Commission upon request.]

Schedule F:
Deposit Account Control Agreement

[Omitted. The registrant agrees to furnish supplementally a copy of such omitted schedule to the U.S. Securities and Exchange Commission upon request.]

Schedule G:
UCC Financing Statement
To be provided.

Schedule H:
Legal opinion of Guarantor's Counsel
To be provided.

Schedule I

[Omitted. The registrant agrees to furnish supplementally a copy of such omitted schedule to the U.S. Securities and Exchange Commission upon request.]

Exhibit 12.1

CERTIFICATION

I, Gilad Glick, certify that:

1. I have reviewed this annual report on Form 20-F of Itamar Medical Ltd.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;

4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and

5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: April 3, 2020

/s/ Gilad Glick
Gilad Glick
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 12.2

CERTIFICATION

I, Shy Basson, certify that:

1. I have reviewed this annual report on Form 20-F of Itamar Medical Ltd.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;

4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and

5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: April 3, 2020

/s/ Shy Basson
Shy Basson
Chief Financial Officer
(Principal Financial Officer)

Exhibit 13.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 20-F for the fiscal year ended December 31, 2019 of Itamar Medical Ltd. (the "Company") as filed with the U.S. Securities and Exchange Commission on the date hereof (the "Report") and pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, I, Gilad Glick, certify that, to the best of my knowledge:

- the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: April 3, 2020

/s/ Gilad Glick
Gilad Glick
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 13.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 20-F for the fiscal year ended December 31, 2019 of Itamar Medical Ltd. (the "Company") as filed with the U.S. Securities and Exchange Commission on the date hereof (the "Report") and pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, I, Shy Basson, certify that, to the best of my knowledge:

- the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Shy Basson

Date: April 3, 2020

Shy Basson
Chief Financial Officer
(Principal Financial Officer)

Exhibit 15.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors

Itamar Medical Ltd.

We consent to the incorporation by reference in the registration statements (Nos. 333-230799 and 333-236883) on Form S-8 of Itamar Medical Ltd. of our report dated March 30, 2020, with respect to the consolidated statements of financial position of Itamar Medical Ltd. as of December 31, 2019 and 2018, the related consolidated statements of operations, comprehensive income (loss), changes in equity, and cash flows for each of the years in the three-year period ended December 31, 2019, and the related notes, which report appears in the December 31, 2019 annual report on Form 20-F of Itamar Medical Ltd.

Our report refers to a change in method of accounting for leases.

/s/ Somekh Chaikin
Certified Public Accountants (Israel)
A member firm of KPMG International

Tel Aviv, Israel
April 3, 2020