

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 20-F

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, 2018

OR

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

OR

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

Commission File No.: 333-209744

TODOS MEDICAL LTD.

(Exact name of registrant as specified in its charter)

State of Israel

(Jurisdiction of incorporation or organization)

1 Hamada Street

Rehovot, 7670301 Israel

(Address of principal executive offices)

Herman Weiss

Chief Executive Officer

+972-058-444-7873

herman.w@todosmedical.com

1 Hamada Street

Rehovot 7670301 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:

None

Name of each exchange on which registered or to be registered:

N/A

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: **Ordinary Shares, par value NIS 0.01 per share.**

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report.

72,230,162 Ordinary Shares, par value NIS 0.01 per share as of December 31, 2018.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes 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

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 and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted 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 and post such files).

Yes No

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

TODOS MEDICAL LTD.

FORM 20-F
ANNUAL REPORT FOR THE FISCAL YEAR ENDED DECEMBER 31, 2018

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INTRODUCTION

We are a clinical-stage cancer in-vitro diagnostic, or IVD, company engaged in the development of a series of patient-friendly blood tests for the detection of a variety of cancers based on our Todos Biochemical Infrared Analysis method, or TBIA, a proprietary technology for detection of solid tumors using peripheral blood analysis. The method incorporates biochemistry, physics and signal processing. The TBIA detection method is based on the cancer's influence on the immune system which triggers biochemical changes in peripheral blood mononuclear cells, or PBMC, and plasma. Our core technology, TBIA, is based on research conducted and technology invented by the research teams at Ben Gurion University, or BGU, and Soroka Medical Center of Israel, or Soroka, whose intellectual property has been licensed to us in consideration of our contractual obligation to pay certain licensing fees.

We were incorporated under the laws of the State of Israel in April 2010. Since March 7, 2017, our ordinary shares par value NIS 0.01 per share, or Ordinary Shares, have been quoted on the U.S. OTCQB marketplace of OTC Link, or OTCQB, under the symbol "TOMDF."

Unless otherwise indicated, all references to the "Company," "we," "our" and "Todos Medical" refer to Todos Medical Ltd. and its subsidiary, Todos Medical Singapore Pte. Ltd., a Singaporean corporation.

The currency of the primary economic environment in which the operations of the Company are conducted is the currency of the United States of America and referenced herein as "U.S. dollars" and "\$." Thus, the functional currency of the Company is the U.S. dollar (which is also the reporting currency of the Company). References to "NIS" are to New Israeli Shekels. References to "Ordinary Shares" are to our Ordinary Shares, par value of NIS 0.01 per share. We report financial information under the accounting principles generally accepted in the United States of America, or US GAAP.

Unless otherwise indicated, U.S. dollar convenience translations of NIS amounts presented in this annual report on Form 20-F for the year ended on December 31, 2018 are translated using the rate of NIS 3.748 to \$1.00, the exchange rate reported by the Bank of Israel on December 31, 2018; U.S. dollar convenience translations of NIS amounts presented in this annual report on Form 20-F for the year ended on December 31, 2017 are translated using the rate of NIS 3.467 to \$1.00, the exchange rate reported by the Bank of Israel on December 31, 2017; and U.S. dollar convenience translations of NIS amounts presented in this annual report on Form 20-F for the year ended on December 31, 2016 are translated using the rate of NIS 3.845 to \$1.00, the exchange rate reported by the Bank of Israel on December 31, 2016.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Certain information included or incorporated by reference in this annual report on Form 20-F may be deemed to be “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995 and other U.S. Federal securities laws. Forward-looking statements are often characterized by the use of forward-looking terminology such as “may,” “will,” “expect,” “anticipate,” “estimate,” “continue,” “believe,” “should,” “intend,” “project” or other similar words, but are not the only way these statements are identified.

These forward-looking statements may include, but are not limited to, statements relating to our objectives, plans and strategies, statements that contain projections of results of operations or of financial condition, expected capital needs and expenses, statements relating to the research, development, completion and use of our products, and all statements (other than statements of historical facts) that address activities, events or developments that we intend, expect, project, believe or anticipate will or may occur in the future.

Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties. We have based these forward-looking statements on assumptions and assessments made by our management in light of their experience and their perception of historical trends, current conditions, expected future developments and other factors they believe to be appropriate.

Important factors that could cause actual results, developments and business decisions to differ materially from those anticipated in these forward-looking statements include, among other things:

- our success in raising additional funding;
- the overall global economic environment;
- the impact of competition and new technologies;
- general market, political and economic conditions in the countries in which we operate;
- projected capital expenditures and liquidity;
- changes in our strategy;
- litigation; and
- those factors referred to in “Item 3. Key Information - D. Risk Factors,” “Item 4. Information on the Company,” and “Item 5. Operating and Financial Review and Prospects,” as well as in this annual report on Form 20-F generally.

Readers are urged to carefully review and consider the various disclosures made throughout this annual report on Form 20-F which are designed to advise interested parties of the risks and factors that may affect our business, financial condition, results of operations and prospects.

You should not put undue reliance on any forward-looking statements. Any forward-looking statements in this annual report on Form 20-F are made as of the date hereof, and we undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

In addition, the section of this annual report on Form 20-F entitled “Item 4. Information on the Company” contains information obtained from independent industry sources and other sources that we have not independently verified.

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**

Our financial statements are prepared in accordance with U.S. GAAP and are presented in U.S. dollars.

The following table summarizes our financial data for the five-year period from January 1, 2014 through December 31, 2018. We have derived the following selected statements of operations data for the years ended December 31, 2018, 2017, and 2016 and the selected consolidated balance sheet data as of December 31, 2018 and 2017 from our audited consolidated financial statements and notes included in this annual report on Form 20-F. Our selected consolidated statements of operations data for the years ended December 31, 2015 and 2014, and the selected consolidated balance sheet data as of December 31, 2016, 2015, and 2014 have been derived from our audited consolidated financial statements not included in this annual report on Form 20-F.

The selected financial data should be read in conjunction with our consolidated financial statements and related notes, as well as the section entitled “Item 5. Operating and Financial Review and Prospects,” included elsewhere in this Annual Report, and are qualified entirely by reference to such consolidated financial statements.

U.S. dollars in thousands, except share data

Consolidated Statements of Operations Data	Year Ended December 31,				
	2018	2017	2016	2015	2014
Research and development expenses, net	\$ (459)	(721)	(318)	(374)	(336)
General and administrative expenses	(920)	(617)	(411)	(457)	(64)
Operating loss	(1,379)	(1,338)	(729)	(831)	(401)
Financing income (expenses), net	921	(1,337)	75	12	(79)
Net loss	(458)	(2,675)	(653)	(819)	(322)
Net loss per share (basic and diluted)	\$ (0.006)	(0.04)	(0.01)	(0.02)	(0.01)
Basic and diluted weighted average number of Ordinary Shares outstanding	70,869,924	68,587,261	62,467,556	45,190,017	28,450,908

Balance Sheet Data*U.S. dollars in thousands, except share data*

	Year Ended December 31,				
	2018	2017	2016	2015	2014
Cash and cash equivalents	\$ 64	\$ 683	\$ 439	\$ 156	\$ 61
Working capital (deficit)	\$ (1,093)	\$ 468	\$ 325	\$ 107	\$ 25
Total assets	\$ 199	\$ 816	\$ 584	\$ 292	\$ 129
Total current liabilities	\$ 1,199	\$ 245	\$ 135	\$ 79	\$ 100
Total long-term liabilities	\$ 217	\$ 1,911	\$ 853	\$ 742	\$ 617
Shareholders' deficit	\$ (1,216)	\$ (1,340)	\$ (404)	\$ (528)	\$ (588)
Number of Ordinary Shares outstanding	72,399,932	70,256,911	63,747,504	59,125,670	33,352,200
Number of Preferred Shares Outstanding	-	-	3,333,471	3,096,195	3,000,000

EXCHANGE RATE INFORMATION

The following table sets forth information regarding the exchange rates of U.S. dollars per NIS for the periods indicated. Average rates are calculated by using the daily representative rates as reported by the Bank of Israel on the last day of each month during the periods presented. As of December 31, 2018, the exchange rate of U.S. dollars to NIS was 3.748.

Year Ended December 31,	NIS per U.S. dollars			
	High	Low	Average	Period End
2018	3.781	3.388	3.597	3.748
2017	3.860	3.457	3.600	3.467
2016	3.983	3.746	3.840	3.845
2015	4.053	3.761	3.884	3.902
2014	3.994	3.402	3.577	3.889

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 risks and uncertainties described below, together with all of the other information in this annual report on Form 20-F including the financial statements and the related notes included elsewhere in this Annual Report. The risks described below are not the only risks we face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial may also materially and adversely affect our business operations. If any of these risks actually occurs, our business and financial condition could suffer and the price of our Ordinary Shares could decline.

Risks Related to Our Business

We have a history of losses, may incur future losses and may not achieve profitability.

We are a clinical-stage medical diagnostics company with a limited operating history. We have incurred net losses in each fiscal year since we commenced operations in 2010. We incurred net losses of \$653,461, \$2,675,375, and \$457,541 in the fiscal years ended December 31, 2016, 2017, and 2018, respectively. As of December 31, 2018, our accumulated deficit was \$5,693,353. Our losses could continue for the foreseeable future, as we continue our investment in research and development and clinical trials to complete the development of our technology and to attain regulatory approvals, begin the commercialization efforts for our cancer detection kits, increase our marketing and selling expenses, and incur additional costs as a result of being a publicly reporting company in the United States. The extent of our future operating losses and the timing of becoming profitable are highly uncertain, and we may never achieve or sustain profitability.

We have a need for substantial additional financing and will have to significantly delay, curtail or cease operations if we are unable to secure such financing.

The Company requires substantial additional financing to fund its operations. As of March 20, 2019, our unaudited cash holdings were \$310,000. In 2018, we managed our research and development activities taking into account our available resources. We continued with clinical trials at Kaplan Hospital and Beilinson Hospital (Israel) for TM-B1 and TM-C1, but did not expand our clinical trials activities. We believe that we will be able to use currently available capital resources for up to three (3) months. We will need to raise additional funds prior to commercializing our products. Additional financing may not be available to us on a timely basis on terms acceptable to us, or at all. In addition, any additional financing may be dilutive to our shareholders or may require us to grant a lender a security interest in our assets.

The report of our independent registered public accounting firm expresses substantial doubt about our ability to continue as a going concern.

Our independent registered public accounting firm indicated in its report on our financial statements included in this annual report on Form 20-F for the year ended December 31, 2018, that conditions exist that raise substantial doubt about our ability to continue as a “going concern.” A going concern paragraph included in our independent registered public accounting firm’s report on our consolidated financial statements, could impair investor perceptions and our ability to finance our operations through the sale of equity, incurring debt, or other financing alternatives. Our ability to continue as a going concern will depend upon many factors beyond our control including the availability and terms of future funding. If we are unable to achieve our goals and raise the necessary funds to finance our operations, our business would be jeopardized, and we may not be able to continue. If we ceased operations, it is likely that all of our investors would lose their investment.

We may not succeed in completing the development of our product, commercializing our product and generating significant revenues.

Since commencing our operations, we have focused on the research and development and limited clinical trials of our cancer detection kits. Our ability to generate revenues and achieve profitability depends on our ability to successfully complete the development of our product, obtain market approval and generate significant revenues. The future success of our business cannot be determined at this time, and we do not anticipate generating revenues from product sales for the foreseeable future. In addition, we face a number of challenges with respect to our future commercialization efforts, including, among others, that:

- we may not have adequate financial or other resources to complete the development of our product;
- We may not be able to manufacture our products in commercial quantities, at an adequate quality or at an acceptable cost;
- we may not be able to meet the timing schedule for (a) completing successful clinical trials in the U.S.; and (b) receiving U.S. Food and Drug Administration, or FDA, approval within our goal of approximately two to four years;
- we may not be able to maintain our CE mark due to the regulatory changes;

- we may never receive FDA approval, for our intended development plan;
- we may not be able to establish adequate sales, marketing and distribution channels;
- healthcare professionals and patients may not accept our cancer detection kits;
- technological breakthroughs in cancer detection, treatment and prevention may reduce the demand for our products;
- changes in the market for cancer detection, new alliances between existing market participants and the entrance of new market participants may interfere with our market penetration efforts;
- third-party payors may not agree to reimburse patients for any or all of the purchase price of our products, which may adversely affect patients' willingness to purchase our cancer detection kits;
- uncertainty as to market demand may result in inefficient pricing of our cancer detection kits;
- we may face third-party claims of intellectual property infringement;
- we may fail to obtain or maintain regulatory approvals for our cancer detection kits in our target markets or may face adverse regulatory or legal actions relating to our cancer detection kits even if regulatory approval is obtained; and
- we are dependent upon the results of ongoing clinical studies relating to our cancer detection kits and the products of our competitors. We may fail in obtaining positive results.

If we are unable to meet any one or more of these challenges successfully, our ability to effectively commercialize our cancer detection kits could be limited, which in turn could have a material adverse effect on our business, financial condition and results of operations.

We are currently in the process of improving our technology and adapting to the high throughput methodology.

We plan to change our protocol and measurement instrument as well as our sample handling in order to adapt it to new high throughput methodology. The changes we plan to implement in the protocol and measurement instrument are significant. The new protocol aims to be more robust, reproducible, fast and easy to handle, however, this transformation from the older manual protocol to the new protocol incurs several risks. To our management's knowledge, the new protocol will not impact the previously obtained European Conformity, or CE, mark of approval of the TBIA test. The results may not be as promising as the former version and although some procedures may be more reproducible, these procedures will unfortunately damage some molecules, which were part of the diagnostic features in the previous protocol.

The previous tests we performed were preliminary or limited un-blinded studies.

We consider the tests conducted by us, as of the current date, under our method, to be preliminary or limited, as they include a relatively small number of test subjects. Thus, there is a risk in having less sufficient sensitivity and/or specificity in the trials we plan on conducting with larger populations, in comparison to the preliminary data we have gathered thus far. Increasing the population can increase the variance in the medical condition of the control patients as well as the cancer patients, thus affecting our test performances with regard to cancer detection.

If healthcare professionals do not recommend our product to their patients, our cancer detection kits may not achieve market acceptance and we may not become profitable.

Cancer detection candidates are generally referred to a specified device by their healthcare professional and detection technologies are purchased by prescription. If healthcare professionals, including physicians, do not recommend or prescribe our product to their patients, our cancer detection kits may not achieve market acceptance and we may not become profitable. In addition, physicians have historically been slow to change their medical diagnostic and treatment practices because of perceived liability risks arising from the use of new products. Delayed adoption of our testing kits by healthcare professionals could lead to a delayed adoption by patients and third-party payors. Healthcare professionals may not recommend or prescribe our testing kits until certain conditions have been satisfied, including, among others:

- sufficient long-term clinical evidence to convince them to supplement their existing detection methods and device recommendations;
- recommendations from other prominent physicians, educators and/or associations that our testing kits are safe and effective;
- obtainment of favorable data from clinical studies for our testing kits; and
- availability of reimbursement or insurance coverage from third-party payors.

We cannot predict when, if ever, healthcare professionals and patients may adopt the use of our testing kits. Even if favorable data is obtained from clinical studies for our testing kits, there can be no assurance that prominent physicians would endorse it or that future clinical studies will continue to produce favorable data regarding our testing kits. In addition, prolonged market exposure may also be a pre-requisite to reimbursement or insurance coverage from third-party payors. If our testing kits do not achieve an adequate level of acceptance by patients, healthcare professionals and third-party payors, we may not generate significant product revenues and we may not become profitable.

Our reliance on limited source suppliers could harm our ability to meet demand for our product in a timely manner or within budget.

We currently depend on a limited number of source suppliers for some of the components necessary for the production of our product. Our current suppliers have been able to supply the required quantities of such components to date. However, if the supply of these components is disrupted or terminated or if our current suppliers are unable to supply required quantities of components, we may not be able to find alternative sources for these key components in a timely manner. Although we are planning to maintain strategic inventory of key components, the inventory may not be sufficient to satisfy the demand for our products if such supply is interrupted or otherwise affected by catastrophic events such as a fire at our storage facility. As a result, we may be unable to meet the demand for our testing kits, which could harm our ability to generate revenues, lead to customer dissatisfaction and damage our reputation. If we are required to change the manufacturer of any of these key components, there may be a significant delay in locating a suitable alternative manufacturer. The delays associated with the identification of a new manufacturer could delay our ability to manufacture our testing kits in a timely manner or within budget. Furthermore, in the event that the manufacturer of a key component of our testing kits ceases operations or otherwise ceases to do business with us, we may not have access to the information necessary to enable another supplier to manufacture the component. The occurrence of any of these events could harm our ability to meet demand for our testing kits in a timely manner or within budget.

The use of any of our cancer detection kits could result in product liability or similar claims that could have an adverse effect on our business, financial condition, results of operations and our reputation.

Our business exposes us to an inherent risk of potential product liability or similar claims related to the manufacturing, marketing and sale of medical devices. The medical device industry has historically been litigious, and we face financial exposure to product liability or similar claims if the use of our kits were to cause or contribute to injury or death, including, without limitation, harm to the body caused by the procedure or inaccurate diagnoses from the procedure that could affect treatment options. There is also the possibility that defects in the design or manufacture of any of these products might necessitate a product recall. Although we plan to maintain product liability insurance, the coverage limits of these policies may not be adequate to cover future claims. In the future, we may be unable to maintain product liability insurance on acceptable terms or at reasonable costs and such insurance may not provide us with adequate coverage against potential liabilities. A product liability claim, regardless of merit or ultimate outcome, or any product recall could result in substantial costs to us, damage to our reputation, customer dissatisfaction and frustration, and a substantial diversion of management attention. A successful claim brought against us in excess of, or outside of, our insurance coverage could have a material adverse effect on our business, financial condition, results of operations and our reputation.

We will require additional funding in order to commercialize our cancer detection kits and to develop and commercialize any future products.

Assuming we are successful in raising additional capital, we will continue our efforts to commercialize our cancer detection kits.

In order to market and sell our products in Israel, we require the approval of the Ministry of Health. To the best of our knowledge, approval of our products by the Ministry of Health requires us to comply with CE mark approval and International Organization for Standardization (ISO) 13485 (both of which we have already obtained). We have started the regulatory approval process in Israel and expect the regulatory approval process in Israel to take approximately an additional six months.

Furthermore, if adequate additional financing on acceptable terms is not available, we may not be able to develop our cancer detection kits at the rate or to the stage we desire, and we may have to delay or abandon the commercialization of our cancer detection kits. Alternatively, we may be required to prematurely license to third parties the rights to further develop or to commercialize our cancer detection kits on terms that are not favorable to us. Any of these factors could materially adversely affect our business, financial condition and results of operations.

We are entering a potentially highly competitive market.

Early detection is vital to the treatment of cancer, which is also the focus area of our products. The diagnostic, pharmaceutical and biopharmaceutical industries are characterized by intense competition and rapid, significant technological changes. Many companies, research institutions and universities are conducting research and development in a number of areas similar to those that we focus on that could lead to the development of new products which could possibly compete with our own. Most of the companies against which we will compete have substantially greater financial, technical, manufacturing, marketing, distribution and other resources. A number of these companies may have or may develop technologies for developing products for detecting various cancers that could prove to be the same or even superior to ours. We expect technological developments in the diagnostic, pharmaceutical, biopharmaceutical and related fields to occur at a rapid rate, and we believe competition will intensify as advances in these fields are made.

Our future success depends in part on our ability to retain our executive officers and to attract, retain and motivate other qualified personnel.

We are highly dependent on the principal members of our management, research and development team and scientific staff. In order to implement our business strategy, we will need to retain our key personnel with expertise in the areas of research and development, clinical testing, government regulation, manufacturing, finance, marketing and sales. The inability to recruit and retain qualified personnel, or the loss of the services of our executive officers, without proper replacement, may impede the progress of our development and commercialization objectives.

Any disruption at our facility could materially adversely affect our business, financial condition and results of operations.

We take precautions to safeguard our facility, including obtaining insurance coverage and implementing health and safety protocols and off-site storage of computer data. However, a natural or other disaster, such as a fire, flood or an armed conflict involving Israel, as detailed further below, could damage or destroy our facility and our manufacturing equipment or inventory, cause substantial delays in our operations and otherwise cause us to incur additional unanticipated expenses. In addition, the insurance we maintain against fires, floods and other natural disasters may not be adequate to cover our losses in any particular case and it does not cover losses resulting from armed conflicts or terrorist attacks in Israel. Damage to our facility, our other property or to any of our suppliers, whether located in Israel or elsewhere, due to fire, a natural disaster or casualty event or an armed conflict, could materially adversely affect our business, financial condition and results of operations, with or without insurance.

There are future financial risks associated with funding our business operations with bank loans.

It is highly likely that we will find it necessary to borrow funds from banks or other financial institutions. No assurances can be given that, at the time we desire to borrow funds, banks or other financial institutions will be willing to loan funds to us or that, if willing, will do so on terms acceptable to us. As a result, we may not be able to acquire data desired by management which might have a material adverse effect on our business, financial condition or operating results.

We may become involved in legal proceedings in the ordinary course of business.

From time to time, we may become involved in various lawsuits and legal proceedings, which arise, in the ordinary course of business. However, litigation is subject to inherent uncertainties, and an adverse result in these or other matters may arise from time to time that may harm our business. Our management is currently not aware of any such legal proceedings or claims that we believe will have a material adverse effect on our business, financial condition or operating results.

We may face tax exposure as a result of the Amaranthus transaction.

On February 27, 2019, the Company entered into a joint venture agreement with Amaranthus Bioscience Holdings, Inc., (“Amaranthus”), pursuant to which the Company issued Ordinary Share representing 19.99% of the Company to Amaranthus, in exchange for Amaranthus transferring to the Company 19.99% of Breakthrough Diagnostics, Inc. (“Breakthrough”), a wholly-owned subsidiary of Amaranthus, and for Amaranthus assigning its amended and restated license agreement with the University of Leipzig for an exclusive license to develop and commercialize the LymPro Test®, an immune-based neurodiagnostic blood test for the detection of Alzheimer’s disease (the “License”) to Breakthrough. To the extent that the value of the assets transferred to the Company in the transaction is not comparable to the value of the shares of the Company issued to Amaranthus in this transaction, then the Company may face a tax exposure.

Risks Related to Our Intellectual Property

We may not successfully maintain our existing license agreement with BGU and Soroka, and we are currently not in compliance with the repayment terms of the license agreement, which could adversely affect our ability to develop and commercialize our product candidates.

We rely on our existing License Agreement with BGU and Soroka with respect to the development of our core technology, TBIA. We expect to establish new collaborative and licensing arrangements in the future. Our failure to maintain our existing license or to develop new collaborative and licensing arrangements in the future, could adversely affect our ability to develop and commercialize our product candidates and could adversely affect our business prospects, financial condition or ability to develop and commercialize our product candidates. We are not currently in compliance with the repayment terms of the license agreement with our licensor. As such, we are currently negotiating an amendment to the license agreement which would allow us to pay the abovementioned payments at a later date.

We may not be able to further establish or maintain such licensing and collaboration arrangements necessary to develop and commercialize our product candidates. Even if we are able to maintain or establish licensing or collaboration arrangements, these arrangements may not be on favorable terms and may contain provisions that will restrict our ability to develop, test and market our product candidates. Any failure to maintain or establish licensing or collaboration arrangements on favorable terms could adversely affect our business prospects, financial condition or ability to develop and commercialize our product candidates.

Our license agreement contains provisions that could give rise to disputes regarding the rights and obligations of the parties. These and other possible disagreements could lead to termination of the agreement or delays in collaborative research, development, supply, or commercialization of certain product candidates, or could require or result in litigation or arbitration. Moreover, disagreements could arise with our collaborators over rights to intellectual property or our rights to share in any of the future revenues of products developed by our collaborators. These kinds of disagreements could result in costly and time-consuming litigation. Any such conflicts with our collaborators could reduce our ability to obtain future collaboration agreements and could have a negative impact on our relationship with existing collaborators.

If we are unable to protect our intellectual property rights, our competitive position could be harmed.

Our success and ability to compete depends in large part upon our ability to protect our intellectual property. We face several risks and uncertainties in connection with our intellectual property rights, including, among others:

- pending and future patent applications may not result in the issuance of patents or, if issued, may not be issued in a form that will be advantageous to us;
- our issued patents may be challenged, invalidated or legally circumvented by third parties;
- our patents may not be upheld as valid and enforceable or prevent the development of competitive products;
- the eligibility of certain inventions related to diagnostic medicine, more specifically diagnostic methods and processes, for patent protection in the United States has been limited recently which may affect our ability to enforce our issued patents in the United States or may make it difficult to obtain broad patent protection going forward in the United States;
- for a variety of reasons, we may decide not to file for patent protection on various improvements or additional features; and
- intellectual property protection and/or enforcement may be unavailable or limited in some countries where laws or law enforcement practices may not protect our proprietary rights to the same extent as the laws of the United States, the European Union, or the EU, or Israel.

Consequently, our competitors could develop, manufacture and sell products that directly compete with our products, which could decrease our sales and diminish our ability to compete. In addition, competitors could attempt to develop their own competitive technologies that fall outside of our intellectual property rights. If our intellectual property does not adequately protect us from our competitors' products and methods, our competitive position could be materially adversely affected.

Because the medical device industry is litigious, we are susceptible to intellectual property suits that could cause us to incur substantial costs or pay substantial damages or prohibit us from selling our cancer detection kits.

There is a substantial amount of litigation over patent and other intellectual property rights in the medical device industry. Whether or not a product infringes a patent involves complex legal and factual considerations, the determination of which is often uncertain. Our management is presently unaware of any other parties' valid patents and proprietary rights which our evolving product designs would infringe. Searches typically performed to identify potentially infringed patents of third parties are often not conclusive and, because patent applications can take many years to issue, there may be applications now pending, which may later result in issued patents which our current or future products may infringe. In addition, our competitors or other parties may assert that our cancer detection kits and the methods employed may be covered by patents held by them. If any of our products infringes a valid patent, we could be prevented from manufacturing or selling such product unless we are able to obtain a license or able to redesign the product in such a manner as to avoid infringement. A license may not always be available or may require us to pay substantial royalties. We also may not be successful in any attempt to redesign our product to avoid infringement. Infringement and other intellectual property claims, with or without merit, can be expensive and time-consuming to litigate and could divert our management's attention from operating our business.

The steps we have taken to protect our intellectual property may not be adequate, which could have a material adverse effect on our ability to compete in the market.

In addition to filing patent applications, we rely on confidentiality, non-compete, non-disclosure and assignment of inventions provisions, as appropriate, with our employees, consultants and, to some extent, our partners, to protect and otherwise seek to control access to, and distribution of, our proprietary information. These measures may not be adequate to protect our intellectual property from unauthorized disclosure, third-party infringement or misappropriation, for the following reasons:

- the agreements may be breached, may not provide the scope of protection we believe they provide or may be determined to be unenforceable;
- we may have inadequate remedies for any breach;
- proprietary information could be disclosed to our competitors; or
- others may independently develop substantially equivalent or superior proprietary information and techniques or otherwise gain access to our trade secrets or disclose such technologies.

Specifically, with respect to non-compete agreements, we may be unable to enforce these agreements, in whole or in part, and it may be difficult for us to restrict our competitors from gaining the expertise that our former employees gained while working for us. If our intellectual property is disclosed or misappropriated, it could harm our ability to protect our rights and could have a material adverse effect on our business, financial condition and results of operations.

We may need to initiate lawsuits to protect or enforce our patents and other intellectual property rights, which could be expensive and, if we lose, could cause us to lose some of our intellectual property rights, which would harm our ability to compete in the market.

We rely on patents to protect a portion of our intellectual property and our competitive position. Patent law relating to the scope of claims in the technology fields in which we operate is still evolving and, consequently, patent positions in the medical device industry are generally uncertain. In order to protect or enforce our patent rights, we may initiate patent and related litigation against third parties, such as infringement suits or interference proceedings. Any lawsuits that we initiate could be expensive, take significant time and divert our management's attention from other business concerns and the outcome of litigation to enforce our intellectual property rights in patents, copyrights, trade secrets or trademarks is highly unpredictable. Litigation also puts our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing. In addition, we may provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, including attorney fees, if any, may not be commercially valuable. The occurrence of any of these events could have a material adverse effect on our business, financial condition and results of operations.

Risks Related to Regulations

If we or our future distributors do not obtain and maintain the necessary regulatory clearances or approvals in a specific country or region, we will not be able to market and sell our cancer detection kits or future products in that country or region.

We intend to market our cancer detection kits in a number of international markets. To be able to market and sell our cancer detection kits in a specific country or region, we or our distributors must comply with the regulations of that country or region. While the regulations of some countries do not impose barriers to marketing and selling part or all of our products or only require notification, others require that we or our distributors obtain the approval of a specified regulatory authorities. These regulations, including the requirements for approvals and the time required for regulatory review, vary from country to country. Obtaining regulatory approvals is expensive and time-consuming, and we cannot be certain that we or our distributors will receive regulatory approvals for our cancer detection kits or any future products in each country or region in which we plan to market such products. If we modify our cancer detection kits or any future products, we or our distributors may need to apply for new regulatory approvals or regulatory authorities may need to review the planned changes before we are permitted to sell them.

The Medicines and Healthcare products Regulatory Agency, or MHRA, is the United Kingdom based European Authority responsible for the issuance of CE Mark approval. In 2013, our regulatory authorized representative in Europe submitted an application to the MHRA for the CE Mark approval of our TBIA method. We obtained this approval on December 9, 2013 with the receipt of a Certificate of Conformance from our regulatory authorized representative in Europe. The European regulatory demands regarding IVD have recently been revised and major changes need to be made in order to keep our CE Mark. These changes need to be made until 2022. We may not meet the quality and safety standards required to maintain any authorizations we receive in the future or maintain the CE Certificate of Conformance that we have already received. If we or our distributors are unable to maintain our authorizations or CE Certificate of Conformance in a particular country or region, we will no longer be able to sell our cancer detection kits or any future products in that country or region, and our ability to generate revenues will be materially and adversely affected.

If we are unable to successfully complete clinical trials with respect to our cancer detection kits, we may be unable to receive regulatory approvals or clearances for our cancer detection kits and/or our ability to achieve market acceptance of our cancer detection kits will be harmed.

The development of cancer diagnostics typically includes pre-clinical studies. Certain other devices require the submission of data generated from clinical trials, which can be a long, expensive and uncertain processes, subject to delays and failure at any stage. The data obtained from the studies and trials may be inadequate to support regulatory clearances or approvals, or to obtain third country approval equivalent to CE approval, or to allow market acceptance of the products being studied. Our cancer detection kits are currently undergoing clinical development.

We conducted clinical studies in cooperation with leading hospitals in Israel. A study with the Soroka (along with BGU) formed the basis of our methodology. We then conducted studies, with both Rabin Medical Center, or Rabin, and Kaplan Medical Center, or Kaplan, which focused on breast and colorectal cancers.

Currently, we are engaged in completing clinical trials at Kaplan Hospital and Belinson Hospital concerning breast cancer and colorectal cancer that are required for product development. The data from these clinical trials may be used or required in order to obtain regulatory approvals for our products including for the purpose of seeking FDA approval.

As for the FDA, our product's intended use or other specifications that are under development today, may not be accepted by the FDA. Thus, our trials may not be relevant as supportive material to the FDA.

We are an IVD company, developing proprietary technology which will analyze a blood test to detect the presence of various cancers. Since we are not developing a drug, we believe that we will not need to submit an investigational new drug application to the FDA prior to conducting clinical trials in the U.S. We believe that we will only need institutional review board, or IRB, approval prior to conducting clinical trials in the U.S.

We expect that obtaining FDA approval for the marketing and selling of our products in the U.S. will take anywhere between two to four years and will cost us approximately \$10 million to \$15 million. As we do not have this amount of money, we would need to raise additional funds to perform clinical trials in the U.S. in order to receive FDA approval. If we are unable to raise such funds, we will not be able proceed with our efforts to obtain FDA approval. Inability to obtain FDA approval would significantly harm our viability as a company.

We estimate that we will need a "small pilot" clinical trial to enable us to approach the FDA with the results and begin a dialogue with the FDA to seek the FDA's recommendation (not their approval) as to trial size and the protocols for future U.S. clinical trials. We plan to submit a formal application to the FDA for approval of the TBIA method after we have completed our clinical trials in the U.S.

Our intentions are to evaluate opening a Clinical Laboratory Improvement Amendments laboratory, or CLIA laboratory, and retain our product as a Laboratory Developed Test, or LDT, which are assays developed in the laboratory for internal use, in parallel to the FDA evaluation.

Further any regulatory authority whose approval we will require in order to market and sell our products in any territory may require us to submit data on a greater number of patients than we originally anticipated and/or for a longer follow-up period or they may change the data collection requirements or data analysis applicable to our clinical trials.

The commencement or completion of any of our clinical studies or trials may be delayed or halted, or be inadequate to support regulatory clearance, approval or product acceptance, or to obtain local regulatory approvals in any country that we wish to sell our products, for numerous reasons, including, among others:

- patients do not enroll in the clinical trial at the rate we expect;
- patients do not comply with trial protocols;
- patient follow-up is not at the rate we expect;
- patients experience adverse side effects;
- patients die during a clinical trial, even though their death may be unrelated to our product;
- regulatory authorities do not approve a clinical trial protocol or a clinical trial, or place a clinical trial on hold;
- IRBs, Ethics Committees and third-party clinical investigators may delay or reject our trial protocol and Informed Consent Form;
- third-party clinical investigators decline to participate in a study or trial or do not perform a study or trial on our anticipated schedule or consistent with the investigator agreements, study or trial protocol, good clinical practices or FDA, IRBs, Ethics Committees, or other applicable requirements;
- third-party organizations such as the Contract Research Organization, do not perform data collection, monitoring and analysis in a timely or accurate manner or consistent with the study or trial protocol or investigational or statistical plans;
- regulatory inspections of our studies, trials or manufacturing facilities may require us to, among other things, undertake corrective action or suspend or terminate our studies or clinical trials;
- changes in governmental regulations or administrative actions;
- the interim or final results of the study or clinical trial are inconclusive or unfavorable as to safety or efficacy; and
- a regulatory agency or our notified body concludes that our trial design is or was inadequate to demonstrate different parameters of the assay.

The results of pre-clinical and clinical studies do not necessarily predict future clinical trial results, and predecessor clinical trial results may not be repeated in subsequent clinical trials. Additionally, any regulatory authority whose approval we will require in order to market and sell our products in any territory may disagree with our interpretation of the data from our pre-clinical studies and clinical trials, or may find the clinical trial design, conduct or results inadequate to demonstrate safety or efficacy, and may require us to pursue additional pre-clinical studies or clinical trials, which could further delay the clearance or approval of the sale of our products. The data we collect from our non-clinical testing, our pre-clinical studies and other clinical trials may not be sufficient to support regulatory approval.

If the third parties on which we rely to conduct our clinical trials and clinical development do not perform as contractually required or expected, we may not be able to obtain regulatory clearance or approval for, or commercialize, our cancer detection kits or future products.

We do not have the ability to independently conduct our clinical trials for our cancer detection kits and we must rely on third parties, such as contract research organizations, medical institutions, clinical investigators and contract laboratories to conduct such trials. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if these third parties need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our pre-clinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory clearance for, or successfully commercialize, our cancer detection kits or future products on a timely basis, if at all, and our business, operating results and prospects may be adversely affected. Furthermore, our third-party clinical trial investigators may be delayed in conducting our clinical trials for reasons outside of their control.

The results of our clinical trials may not support our product candidate claims or may result in the discovery of adverse side effects.

Even if our clinical trials are completed as planned, we cannot be certain that their results will support our product claims or that any regulatory authority whose approval we will require in order to market and sell our products in any territory will agree with our conclusions regarding them. Success in pre-clinical studies and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that clinical trials will replicate the results of prior trials and pre-clinical studies. The clinical trial process may fail to demonstrate that our cancer detection kits, or any future products, are safe and effective for the proposed indicated uses, which could cause us to abandon a product and may delay development of others. Any delay or termination of our clinical trials will delay the filing of our product submissions and, ultimately, our ability to commercialize our cancer detection kits, or any future products, and generate revenues. It is also possible that patients enrolled in clinical trials will experience adverse side effects that are not currently part of the product candidate's profile.

Our cancer detection kits may in the future be subject to product recalls that could harm our reputation, business and financial results.

The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture. In the case of the FDA, the authority to require a recall must be based on an FDA finding that there is a reasonable probability that the device would cause serious injury or death. In addition, foreign governmental bodies have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. A government-mandated or voluntary recall by us or one of our distributors could occur as a result of component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Once marketed, recalls of any of our products, including our cancer detection kits, would divert managerial and financial resources and have an adverse effect on our business, financial condition and results of operations. The FDA requires that certain classifications of recalls be reported to the FDA within 10 working days after the recall is initiated. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. We may initiate voluntary recalls involving our products in the future that we determine do not require us to notify the FDA. If the FDA disagrees with our determinations, they could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA could take enforcement action against us based on our failure to report the recalls when they were conducted.

If we are unable to achieve reimbursement and coverage from third-party payors for laboratory tests using our cancer detection kits, or if reimbursement is insufficient to create an economic benefit for purchasing or using our cancer detection kits when compared to alternative tests, demand for our products may not grow at the rate we expect.

The demand for our cancer detection kits will depend significantly on the eligibility of the tests performed using our cancer detection kits for reimbursement through government-sponsored healthcare payment systems and private third-party payors. Reimbursement practices vary significantly from country to country and within some countries, by region, and we must obtain reimbursement approvals on a country-by-country and/or region-by-region basis. In general, the process of obtaining reimbursement and coverage approvals has been longer outside of the United States. We may not be able to obtain reimbursement approvals in a timely manner or at all and existing reimbursement and coverage policies may be revised from time to time by third-party payors. If physicians, hospitals and other healthcare providers are unable to obtain sufficient coverage and reimbursement from third-party payors for tests using our cancer detection kits, if reimbursement is, or is perceived by our customers to be, insufficient to create an economic incentive for purchasing or using our cancer detection kits, or if such reimbursement does not adequately compensate physicians and health care providers compared to the other tests they offer, demand for our products may not grow at the rate we expect.

Federal and state privacy laws, and equivalent laws of third countries, may increase our costs of operation and expose us to civil and criminal sanctions.

The Health Insurance Portability and Accountability Act of 1996, as amended, and the regulations that have been issued under it, or collectively HIPAA, and similar laws outside the United States, contain substantial restrictions and requirements with respect to the use and disclosure of individuals' protected health information. The HIPAA privacy rules prohibit "covered entities," such as healthcare providers and health plans, from using or disclosing an individual's protected health information, unless the use or disclosure is authorized by the individual or is specifically required or permitted under the privacy rules. Under the HIPAA security rules, covered entities must establish administrative, physical and technical safeguards to protect the confidentiality, integrity and availability of electronic protected health information maintained or transmitted by them or by others on their behalf. While we do not believe that we will be a covered entity under HIPAA, we believe many of our customers will be covered entities subject to HIPAA. Such customers may require us to enter into business associate agreements, which will obligate us to safeguard certain health information we obtain in the course of our relationship with them, restrict the manner in which we use and disclose such information and impose liability on us for failure to meet our contractual obligations.

In addition, under The Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, which was signed into law as part of the U.S. stimulus package in February 2009, certain of HIPAA's privacy and security requirements are now also directly applicable to "business associates" of covered entities and subject them to direct governmental enforcement for failure to comply with these requirements. We may be deemed as a "business associate" of some of our customers. As a result, we may be subject as a "business associate" to civil and criminal penalties for failure to comply with applicable privacy and security rule requirements. Moreover, HITECH created a new requirement obligating "business associates" to report any breach of unsecured, individually identifiable health information to their covered entity customers and imposes penalties for failing to do so.

In addition to HIPAA, most U.S. states have enacted patient confidentiality laws that protect against the disclosure of confidential medical information, and many U.S. states have adopted or are considering adopting further legislation in this area, including privacy safeguards, security standards, and data security breach notification requirements. These U.S. state laws, which may be even more stringent than the HIPAA requirements, are not preempted by the federal requirements, and we are therefore required to comply with them to the extent they are applicable to our operations.

These and other possible changes to HIPAA or other U.S. federal or state laws or regulations, or comparable laws and regulations in countries where we conduct business, could affect our business and the costs of compliance could be significant. Failure by us to comply with any of the standards regarding patient privacy, identity theft prevention and detection, and data security may subject us to penalties, including civil monetary penalties and in some circumstances, criminal penalties. In addition, such failure may damage our reputation and adversely affect our ability to retain customers and attract new customers.

The protection of personal data, particularly patient data, is subject to strict laws and regulations in many countries. The collection and use of personal health data in the EU is governed by the provisions of Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, commonly known as the Data Protection Directive. The Directive imposes a number of requirements including an obligation to seek the consent of individuals to whom the personal data relates, the information that must be provided to the individuals, notification of data processing obligations to the competent national data protection authorities of individual EU Member States and the security and confidentiality of the personal data. The Data Protection Directive also imposes strict rules on the transfer of personal data out of the EU to the U.S. Failure to comply with the requirements of the Data Protection Directive and the related national data protection laws of the EU Member States may result in fines and other administrative penalties and harm our business. We may incur extensive costs in ensuring compliance with these laws and regulations, particularly if we are considered to be a data controller within the meaning of the Data Protection Directive.

Once we commercialize our product, if ever, security breaches, loss of data and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.

Once we commercialize our product, in the ordinary course of our business, it is highly likely that we and our third-party providers will collect and store sensitive data, including legally-protected health information and personally identifiable information about patients, our healthcare provider customers and payors. We also may store sensitive intellectual property and other proprietary business information, including that of our customers and payors. We plan to manage and maintain our data utilizing a combination of on-site systems and cloud-based data center systems. This data will encompass a wide variety of business-critical information, including research and development information, commercial information and business and financial information.

We face four primary risks relative to protecting this critical information: loss of access risk, inappropriate disclosure risk, inappropriate modification risk and the risk of our being unable to identify and audit our controls over the first three risks.

We will be highly dependent on information technology networks and systems, including the Internet, to securely process, transmit and store this critical information. Security breaches of this infrastructure, including physical or electronic break-ins, computer viruses, attacks by hackers and similar breaches, can create system disruptions, shutdowns or unauthorized disclosure or modification of confidential information. The secure processing, storage, maintenance and transmission of this critical information will be vital to our operations and business strategy, and we plan to devote significant resources to protecting such information. Although we will take measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure, and that of our third-party providers, may be vulnerable to attacks by hackers or viruses or breached due to employee error, malfeasance or other disruptions.

A security breach or privacy violation that leads to disclosure or modification of or prevents access to consumer information (including personally identifiable information or protected health information) could harm our reputation, compel us to comply with disparate state breach notification laws, require us to verify the correctness of database contents and otherwise subject us to liability under laws that protect personal data, resulting in increased costs or loss of revenue. If we are unable to prevent such security breaches or privacy violations or implement satisfactory remedial measures, our operations could be disrupted, and we may suffer loss of reputation, financial loss and other regulatory penalties because of lost or misappropriated information, including sensitive consumer data. In addition, these breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above.

Any such breach or interruption could compromise our networks or those of our third-party providers, and the information stored there could be inaccessible or could be accessed by unauthorized parties, publicly disclosed, lost or stolen. Any such interruption in access, improper access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, such as HIPAA, and regulatory penalties. Unauthorized access, loss or dissemination could also disrupt our operations, including our ability to perform tests, provide test results, bill payers or patients, process claims and appeals, provide customer assistance services, conduct research and development activities, collect, process and prepare company financial information, provide information about our current and future products and other patient and clinician education and outreach efforts through our website, and manage the administrative aspects of our business and damage our reputation, any of which could adversely affect our business. Any such breach could also result in the compromise of our trade secrets and other proprietary information, which could adversely affect our competitive position.

In addition, the interpretation and application of consumer, health-related, privacy and data protection laws in the U.S., the EU and elsewhere are often uncertain, contradictory and in flux. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business. Complying with these various laws could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business.

If we fail to comply with the U.S. federal Anti-Kickback Statute and similar state and third country laws, we could be subject to criminal and civil penalties and exclusion from federally funded healthcare programs including the Medicare and Medicaid programs and equivalent third country programs, which would have a material adverse effect on our business and results of operations.

A provision of the Social Security Act, commonly referred to as the federal Anti-Kickback Statute, prohibits the knowing and willful offer, payment, solicitation or receipt of any form of remuneration, directly or indirectly, in cash or in kind, to induce or reward the referring, ordering, leasing, purchasing or arranging for, or recommending the ordering, purchasing or leasing of, items or services payable, in whole or in part, by Medicare, Medicaid or any other federal healthcare program. Although there are a number of statutory exemptions and regulatory safe harbors to the federal Anti-Kickback Statute protecting certain common business arrangements and activities from prosecution or regulatory sanctions, the exemptions and safe harbors are drawn narrowly, and practices that do not fit squarely within an exemption or safe harbor may be subject to scrutiny. The federal Anti-Kickback Statute is very broad in scope and many of its provisions have not been uniformly or definitively interpreted by existing case law or regulations. In addition, most of the states have adopted laws similar to the federal Anti-Kickback Statute, and some of these laws are even broader than the federal Anti-Kickback Statute in that their prohibitions may apply to items or services reimbursed under Medicaid and other state programs or, in several states, apply regardless of the source of payment. Violations of the federal Anti-Kickback Statute may result in substantial criminal, civil or administrative penalties, damages, fines and exclusion from participation in federal healthcare programs.

All of our future financial relationships with U.S. healthcare providers, purchasers, formulary managers, and others who provide products or services to federal healthcare program beneficiaries will potentially be governed by the federal Anti-Kickback Statute and similar state laws. We believe our operations will be in compliance with the federal Anti-Kickback Statute and similar state laws. However, we cannot be certain that we will not be subject to investigations or litigation alleging violations of these laws, which could be time-consuming and costly to us and could divert management's attention from operating our business, which in turn could have a material adverse effect on our business. In addition, if our arrangements were found to violate the federal Anti-Kickback Statute or similar state laws, the consequences of such violations would likely have a material adverse effect on our business, results of operations and financial condition.

There are other federal and state laws that may affect our ability to operate, including the federal civil False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, a false or fraudulent claim 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 concealing or knowingly and improperly avoiding, decreasing, or concealing an obligation to pay money to the federal government. Moreover, we may be subject to other federal false claim laws, including, among others, federal criminal healthcare fraud and false statement statutes that extend to non-government health benefit programs. Moreover, there are analogous state laws. Violations of these laws can result in substantial criminal, civil or administrative penalties, damages, fines and exclusion from participation in federal healthcare programs.

Similar restrictions are imposed by the national legislation of many third countries in which our medical devices will be marketed. Moreover, the provisions of the Foreign Corrupt Practices Act of 1997 and other similar anti-bribery laws in other jurisdictions generally prohibit companies and their intermediaries from providing money or anything of value to officials of foreign governments, foreign political parties, or international organizations with the intent to obtain or retain business or seek a business advantage. Recently, there has been a substantial increase in anti-bribery law enforcement activity by U.S. regulators, with more aggressive and frequent investigations and enforcement by both the SEC and the Department of Justice. A determination that our operations or activities violated U.S. or foreign laws or regulations could result in imposition of substantial fines, interruption of business, loss of supplier, vendor or other third-party relationships, termination of necessary licenses and permits, and other legal or equitable sanctions. In addition, lawsuits brought by private litigants may also follow as a consequence.

Risks Related to Our Operations in Israel

Exchange rate fluctuations between the U.S. dollar, the NIS and the Euro and inflation may negatively affect our earnings and we may not be able to hedge our currency exchange risks successfully.

The U.S. dollar is our functional and reporting currency. However, a portion of our operating expenses, including personnel and facilities related expenses, are incurred in NIS. As a result, we are exposed to the risks that the NIS may appreciate relative to the U.S. dollar, or, if the NIS instead devalues relative to the U.S. dollar, that the inflation rate in Israel may exceed such rate of devaluation of the NIS, or that the timing of such devaluation may lag behind inflation in Israel. In any such event, the dollar cost of our operations in Israel would increase and our dollar-denominated results of operations would be adversely affected. The Israeli rate of inflation has not had a material adverse effect on our financial condition during 2016, 2017, and 2018. In addition, we expect to incur operating expenses denominated in various currencies, and therefore, our operating results are also subject to fluctuations due to changes in the various exchange rates. Given our general lack of currency hedging arrangements to protect us from fluctuations in the exchange rates of the NIS, the Euro and other foreign currencies in relation to the U.S. dollar (and/or from inflation of such foreign currencies), we may be exposed to material adverse effects from such movements. We cannot predict any future trends in the rate of inflation in Israel or the rate of devaluation (if any) of the NIS against any other currency.

Our principal offices, research and development facilities and some of our suppliers are located in Israel and, therefore, our business, financial condition and results of operation may be adversely affected by political, economic and military instability in Israel.

We are incorporated under Israeli law and our principal executive offices are located in Israel. In addition, all of our employees and officers, and most of our directors, are residents of Israel. Accordingly, political, economic and military conditions in Israel may directly affect our business. Since the establishment of the State of Israel in 1948, a number of armed conflicts have taken place between Israel and its neighboring Arab countries, the Hamas (an Islamist militia and political group that has historically controlled the Gaza strip) and the Hezbollah (an Islamist militia and political group based in Lebanon). Any hostilities involving Israel or the interruption or curtailment of trade between Israel and its trading partners could adversely affect our operations and results of operations. Ongoing and revived hostilities or other Israeli political or economic factors, such as, an interruption of operations at the Tel Aviv airport, could prevent or delay shipments of our components or products. If continued or resumed, these hostilities may negatively affect business conditions in Israel in general and our business in particular. In the event that hostilities disrupt the ongoing operation of our facilities or the airports and seaports on which we depend to import and export our supplies and product candidates, our operations may be materially adversely affected.

In addition, instability in the region may lead to deterioration in the political and trade relationships that exist between the State of Israel and certain other countries. Any armed conflicts, terrorist activities or political instability in the region could adversely affect business conditions, could harm our results of operations and could make it more difficult for us to raise capital. Parties with whom we do business may sometimes decline to travel to Israel during periods of heightened unrest or tension, forcing us to make alternative arrangements when necessary in order to meet our business partners face to face. Several countries, principally in the Middle East, still restrict doing business with Israel and Israeli companies, and additional countries may impose restrictions on doing business with Israel and Israeli companies if hostilities in Israel or political instability in the region continues or increases. Similarly, Israeli companies are limited in conducting business with entities from several countries. For instance, in 2008, the Israeli legislature passed a law forbidding any investments in entities that transact business with Iran. In addition, the political and security situation in Israel may result in parties with whom we have agreements involving performance in Israel claiming that they are not obligated to perform their commitments under those agreements pursuant to force majeure provisions in such agreements.

Our commercial insurance does not cover losses that may occur as a result of an event associated with the security situation in the Middle East. Although the Israeli government has in the past covered the reinstatement value of certain damages that were caused by terrorist attacks or acts of war, we cannot assure you that this government coverage will be maintained or, if maintained, will be sufficient to compensate us fully for damages incurred. Any losses or damages incurred by us could have a material adverse effect on our business. Any armed conflicts or political instability in the region would likely negatively affect business conditions generally and could harm our results of operations and product development.

Furthermore, in the past, the State of Israel and Israeli companies have been subjected to economic boycotts. Several countries still restrict business with the State of Israel and with Israeli companies. These restrictive laws and policies may have an adverse impact on our operating results, financial conditions or the expansion of our business. Similarly, Israeli corporations are limited in conducting business with entities from several countries.

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 U.S. companies.

The rights and responsibilities of the holders of our Ordinary Shares are governed by our articles of association, as most recently amended on March 16, 2017, or the Amended Articles and by Israeli law. These rights and responsibilities differ in some material respects from the rights and responsibilities of shareholders in U.S.-based corporations. In particular, 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, in 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 this duty or the implications of these provisions. These provisions may be interpreted to impose additional obligations and liabilities on holders of our Ordinary Shares that are not typically imposed on shareholders of U.S. corporations.

It may be difficult to enforce a judgment of a U.S. court against us, our officers and directors in Israel or the United States, to assert U.S. securities laws claims in Israel or to serve process on our officers and directors.

We were incorporated in Israel. All of our executive officers and directors reside outside of the U.S., and all of our assets and most of the assets of these persons are located outside the U.S. Therefore, a judgment obtained against us, or any of these persons, including a judgment based on the civil liability provisions of the U.S. federal securities laws, may not be collectible in the U.S. and may not necessarily be enforced by an Israeli court. It also may be difficult to affect service of process on these persons in the United States or to assert U.S. securities law claims in original actions instituted in Israel. Additionally, it may be difficult for an investor, or any other person or entity, to initiate an action with respect to U.S. securities laws in Israel. Israeli courts may refuse to hear a claim based on an alleged violation of U.S. securities laws reasoning that Israel is not the most appropriate forum in which 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 U.S. law is applicable to the claim. If U.S. law is found to be applicable, the content of applicable U.S. law must be proven as a fact by expert witnesses, which can be a time consuming and costly process. Certain matters of procedure will also be governed by Israeli law. There is little binding case law in Israel that addresses the matters described above. As a result of the difficulty associated with enforcing a judgment against us in Israel, you may not be able to collect any damages awarded by either a U.S. or foreign court. See "Enforceability of Civil Liabilities" for additional information on your ability to enforce a civil claim against us and our executive officers or directors named in this annual report on Form 20-F.

Provisions of Israeli law and our Amended Articles may delay, prevent or otherwise impede a merger with, or an acquisition of, us, even when the terms of such a transaction are favorable to us and our shareholders.

Israeli corporate law regulates mergers, requires tender offers for acquisitions of shares above specified thresholds, requires special approvals for transactions involving directors, officers or significant shareholders and regulates other matters that may be relevant to such types of transactions. For example, a tender offer for all of a company's issued and outstanding shares can only be completed if the acquirer receives positive responses from the holders of at least 95% of the issued share capital and the approval of a majority of the offerees that do not have a personal interest in the tender offer, unless at least 98% of the company's outstanding shares are tendered. Furthermore, the shareholders, including those who indicated their acceptance of the tender offer (unless the acquirer stipulated in its tender offer that a shareholder that accepts the offer may not seek appraisal rights), may, at any time within six months following the completion of the tender offer, petition an Israeli court to alter the consideration for the acquisition. In addition, a merger may not be consummated unless at least 50 days have passed from the date on which a proposal for approval of the merger was filed by each party with the Israeli Registrar of Companies and at least 30 days have passed from the date on which the merger was approved by the shareholders of each party. See "Provisions Restricting Change in Control in our Company" for additional information.

Furthermore, Israeli tax considerations may make potential transactions unappealing to us or to our shareholders whose country of residence does not have a tax treaty with Israel exempting such shareholders from Israeli tax. For example, Israeli tax law does not recognize tax-free share exchanges to the same extent as U.S. 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 received Israeli government grants for certain of our research and development activities. The terms of those grants may require us to pay royalties and to satisfy specified conditions in order to manufacture products and transfer technologies outside of Israel. We may be required to pay penalties in addition to repayment of the grants.

From inception through December 31, 2018, we have been awarded an aggregate of approximately \$272,237 in the form of grants from Israel Innovation Authority, or the IIA, formerly known as Israel's Office of the Chief Scientist of the Ministry of Economy. The requirements and restrictions for such grants are found in the Israeli Encouragement of Research and Development Law, 5744-1984 and the regulations, or the Research Law. Under the Research Law, royalties of 3% to 5% on the revenues derived from sales of products or services developed in whole or in part using these IIA grants are payable to the Israeli government. We developed our technologies, at least in part, with funds from these grants, and accordingly we would be obligated to pay these royalties on sales of any of our product candidates that achieve regulatory approval. The maximum aggregate royalties paid generally cannot exceed 100% of the grants made to us, plus annual interest equal to the 12-month LIBOR applicable to dollar deposits, as published on the first business day of each calendar year. As of December 31, 2018, we had not paid any royalties to the IIA. In 2018, we did not receive a grant from the IIA. When a company develops know-how, technology or products using IIA grants, the terms of these grants and the Research Law restrict the transfer of such know-how, and the transfer of manufacturing or manufacturing rights of such products, technologies or know-how outside of Israel, without the prior approval of the IIA. Therefore, the discretionary approval of an IIA committee would be required for any transfer to third parties inside or outside of Israel of know-how or manufacturing or manufacturing rights related to those aspects of such technologies. We may not receive those approvals. Furthermore, the IIA may impose certain conditions on any arrangement under which it permits us to transfer technology or development out of Israel.

The transfer of IIA-supported technology or know-how outside of Israel may involve the payment of significant amounts, depending upon the value of the transferred technology or know-how, our research and development expenses, the amount of IIA support, the time of completion of the IIA-supported research project and other factors. These restrictions and requirements for payment may impair our ability to sell or otherwise transfer our technology assets outside of Israel or to outsource or transfer development or manufacturing activities with respect to any product or technology outside of Israel. Furthermore, the consideration available to our shareholders in a transaction involving the transfer outside of Israel of technology or know-how developed with IIA funding (such as a merger or similar transaction) may be reduced by any amounts that we are required to pay to the IIA.

These restrictions will continue to apply even after we have repaid the full amount of royalties on the grants. For the years ended December 31, 2016, 2017, and 2018, we recorded grants totaling \$166,046, \$0, and \$0 from the IIA, respectively. The grants represented 23%, 0%, and 0%, respectively, of our gross research and development expenditures for the years ended December 31, 2016, 2017, and 2018.

Risks Related to Our Ordinary Shares

There is no established public trading market for our Ordinary Shares and our shareholders may not be able to resell their Ordinary Shares.

There is no established public trading market for our securities. Our shares were initially quoted on the OTCQB on March 7, 2017. We cannot assure that a regular trading market will develop or that if developed, will be sustained. In the absence of a trading market, a shareholder may be unable to liquidate its investment, which will result in the loss of such shareholder's investment.

Future issuance of our Ordinary Shares could dilute the interests of existing shareholders.

We may issue additional Ordinary Shares in the future. The issuance of a substantial number of Ordinary Shares could have the effect of substantially diluting the interests of our shareholders. In addition, the sale of a substantial amount of Ordinary Shares in the public market, in the initial issuance, in a situation in which we acquire a company and the acquired company receives Ordinary Shares as consideration and the acquired company subsequently sells its Ordinary Shares, or by investors who acquired such Ordinary Shares in a private placement, could have an adverse effect on the market price of our Ordinary Shares.

We have a significant number of options and warrants outstanding, and while these options and warrants are outstanding, it may be more difficult to raise additional equity capital.

As of March 1, 2019, we had outstanding options and warrants to purchase 1,758,315 and 4,730,906 Ordinary Shares, respectively. The holders of these options and warrants are given the opportunity to profit from a rise in the market price of our Ordinary Shares. We may find it more difficult to raise additional equity capital while these options and warrants are outstanding. At any time during which these warrants are likely to be exercised, we may be unable to obtain additional equity capital on more favorable terms from other sources. Additionally, the exercise of these options and warrants will cause the increase of our outstanding Ordinary Shares, which could have the effect of substantially diluting the interests of our current shareholders.

We are an Emerging Growth Company, which may reduce the amount of information available to investors

The Jumpstart Our Business Startups Act, or the JOBS Act, and our status as a foreign private issuer will allow us to postpone the date by which we must comply with some of the laws and regulations intended to protect investors and to reduce the amount of information we provide in our reports filed with the SEC, which could undermine investor confidence in our company and adversely affect the market price of our Ordinary Shares.

For as long as we remain an "emerging growth company" as defined in the JOBS Act, we intend to take advantage of certain exemptions from various requirements that are applicable to public companies that are not emerging growth companies including:

- the provisions of the Sarbanes-Oxley Act requiring that our independent registered public accounting firm provide an attestation report on the effectiveness of our internal control over financial reporting;
- Section 107 of the JOBS Act, which provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, or the Securities Act, for complying with new or revised accounting standards. This means that an "emerging growth company" can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We may elect to delay such adoption of new or revised accounting standards. As a result of this adoption, our financial statements may not be comparable to companies that comply with the public company effective date; and
- any rules that may be adopted by the Public Company Accounting Oversight Board requiring mandatory audit firm rotation or a supplement to the auditor's report on the financial statements.

We intend to take advantage of these exemptions until we are no longer an “emerging growth company.” We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the date of our first sale of common equity securities pursuant to an effective registration statement under the Securities Act, (b) in which we have total annual gross revenue of at least \$1.07 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our Ordinary Shares that is held by non-affiliates exceeds \$700 million as of the prior June 30, and (2) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period.

We cannot predict if investors will find our Ordinary Shares less attractive because we may rely on these exemptions. If some investors find our Ordinary Shares less attractive as a result, there may be a less active trading market for our Ordinary Shares, and our share price may be more volatile and may decline.

We are a foreign private issuer and, as a result, we are not subject to U.S. proxy rules and are subject to reporting obligations that, to some extent, are more lenient and less frequent than those applicable to a U.S. issuer.

Because we qualify as a foreign private issuer under the Exchange Act, we are exempt from certain provisions of the Exchange Act that are applicable to U.S. publicly reporting companies, including (i) the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations in respect of a security registered under the Exchange Act, (ii) the sections of the Exchange Act requiring insiders to file public reports of their stock ownership and trading activities and liability for insiders who profit from trades made in a short period of time, and (iii) the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q containing unaudited financial and other specified information, or current reports on Form 8-K, upon the occurrence of specified significant events. In addition, while U.S. domestic issuers that are not large accelerated filers or accelerated filers are required to file their annual reports on Form 10-K within 90 days after the end of each fiscal year, foreign private issuers are not required to file their annual report on Form 20-F until 120 days after the end of each fiscal year. Foreign private issuers are also exempt from the Regulation Fair Disclosure, aimed at preventing issuers from making selective disclosures of material information.

We have never paid cash dividends on our capital stock and we do not anticipate paying any dividends in the foreseeable future. Consequently, any gains from an investment in our Ordinary Shares will likely depend on whether the price of our Ordinary Shares increases, which may not occur.

We have not paid cash dividends on any of our classes of capital stock to date and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. In addition, the Israeli Companies Law 5759-1999, or the Companies Law, imposes restrictions on our ability to declare and pay dividends. As a result, capital appreciation, if any, of our Ordinary Shares will be your sole source of gain for the foreseeable future. Consequently, in the foreseeable future, you will likely only experience a gain from your investment in our Ordinary Shares if the price of our Ordinary Shares increases beyond the price in which you originally acquired the Ordinary Shares.

The potential future application of the SEC’s “penny stock” rules to our Ordinary Shares could limit trading activity in the market, and our shareholders may find it more difficult to sell their shares.

Our Ordinary Shares are trading at less than \$5.00 per share and are therefore subject to the SEC’s penny stock rules. Penny stocks generally are equity securities with a price of less than \$5.00. Penny stock rules require a broker-dealer, prior to a transaction in a penny stock not otherwise exempt from the rules, to deliver a standardized risk disclosure document that provides information about penny stocks and the risks in the penny stock market. The broker-dealer also must provide the customer with current bid and offer quotations for the penny stock, the compensation of the broker-dealer and its salesperson in the transaction, and monthly account statements showing the market value of each penny stock held in the customer’s account. The broker-dealer must also make a special written determination that the penny stock is a suitable investment for the purchaser and receive the purchaser’s written agreement to the transaction. These requirements may have the effect of reducing the level of trading activity, if any, in the secondary market for a security that becomes subject to the penny stock rules. The additional burdens imposed upon broker-dealers by such requirements may discourage broker-dealers from effecting transactions in our securities, which could severely limit their market price and liquidity of our securities. These requirements may restrict the ability of broker-dealers to sell our Ordinary Shares and may affect our shareholders’ ability to resell their Ordinary Shares.

In the event a market develops for our Ordinary Shares, the market price of our Ordinary Shares may be volatile.

In the event a market develops for our Ordinary Shares, the market price of our Ordinary Shares may be highly volatile, as is the stock market in general, and the market for OTC quoted stocks in particular. Some of the factors that may materially affect the market price of our Ordinary Shares are beyond our control, such as changes in financial estimates by industry and securities analysts, conditions or trends in the industry in which we operate or sales of our Ordinary Shares. These factors may materially adversely affect the market price of our Ordinary Shares, regardless of our performance. In addition, the public stock markets have experienced extreme price and trading volume volatility. This volatility has significantly affected the market prices of securities of many companies for reasons frequently unrelated to the operating performance of the specific companies. These broad market fluctuations may adversely affect the market price of our Ordinary Shares.

ITEM 4. INFORMATION ON THE COMPANY

A. History and Development of the Company

Our legal and commercial name is Todos Medical Ltd. We were incorporated in the State of Israel in April 2010, and are subject to the Companies Law. Since March 7, 2017, our Ordinary Shares have been quoted on the OTCQB under the symbol TOMDF. In January 2016, we incorporated our fully held subsidiary, Todos (Singapore) Pte. Ltd. In March 2016, Todos (Singapore) Pte. Ltd. changed its name to Todos Medical Singapore Pte. Ltd., or Todos Singapore. As of December 31, 2018, Todos Singapore has not yet commenced its business operations.

In 2018, we managed our research and development activities and other operational activities taking into account our available resources. We continued our clinical trials at Kaplan Hospital and Beilinson Hospital (Israel) for TM-B1 and TM-C1. We are in the process of inquiring into different fundraising routes through which we may successfully raise additional funding in order to commercialize our cancer detection kits and to develop and commercialize future products.

We are an IVD for cancer diagnosis company, engaged in the development of a series of patient-friendly blood tests for the detection of a variety of cancers based on our TBIA, a proprietary method for detection of solid tumors using peripheral blood analysis. The method incorporates biochemistry, physics and signal processing. The TBIA detection method is based on the cancer's influence on the immune system which triggers biochemical changes in the Peripheral Blood Mononuclear Cell, or PBMC, and plasma. Our core technology, TBIA, is based on research conducted and technology invented by the research teams at BGU and Soroka, whose intellectual property has been licensed to us in consideration of our contractual obligation to pay certain licensing fees. On December 9, 2013, our TBIA test obtained the CE mark approval.

We focus our efforts on the goal of creating a new methodology for cancer detection tests that make cancer detection more accurate, accessible, and affordable to the general public.

Currently, we are developing cancer detection tests using IVD for both colon cancer and breast cancer. It is our plan to develop additional tests for other types of cancers in the future.

Our principal executive office is located at 1 Hamada Street, Rehovot, Israel and our telephone number in Israel is +972-8-633-3964.

Our web address is www.todosmedical.com. The information contained on our website or available through our website is not incorporated by reference into and should not be considered a part of this annual report on Form 20-F, and the reference to our website in this annual report on Form 20-F is an inactive textual reference only. Puglisi & Associates is our agent in the United States, and its address is 850 Library Avenue, Suite 204, Newark, Delaware 19711.

We are an “emerging growth company,” as defined in Section 2(a) of the Securities Act, as implemented under the JOBS Act. As such, we are eligible to, and intend to, take advantage of certain exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies including but not limited to not being required to comply with the auditor attestation requirements of the SEC rules under Section 404 of the Sarbanes-Oxley Act. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the date of our first sale of equity securities pursuant to an effective registration statement under the Securities Act, (b) in which we have annual gross revenue of at least \$1.07 billion, or (c) in which we are deemed to be a “large accelerated filer,” which means the market value of our Ordinary Shares that is held by non-affiliates exceeds \$700 million as of the prior June, and (2) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period.

We are a foreign private issuer as defined by the rules under the Securities Act and the Exchange Act. Our status as a foreign private issuer also exempts us from compliance with certain laws and regulations of the SEC including the proxy rules, the short-swing profits recapture rules, and certain governance requirements such as independent director oversight of the nomination of directors and executive compensation. In addition, we will not be required to file annual, quarterly and current reports and financial statements with the SEC as frequently or as promptly as U.S. domestic companies registered under the Exchange Act.

Our capital expenditures for the years 2018, 2017, and 2016 amounted to \$15,370, \$3,596, and \$34,971, respectively. These expenditures are primarily attributable to the purchase of laboratory equipment used in our research and development program. Our purchases of fixed assets primarily include leasehold improvements, computers, and equipment used for the research and development of our products, and we financed these expenditures primarily from cash on hand and partially from grants received from the IIA as detailed above.

B. Business Overview

Since our inception, we have focused our efforts on the goal of creating a new methodology for cancer detection tests that make cancer detection more accurate, accessible, and affordable to the general public. Our core technology, which serves as the foundation of our company, was originally researched and developed by BGU along with Soroka. Both institutions are located in Israel. We have the exclusive worldwide rights to use this intellectual property for commercial and research and development purposes under a license agreement. We are not currently in compliance with the repayment terms of the license agreement with our licensor. As such, we are currently negotiating an amendment to the license agreement which would allow us to pay the accrued but unpaid payments due thereunder at a later date. Currently, we are developing cancer detection tests using IVD for both colon cancer and breast cancer. In the future, we intend to develop additional tests for other types of cancers.

Recent Developments

Amarantus Transaction

On February 27, 2019, the Company entered into a joint venture agreement with Amarantus Bioscience Holdings, Inc., (“Amarantus”), pursuant to which the Company issued Ordinary Share representing 19.99% of the Company to Amarantus, in exchange for Amarantus transferring to the Company 19.99% of Breakthrough Diagnostics, Inc. (“Breakthrough”), a wholly-owned subsidiary of Amarantus, and for Amarantus assigning its amended and restated license agreement with the University of Leipzig for an exclusive license to develop and commercialize the LymPro Test®, an immune-based neurodiagnostic blood test for the detection of Alzheimer’s disease (the “License”) to Breakthrough. In addition, as part of the transaction, the Company provided Amarantus with an interest-free loan in the amount of \$45,000 to be used to pay certain financial obligations of Amarantus owed to the University of Leipzig prior to the assignment of the License to Breakthrough, in connection with the license agreement and a related sponsored research agreement. The maturity date of the loan is May 1, 2019. In addition, the Company provided Breakthrough with an interest-free loan in the amount of \$135,000 to be used to pay certain financial obligations of Breakthrough owed to the University of Leipzig after the assignment of the License to Breakthrough, in connection with the license agreement and the related sponsored research agreement. The maturity date of this loan is September 30, 2019. The Company expects to loan up to an additional \$180,000 to cover additional fees that will be owed by Breakthrough to the University of Leipzig in connection with the license agreement and the sponsored research agreement.

As part of the joint venture with Amaranthus, the Company was granted an option, in effect for sixty days, to acquire the remaining 80.01% of Breakthrough held by Amaranthus in exchange for the issuance to Amaranthus of Ordinary Shares of the Company representing an additional thirty percent (30%) of the Company, such that upon consummation of the transaction the Company will own 100% of Breakthrough and Amaranthus will own 49.99% of the Company. At the annual meeting of shareholders of the Company scheduled for April 29, 2019, the Company's shareholders will vote on a resolution approving the Company's exercise of this option.

The LymPro Test is a diagnostic blood test that determines the ability of peripheral blood lymphocytes (PBLs) and monocytes to withstand an exogenous mitogenic stimulation that induces them to enter the cell cycle. Scientists believe that certain diseases, most notably Alzheimer's disease, may be the result of compromised cellular machinery that leads to aberrant cell cycle re-entry by neurons which then leads to apoptosis. LymPro Test uses peripheral blood lymphocytes as a surrogate for neuronal cell function, suggesting a common relationship between PBLs and neurons in the brain. The LymPro Test focuses on measuring immune markers that are directly linked to the cell proliferation processes and expands our understanding of how the body's immune system responds to disease. The Company believes that the LymPro Test may use the body's immune system response to diagnose early and monitor the progression of Alzheimer's disease, which has the potential to be an invaluable tool for pharmaceutical companies' development of novel treatments for Alzheimer's.

Convertible Bridge Loan Transaction

On February 27, 2019, we entered into a convertible bridge loan agreement, and issued notes and warrants relating thereto, to obtain an aggregate loan of \$1,350,500 from several private lenders, including DPH Investment Ltd., a holder of 11.5% of our shares (as of such date), to finance the Company's activities through the consummation of a proposed public offering and our planned uplisting to the NASDAQ Capital Market. The loan, which has an original issue discount of ten percent (10%), bears interest at a flat rate of ten percent (10%) and has a maturity date six months after receipt of the loan funds. The loan is convertible into ordinary shares of the Company after the maturity date at a conversion price equal to 70% of the average closing bid price of the Company's Ordinary Shares in the five days prior to the conversion. In the event the Company's defaults under the loan agreement, the conversion price will be reduced to 60% of the average closing bid price of the Company's Ordinary Shares in the 15 days prior to the conversion. In addition, the lenders received 25% warrant coverage, with the warrant exercise price to be equal to the offering price in the proposed public offering, or, in the event the loan is converted into shares, the warrant exercise price will be equal to the applicable closing bid price of the Company's shares at the time of the conversion of the loan. The warrant may be exercised upon the lapse of six months following the determination of the warrant exercise price and the number of warrant shares, and for a period of three years thereafter.

On March 10, 2019, we entered into an amendment to the bridge loan agreement. The amendment provides for a 10% penalty if we repay the loan prior to the maturity date. In addition, we agreed to grant the lenders an additional 25% warrant coverage, under the same terms as the original warrant, but with a warrant exercise price equal to 150% of the closing bid price of our shares on the day prior to the closing of the bridge loan transaction.

Distribution Agreements

On December 20, 2018, we entered into a Marketing and Reseller Agreement with Care G.B. Plus Ltd. ("Care") for the resale of our breast cancer screening products in Israel. We appointed Care as our exclusive distributor in Israel, and Care undertook to establish at least one laboratory in Israel to support the assay protocol and to run a fifty (50) patient pilot trial to evaluate the performance of the laboratory and Care's support team. Care is fifty-percent owned by Assaf Gold, who was the beneficial owner of 5.49% of our issued and outstanding shares at the time the Care agreement was signed by the Company. Since Care is a related party, this agreement is subject to shareholder approval. At the annual meeting of shareholders of the Company scheduled for April 29, 2019, the Company's shareholders will vote on a resolution approving the entry into this agreement with Care.

Maxim Agreement

In December 2018, the Company entered into a new engagement agreement with Maxim Partners LLC (“Maxim”) which superseded the Company’s April 2015 agreement with Maxim. Pursuant to the new agreement, the Company appointed Maxim as its exclusive financial and sole management underwriter in connection with a proposed public offering to raise up to \$7 million. Maxim will be provided with an underwriting discount or spread of up to eight percent (8.0%) of the public offering price. The Company agreed that upon the Company’s receipt of bridge financing, the Company would transfer to Maxim, an amount of \$15,000 as an advance to be applied towards such underwriting discount.

Industry Overview

Cancer is the second largest cause of morbidity and mortality worldwide. According to the World Health Organization, in 2012, 14 million people were newly diagnosed with cancer and there were 8.8 million cancer related deaths in 2015. This number is expected to rise by 70% in the next twenty years. The World Health Organization further states that early detection can greatly reduce the current mortality rates. The cost of cancer in the EU alone was stated at over 51 billion Euro for 2009 (Report from The Commission to The European Parliament, The Council, The European Economic and Social Committee and The Committee of The Regions published September 23, 2014). Meanwhile, the cost of cancer in the United States for the year 2001 was over \$88.7 billion. The costs of cancer in terms of lives and suffering as well as financial, are staggering on a global basis.

While much work must be done to reduce the incidence rates of cancer and the treatment of cancer itself, we believe the early detection of cancer is a critical step towards saving lives. The EU has established a target of conducting cancer detection for 300 million people, annually. In 2008, only 56 million cancer detections were performed (International Agency for Research on Cancer, Cancer Detection in EU 2008). Similarly, the United States has set a target to screen 200 million people per year (American Cancer Society, Cancer Detection in 2008).

Although cancer detections are necessary if not vital, there are many reasons that they are not more widely used. We believe these reasons include:

- High cost per screen;
- Uncomfortable for the patient (mammogram, colonoscopy, MRI);
- Not accessible to large segments of the population;
- Risk is involved (Radiation and Invasive tests);
- Requires specialists to interpret results; and
- Low sensitivity or specificity.

In summary, we believe that a large segment of the world-wide population who need to be checked regularly for cancer forego the detection process due to the above reasons.

Products

Cancer Detection Kits

Our product serves as preliminary cancer detection tool and cannot be regarded as a final diagnosis. Our product consists of a simple blood test that causes what we believe to be minor risk and pain to the patient (as demonstrated by the diagram below) that is analyzed by our proprietary technology to detect the presence of various cancers. Our test analysis results will be provided to the healthcare provider who may decide to refer the patient for additional detections such as colonoscopy for further determination of cancer presence. Our cancer detection kit includes a special glass slide upon which the PBMC and the plasma are placed. Some tests might also include a salt solution that is needed for the blood separation process. There is a different test for each cancer type.

We are developing several products for cancer screening and diagnosis as follows:

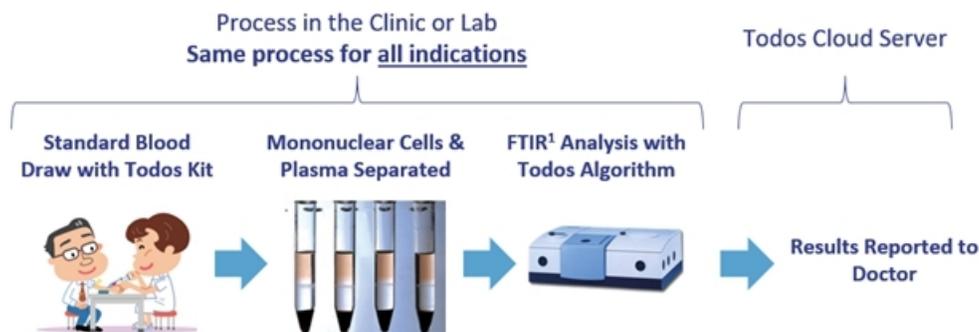
TM-B1 is a test designed specifically for breast cancer screening. It is indicated for women who meet the following criteria: female subjects aged 25 years and older, without a diagnosis of inflammatory or autoimmune disease. TM-B1 is to be used as a diagnostic method to indicate whether a malignancy is present or not. TM-B1 assay results should be used in conjunction with other common diagnostic tests as part of breast cancer screening.

TM-B2 is a test indicated for women who meet the following criteria: Female subjects, aged 25 years and older, without a diagnosis of inflammatory or autoimmune disease, who were diagnosed as presenting with a Breast Imaging-Reporting and Data System, or BI-RADS, score of three or four (or equivalent). TM-B2 is to be used to further assess if a malignancy is present or not. TM-B2 test results should be used in conjunction with other common diagnostic tests as part of breast cancer screening and should not be used as stand-alone assay.

The TM-C1 analysis method is intended for the qualitative detection, and for the semi-quantitative detection, of biochemical characteristics of the infrared readings of peripheral blood mononuclear cells and plasma, which may be indicative of polyps and colorectal cancer. The TM-C1 screening method may integrate with an overall screening program for colorectal cancer.

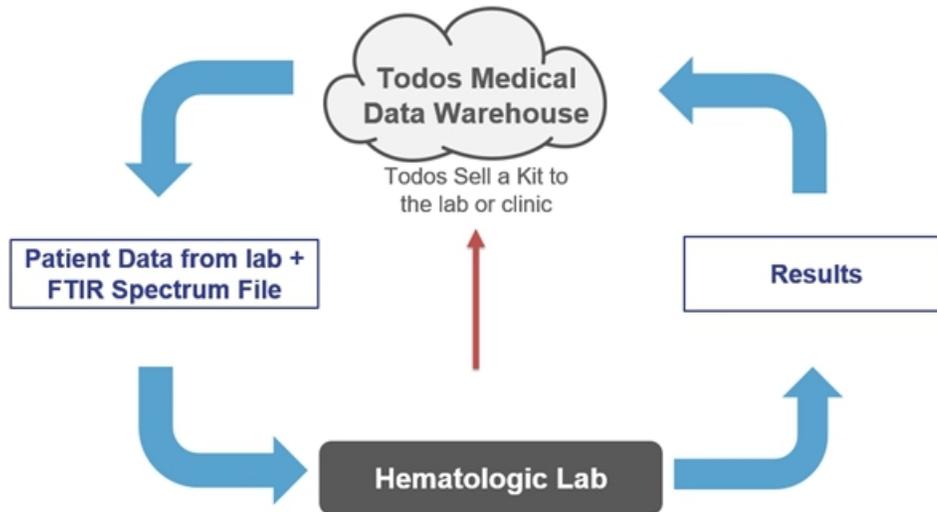
Work Flow

Blood samples are taken from the patient in the clinic. The mononuclear cells and plasma are separated from the blood and measured by the infrared, or IR, spectrometer. This data is sent to our server via the internet cloud, which will process the data and send the results via the internet cloud to the respective doctors.



Data flow

We will sell the test kit to the lab or clinic, that lab will process the blood sample and send the spectrum from the spectrometer to our server via the internet cloud. After our analysis (instant process) we will send the result to the lab.



Our Challenges

Because we are still in the clinical trials stage, we are subject to certain challenges, including, among others:

- our technology has been tested on a limited basis and therefore we cannot assure the product's clinical value;
- although we have obtained CE mark approval for our tests in the EU, the European regulatory demands, regarding IVD, have been recently revised and major changes need to be made in order to keep our CE Mark. These changes need to be made until 2022. It will require significant efforts and funds to update our test accordingly;
- although we have obtained CE mark approval for our tests in the EU, we still need to obtain the requisite regulatory approvals in the United States and other markets where we plan to focus our commercialization efforts;
- as of March 20, 2019, our cash holdings amounted to \$310,000. We believe that we will be able to use currently available capital resources for up to three (3) months. We need to raise an amount of capital sufficient to continue the development of our technology, obtain the requisite regulatory approvals, and commercialize our current and future products; and
- we need to obtain reimbursement coverage from third-party payors for procedures using our tests.

Our ability to operate our business and achieve our goals and strategies is subject to numerous risks as described more fully in "Risk Factors" above.

Our Technology

In the last decade many scientific articles have been published showing that the body's immune system detects the existence of cancer but, for various reasons, fails to attack it. For our developed detection methodology, only a small amount of peripheral blood from the patient is needed. The method is multidisciplinary and incorporates hematology, biochemistry, physics and signal processing and is based on infrared spectroscopy measurements of the blood sample and computerized analysis. The basic concept in our technology is to measure the biochemical changes in the PBMC and plasma, due to cancer presence. As the PBMC are part of the body's immune system, we believe our methodology will detect overall biochemical changes of the immune system due to cancer presence. The technology involves special IR, measurement of a simple blood sample. We are using the Fourier Transform Infrared Analysis, or FTIR, spectrometer for reading the biochemical content of the PBMC and plasma. We believe the FTIR has some unique advantages in this aspect as it requires no reagents and the reading is swift. Most of the biochemical materials can be detected using the FTIR. The test uses conventional lab methods and the mathematical analysis is made automatically by proprietary algorithms.

The TBIA detection method is based on the cancer's influence on the immune system which triggers cellular and biochemical changes in the PBMC and plasma. These biochemical changes are detected by the FTIR whose results undergo rigorous testing of sophisticated signal processing in order to detect if the entire biochemical signature under detection have the typical biochemical indications for cancer existence. The principle behind our proprietary technology, TBIA, is to observe the immune system response to tumor presence anywhere in the body rather than looking for the tumor cells themselves. We analyze multiple elements of the biochemical signature (including proteins, lipids, nucleic acids and carbohydrates) of the effected immune cells from the peripheral blood in conjunction with plasma using infrared spectroscopy, instead of focusing on a single specific protein as a biomarker.

Our research, using spectral analysis, thus far indicates that the "IR signatures" of several types of cancer are significantly distinct from the "infrared signatures" of healthy patients. These differences can be related to several biological effects which exist during malignancy.

Our plan was to conduct two-stage clinical trials - the first was a training stage and the second is a validation stage. We define, in consultation with our bio-statisticians, our algorithm development team and our future hospital partners, the number of participants needed for each clinical trial. While the minimum number we are targeting is 200 participants per trial, the number may vary from trial to trial. We completed the first stage (training) for breast cancer at a single site in Israel and a single site in Singapore. We intend to complete the first stage of the clinical trials for colorectal cancer at two sites in Israel. In the training stage, we aim to train our algorithm to: (a) determine the final performances of the test in terms of accuracy and reproducibility; and (b) optimize the algorithm so that it will be compatible with the population of a country where we perform such clinical trials. In this process, we make the necessary adaptation to our proprietary technology, using mathematical tools in order to reach substantially the same diagnosis results as are found in earlier clinical studies we conducted between 2010 and 2013, as described under "Business - Past Clinical Studies" (which form the baseline of comparison). This baseline may, in the future, include the diagnosis results found in the fifth clinical study, which ended on October 2017, described under "Business - Past Clinical Studies". Once the necessary adaptation to our proprietary technology is made, the second stage of clinical trials will be to validate that the tests are indeed able to detect breast cancer and colorectal cancer. Prior to beginning any clinical trials, a local Institutional review board, or IRB, needs to grant us approval to begin the trial. The second stage (validation) is a blinded trial and intended to verify the performances of our product following the aforementioned amendments implemented following the first stage. The validation may not meet our expectations, regulatory demands and/or other partner's demands.

Past Clinical Studies

Four clinical studies whose results were published in what we believe to be well-known peer-reviewed journals have been conducted to date, all of which were not blind tests. The first of these studies was conducted by B.G. Negev Technologies and Applications Ltd., or BG Negev, a wholly owned subsidiary of BGU while we conducted the other three studies. The goal of these studies was to evaluate whether TBIA could be a novel, simple, and low-cost method for the early detection of cancer.

"Sensitivity" as used below is the number of detected cancers divided by the full population having cancer that participated in the study. A sensitivity of 100% means that our product detected cancer in all of the people with cancer that were diagnosed using our product. A sensitivity of 80% means that out of 100 people with cancer the test will detect 80 people as being diagnosed with the relevant cancer and the rest will be defined as healthy.

"Specificity" as used below is the number of detected healthy subjects divided by the full population of healthy subjects that participated in the study. A specificity of 80% means that out of 100 healthy people who participated in the study - we diagnosed 80 people as healthy. The 20 other healthy subjects were falsely diagnosed as having cancer.

The First Study was conducted by BGU. This study included 15 acute leukemic children, 19 children who had a high fever with a diagnosis of infection or inflammation, and 27 healthy volunteers. T test and cluster analysis was done with the following results for control versus leukemia and infection versus leukemia. For all, P value ≤ 0.05 . Cluster analysis - all cancers were distinct in a different branch for healthy and infection. Based on the chosen wave numbers the cluster analysis was able to distinguish completely between leukemia and control groups. The first objective of the study was to distinguish between children diagnosed as having acute leukemia and healthy subjects by FTIR spectroscopy analysis of PBMCs. The second objective was to follow and analyze leukemic patients' response to chemotherapy by FTIR spectroscopy of PBMCs in comparison to what we believe to be the standard practice of bone marrow examination by flow cytometry. A third objective of the clinical trial was to distinguish between leukemic children and children with similar clinical symptoms such as high fever and white blood count (which also appears following infection or inflammation) using FTIR technology.

Results of study:

The first objective was achieved successfully - all subjects, healthy and leukemic, were diagnosed correctly - 100% sensitivity and specificity. The second objective of the follow-up treatment was achieved by identifying three different responses to treatment by FTIR method - good, intermediate and unfavorable response. FTIR identified responses to treatment earlier (33 days vs. 100 days) than flow-cytometry analysis of bone marrow. A good response (meaning, a good response to chemotherapy) was a fast return of the PBMC values towards normal control values (according to the FTIR method). An intermediate response was a slow return of the PBMC values towards normal control values. An unfavorable response was the PBMC values not returning towards normal control values. No T test was done in order to distinguish between the three tendencies. The third objective was achieved as well. The children having similar symptoms to leukemia were successfully distinguished from children with acute leukemia by FTIR analysis - 100% sensitivity and specificity. These results were published in the *Biochimica et Biophysica Acta* (Zelig et al. *Biochimica et Biophysica Acta* 1810 (2011) 827-835).

Below are details regarding the other three studies that we completed on our own. The results are described as sensitivity and specificity.

The Second Study included 41 cancer patients and 45 healthy volunteers. This study was intended to evaluate the utility of our method in detecting several types of cancers using an advance computerized algorithm. The performances of the algorithm presented what we believe were promising results for breast and colorectal cancer as well as other cancers. Following these results, we chose to focus our efforts into the detection of breast and colorectal cancers.

The first objective of the study was to distinguish between cancer patients of multiple types and healthy subjects by FTIR spectroscopy analysis of PBMCs and plasma - we refer to this as the TM-T1 method - our product for diagnosing multiple types of cancers. All patients were diagnosed by standard practice such as histopathology of tissue samples taken from the tumor. The second objective was to distinguish between different types of cancers utilizing FTIR spectroscopy analysis of PBMCs and plasma.

Results of study:

The first objective of the study was achieved successfully - 93% sensitivity for detecting different types of cancers and 80% specificity for identifying correctly the healthy population. As for the second objective, although different spectral patterns were observed for each type of cancer, indicating that there is the potential of successful classification between the various cancers, the statistical parameters were not established due to low patient numbers for each individual type of cancer, preventing a reliable statistical analysis. As for this objective, our observation was qualitative rather than quantitative. We will need to conduct larger trials in the future in order to better understand and distinguish between different cancers. The results of the study were published in the *Institute of Electrical and Electronics Engineers Journal* (Ostrovsky et al. *IEEE Transactions on Biomedical Engineering*, Vol. 60, No. 2, February 2013, 343-353).

The Third Study was conducted between April 27, 2011 and April 26, 2013 at Rabin in Israel. The number of the study was 0336-10-RMC and its purpose was evaluation of our detection method for breast cancer. This study included 29 breast cancer patients and 30 subjects who were healthy or had benign tumors. All subjects were tested for breast cancer by standard detection procedures (mammography / ultrasound) and had not yet undergone surgical treatment, chemotherapy or radiotherapy.

The first objective of the study was to distinguish between cancer patients and healthy subjects or patients having benign tumor using FTIR spectroscopy analysis of PBMCs and plasma - we refer to this as the TM-B1 method - our product for diagnosing breast cancer. The second objective was to distinguish between three groups: cancer patients, patients having benign tumors, and healthy subjects without pathological findings related to breast tumors.

Results of study:

The first objective of the study was achieved successfully - approximately 90% sensitivity for detection of breast cancer and approximately 80% specificity for identifying correctly the healthy patients and patients with benign tumors. As for the second objective, although different spectral patterns were observed for each group - healthy, benign, and malignant, the statistical parameters were not established due to low patient numbers in each group, preventing a reliable statistical analysis. As for this objective, our observation was qualitative rather than quantitative. We will need to conduct larger trials in the future in order to better understand and distinguish between different groups. The results of the study were published in the BMC Cancer Journal (Zelig et al. BMC Cancer (2015) 15:408).

The Fourth Study was conducted between April 27, 2011 and April 26, 2013 at the Rabin in Israel. The number of the study was 0336-10-RMC and its purpose was to evaluate our detection method for colorectal cancer. This study included 30 colorectal cancer and high-grade dysplasia, or HGD, patients, 10 patients with benign polyps and 18 healthy subjects, all tested for colorectal cancer by colonoscopy. The premalignant HGD was joined with the malignant group.

The first objective of the study was to distinguish between cancer patients and healthy subjects using FTIR spectroscopy analysis of PBMCs and plasma, which we refer to as the "TM-C1 method", our product for diagnosing colorectal cancer. The second objective was to distinguish between three groups: colorectal cancer patients, patients having benign tumors, and healthy subjects without pathological findings related to colorectal tumors such as polyps.

Results of study:

The first objective of the study was achieved successfully - approximately 82% sensitivity for detection of colorectal cancer and approximately 71% specificity for detecting healthy populations without pathological findings. The benign tumors were classified in between the cancer and healthy groups. As for the second objective, although different spectral patterns were observed for each group - healthy, benign, and malignant, the statistical parameters were not established due to low patient numbers in each group preventing a reliable statistical analysis. As for this objective, our observation was qualitative rather than quantitative. We will need to conduct larger trials in the future in order to better understand and distinguish between different groups. The results of the study were published in the Journal of Gastroenterology (Barlev et al. Journal of Gastroenterology (First Online: 26 June 2015): 1-8.).

Clinical Studies in Process

Multi-center (Kaplan and Rabin) breast cancer verification (training) study

The objectives of the multi-center breast cancer verification study are twofold. The first objective is to distinguish between cancer patients and healthy subjects or patients having benign tumors using FTIR spectroscopy analysis of PBMCs and plasma - the TBIA method. The second objective is to distinguish between all three groups: cancer patients, patients with benign tumors, and healthy subjects without pathological findings related to breast tumors.

Kaplan Medical Center Trial

On June 6, 2013, we initiated a verification study at Kaplan Medical Center in Israel. The number of the study is 0152-12-KMC. The recruiting phase at Kaplan has been completed and included 220 patients. All subjects were tested for breast cancer by standard detection procedures (mammography / ultrasound / biopsy) and have not yet undergone surgical treatment, chemotherapy or radiotherapy. We added Rabin Medical Center as an additional site for this multi-center study. The number of the study at Rabin Medical Center is 0386-17-RMC and will include about 105 patients.

We are in the process of analyzing the results. In the training phase, an accuracy (sensitivity and specificity) of about 90% was demonstrated. The validation phase has not been completed yet; hence, final results for this study are not yet available.

Rabin Medical Center Trial

We added Rabin Medical Center as an additional site for this multi-center study. The number of the study at Rabin Medical Center is 0386-17-RMC and will include about 105 patients. The recruitment of patients for this trial is still in progress.

Singapore breast cancer verification (training) study

On June 1, 2016, we entered into a clinical trial agreement with the Singapore Hospital for a training trial. We made a judgment, along with the Singapore Hospital, that 280 participants is the appropriate number for the purpose of this training trial. This clinical study evaluated, in terms of sensitivity and specificity, our TM-B1 method for the detection of malignant and benign breast cancer tumors in comparison with standard diagnostic methods.

Under the agreement, the Singapore Hospital was primarily in charge of the recruitment procedure and blood sample collection from recruited participants, all pursuant to the clinical study protocol, which was approved by the Singapore Centralized IRB in April 2016. The Singapore Hospital also provided the prognosis of the recruited participants which will enable us to measure the sensitivity and specificity of the TM-B1 method.

Enrolment of the patients has been completed and we are in the process of analyzing the results.

Multi-center (Rabin and Kaplan) colon cancer verification (training) study

In addition, on April 27, 2017, we commenced a training study at Rabin Medical Center for TM-C1 for colorectal cancer screening. The Kaplan site is about to join Rabin Medical Center as a multi-center study. In total we aim to recruit 350 patients. The study is prospective, un-blinded, tree arms.

Multi-center (Rabin and Kaplan) breast cancer validation study

On January 22, 2018, we initiated the validation study at Kaplan for screening for breast cancer. NIH number NCT03343691. Rabin intends to join to this study as a multi-center study. A total of 200 patients are expected to participate in the multi-center validation study. The study is prospective, blinded, double arm.

For further details, please refer to "Item 5. Operating and Financial Review and Prospects - Overview."

Intellectual Property

The proprietary nature of, and protection for, our current and/or any future product candidates, processes and know-how are important to our business as is our ability to operate without infringing on the proprietary rights of others, and to prevent others from infringing our proprietary rights. We seek patent protection in the United States and internationally for our current and future product candidates we may develop and other technology. In order to protect our proprietary technologies, we rely on combinations of application for patent and trade secret protection, as well as confidentiality agreements with employees, consultants, and third parties.

We have filed and own all rights in the following patent applications, all of which are currently pending or have been issued as patents:

Category I: These applications relate to analysis of an IR spectrum of a PBMC sample. Claims are generally directed to indicating the presence of a solid tumor based on analysis of an IR spectrum of a PBMC sample.

- (1) US Patent Application 13/701,262. This has claims for a method (process). The claims in this application are generally directed to indicating the presence of a solid tumor in breast tissue based on analysis of an IR spectrum of a PBMC sample. On March 28, 2017, this application issued as US Patent 9,606,057. This patent is expected to expire on June 1, 2031.
- (2) US Patent Application 15/443,674. This application is a continuation application of US 13/701,262 and has claims for a method (process) and is expected to expire on June 1, 2031. The claims in this application are generally directed to indicating the presence of a solid tumor in tissue of a gastrointestinal tract based on analysis of an IR spectrum of a PBMC sample.
- (3) European Patent Application No. 11789348.7. This has claims for a method (process) and a system and is expected to expire on June 1, 2031.
- (4) Israel Patent Application 223,237. This has claims for a method (process), a system, and for a computer program product and is expected to expire on June 1, 2031.

Category II: These applications relate to analysis of an IR spectrum of a blood plasma sample. Claims are generally directed to indicating the presence of a solid tumor based on analysis of an IR spectrum of a blood plasma sample.

- (5) US Patent Application 14/116,506. This has claims for a method (process), a system, and for a computer program product. The claims in this application are generally directed to indicating the presence of a solid tumor in a gastrointestinal tract based on analysis of an IR spectrum of a blood plasma sample. On August 1, 2017, this application issued as US Patent 9,719,937. This patent is expected to expire on May 10, 2032.
- (6) US Patent Application 15/645,168. This application is a continuation application of US 14/116,506. This has claims for a method (process), a system, and for a computer program product and is expected to expire on May 10, 2032. The claims in this application are generally directed to indicating the presence of a solid tumor in breast tissue based on analysis of an IR spectrum of a blood plasma sample.
- (7) European Patent Application No. 12782256.7. This has claims for a method (process) and a system and is expected to expire on May 10, 2032.
- (8) Israel Patent Application 229,109. This has claims for a method (process), a system, and for a computer program product and is expected to expire on May 10, 2032. On September 13, 2017, we received a notice of allowance from the Israel Patent Office regarding this application.

Category III: These applications relate to analysis of an IR spectrum of a blood plasma sample and PBMC samples.

- (9) US Patent Application 14/894,128. This has claims for a method (process). The claims in this application are generally directed to (i) analysis of an IR spectrum of a PBMC to indicate the presence of a benign tumor in breast tissue and in the gastrointestinal tract, and (ii) analysis of an IR spectrum of a blood plasma sample to indicate the presence of a benign tumor. On October 31, 2017, this application issued as US Patent 9,804,145. This patent is expected to expire on November 14, 2033.
- (10) US Patent Application 15/785,801. This application is a continuation application of US 14/894,128. This has claims for a method (process), a system, and for a computer program product and is expected to expire on November 14, 2033. The claims in this application are generally directed to (i) analysis of an IR spectrum of a PBMC sample, and a blood plasma sample to indicate the presence of a benign tumor in ovarian tissue, and (ii) preparation of a sample for analyzing by infrared spectroscopy.

- (11) European Patent Application No. 13885931.9. This has claims for a method (process), and is expected to expire on November 14, 2033. The claims in this application are generally directed to indicating the presence of a benign tumor in breast tissue based on analysis of an IR spectrum of a PBMC sample.

There are no patents or patent applications which are licensed to the Company pursuant to the Company's License agreement with BG Negev and Mor Research Applications Ltd. (a wholly owned subsidiary of Clalit Medical Services - Israel) referenced below. Nevertheless, the Company's products are based on intellectual property licensed from BG Negev and Mor.

There are no patents or patent applications which are licensed to the Company from any other entity.

To the knowledge of the Company's management, there are no contested proceedings or third-party claims over any of our patent applications. Our success depends upon our ability to protect our technologies through intellectual property agreements including patents, trademarks, know-how, and confidentiality agreements. However, there can be no assurance that the above-mentioned patent applications will be approved by the appropriate agencies.

All of the technology for which the patents are sought is owned by the Company. The patents are entirely owned by the Company.

Licensing Agreement

In April 2010, we entered into a research and license agreement with BG Negev and Mor Research Applications Ltd. (a wholly owned subsidiary of Clalit Medical Services - Israel), or together with BG Negev, the Licensor. The Licensor, pursuant to the agreement, granted us an exclusive, worldwide, license to commercialize certain intellectual property covered by the agreement (i.e. research, development, manufacturing, marketing, distribution, and sale of any product containing the licensable IP under the agreement).

Pursuant to the agreement, we are under an obligation to pay to the Licensor a minimum annual royalty of \$10,000 in 2015, \$25,000 in 2016 and, from 2017 through the termination of the agreement, \$50,000 per year. We have not paid any royalties yet under the Agreement. In March 2017, we agreed with the Licensor that the \$85,000 we owed the Licensor will be paid by us by the earlier of (a) August 2017, or (b) our sale of equity securities to investors with gross proceeds to the Company of at least \$10,000,000. We are not currently in compliance with the payment terms of the license agreement with our Licensor. As such, we are currently negotiating an amendment to the license agreement which would allow us to pay the accrued but unpaid payments due thereunder at a later date. Once there are sales of products or sublicensing receipts based on the licensed intellectual property, we are under an obligation to pay the Licensor a certain percentage of such sales or sublicensing receipts, as running royalties, but in any event not less than the minimum annual royalties. Any minimum annual royalties will be credited against the running royalties in any given year.

According to the license agreement, the royalty rates are as follows:

On net sales of:

○ leukemia related products	3.0%
○ other products	2.5%
○ in certain limited circumstances, rates may be reduced to	2.0%

On fixed sublicense income (with no sub license income on sales by sub licensee):

○ leukemia related products	20.0%
○ other products	15.0%

On fixed sublicense income (with Company income on sales by the sub licensee. These rates are in addition to the net sales rates listed above.):

○ leukemia related products	10.0%
○ Other products	7.5%

The minimum royalties will be paid to the Licensor regardless of whether we are able to generate sales from the products arising from the usage of the license.

The license agreement is for an unlimited term, unless terminated earlier by either of the parties under certain circumstances as described in the agreement, including termination as a result of a material breach or a failure to comply with a material term by the other party, as a result of liquidation or insolvency of the other party. In addition, we were entitled to terminate the agreement if at any time, during the period of 7 years following the effective date of the transaction, we, at our sole discretion, would determine that commercialization of the leukemia licensed products is not commercially viable.

Dr. Udi Zelig, our Chief Technical Officer, is one of the inventors of the know-how licensed under the agreement and, to the best of our knowledge, is entitled to receive from BG Negev between 10% to 15% of all payments that BG Negev is entitled to receive from us under the license agreement.

Scientific Advisors

We consult with a number of leading scientists and physicians in the evaluation of our technology and the development of our pipeline and we seek advice from them on various scientific matters. The following table sets forth information about our scientific advisors.

Name	Position / Institutional Affiliation
<i>Michael C. Little, PhD</i>	<p>Dr. Little was senior vice president of research and development for Natera and president of Futura Partners, a healthcare advisory firm. At Futura, he advises clients from the pharma, life sciences and diagnostics industries in areas including diagnostics, companion diagnostics, and technical leadership development. He is a member of the board of directors of a Cambridge, MA private startup company focused on personalized medicine (pulmonology), and has been a consultant to the investors and board of directors of another personalized medicine company (breast cancer).</p> <p>Previously, he was vice president at Novartis. For the first two years, he oversaw research and development, medical affairs, and regulatory affairs for Novartis (Chiron) Diagnostics in Emeryville, CA. Over a period of five years he had responsibility, as a founding member of a Novartis Diagnostics Development organization, for nearly 30 programs spanning Novartis' entire oncology and general medicine portfolio.</p> <p>Prior to Novartis, he was the chief operating officer of Adlyfe, a venture-funded company focused on misfolded protein diagnostics. During this time, he had accountability for both finance-raising and research and development programs.</p> <p>Dr. Little spent 16 years with Becton Dickinson, or BD, where he began as a research and development scientist developing a proprietary nucleic acid amplification technology, Strand Displacement Amplification, or SDA, and would ultimately run the business resulting from this initial research work. He assumed responsibility for and ran the research and development programs for BD's flagship SDA platforms, the BDProbeTecET and BDViper. After BD gained FDA clearance for the first real-time DNA amplification system, he assumed the leadership of the resulting molecular business. This business grew from \$0 to \$100 million in revenue within five years and has since achieved an aggregate of over \$1 billion in revenue.</p> <p>Dr. Little received his PhD in Microbiology from the University of Florida and completed post-doctoral training at the University of Arizona in Tucson.</p>

Name	Position / Institutional Affiliation
<i>Dr. Jürgen Schmitt</i>	<p>Dr. Jürgen Schmitt has more than 25 years of experience in research and development projects of microbiological and biomedical applications of FT-IR and Raman spectroscopy. He has worked in both government and industry to apply FT-IR and Raman spectroscopic techniques in Biotechnology, Medicine and Pharmaceutical Research. For example, in the development of a TSE/BSE antemortem Diagnostic Test on Serum by FT-IR Spectroscopy (Co-Inventor with Robert-Koch-Institute, Berlin), licensed to Roche Diagnostics; and development of a FT-IR Detection Technique for Rapid Mode-of-Action Detection in Antibacterial Drug Research.</p> <p>Dr. Schmitt has published more than 70 reviewed research papers in this field and holds several patents. Together with Prof. Dieter Naumann, he founded a scientific workshop about FTIR spectroscopy in biomedical research at the RKI in Berlin. He is also cofounder of the SPEC conference series, which recently formed the structural basis for the ClirSpec society, a society dedicated to clinical spectroscopy, where he is in the society council.</p> <p>Dr. Schmitt started his spectroscopic expertise 1991 at Oak Ridge National Laboratory with Prof. D.C. White and continued at the University of Stuttgart and at the IWW institute of the University of Duisburg before he founded Synthon analytics in 2000, where he currently serves as chief executive officer.</p>
<i>Walter Carney, PHD</i>	<p>Dr. Carney received his PhD in Medical Microbiology and Infectious Diseases from Thomas Jefferson Medical School in Philadelphia, PA in 1978. Over the past two years, Dr. Carney has founded and been the chief executive officer of Walt Carney Biomarkers Consulting. Prior to establishing his own consulting firm, Dr. Carney had a distinguished career at Oncogene Science. Dr. Carney was employed at Oncogene for over 23 years in a variety of positions. These positions include chief scientific officer, executive vice president and president. Dr. Carney serves on the advisory board of Sigmet Laboratories and Vermillion. Dr. Carney has also garnered many awards including the Forever Fellowship, NIH Fellow and the Otto Bayer Science award. Dr. Carney is a respected member of the American Association for Cancer Research, the American Society for Clinical Oncology, the American Association for the Advancement of Clinical Science as well as the American Association for Clinical Chemistry.</p>

Competition

Current prevailing cancer detection tests utilize the standard procedures which, we believe, are typically uncomfortable, such as colonoscopy for colorectal cancer and mammography for breast cancer. In addition, we believe, these tests generally have medium to low sensitivities/specificity, along with adverse risks. Furthermore, many of the existing detection methods depend on the technician's or the physician's capabilities, knowledge and interpretation. The existing detection methods also carry a high cost.

In light of these drawbacks, our assays will be a part of standard clinical protocol for cancer screening and not a replacement of any of these gold standard procedures. Our aim is to improve the screening process, reducing false negatives and increasing sensitivity thus, saving lives, pain and expenses.

Many of our anticipated competitors, such as those listed in the below figure, have substantially greater financial, technical, and other resources and larger, more established marketing, sales and distribution systems than we have. Many of our competitors also offer broad product lines outside of the diagnostic testing market and have brand recognition. Moreover, our competitors may make rapid technological developments that may result in our intended technologies and products becoming obsolete before we are able to enter the market, recover the expenses incurred to develop them or generate significant revenue. Our success will depend, in part, on our ability to develop our intended products in a timely manner, keep our future products current with advancing technologies, achieve market acceptance of our future products, gain name recognition and a positive reputation in the healthcare industry, and establish successful marketing, sales and distribution efforts.

Company	Symbol	Company Description
Exact Sciences	EXAS	Marketing Cologuard stool-based detection test for the detection of colorectal cancer
Volition Rx	VNRX	Developing blood-based diagnostic tests for colorectal, lung, prostate, ovarian and other cancer types based on nucleosomics
Epigenomics	EPGNF	Engages in developing and commercializing in vitro diagnostic tests for the detection and diagnosis of cancer (EpiProColon - methylated Septin9 DNA in human plasma)
Cancer Genetics	CGIX	Focuses on developing and commercializing proprietary genomic tests to improve and personalize the diagnosis and response to treatment of cancer.

Existing or Probable Government Regulations

Our cancer screening products are subject to governmental regulation, which regulation may be different for each country or region where we intend to commercialize our products. We plan to initially commercialize our products in Israel and the European Union (EU), and then afterwards enter the U.S. market.

EU

In Europe, medical devices are regulated by self-certification through the CE Mark system. Under the system, developers and manufacturers must operate a Quality System and validate medical devices in a limited clinical trial to demonstrate the manufacturer has met analytical and clinical performance criteria. We have implemented an International Organization for Standardization standard - ISO 13485 - quality management system for the design and manufacture of medical devices. ISO 13485 addresses managerial awareness of regulatory requirements, control systems, inspection and traceability, device design, risk and performance criteria as well as verification for corrective and preventative measures for device failure. ISO 13485 certification establishes conformity to specific European Union directives related to medical devices and allows CE Marking and sale of the device.

The Medicines and Healthcare products Regulatory Agency, or MHRA, is the United Kingdom based European Authority responsible for the issuance of CE Mark approval. In 2013, our regulatory authorized representative in Europe submitted an application to the MHRA for the CE Mark approval of our TBIA method. We obtained this approval on December 9, 2013 with the receipt of a Certificate of Conformance from our regulatory authorized representative in Europe. The European regulatory demands regarding IVD have recently been revised and major changes need to be made in order to keep our CE Mark. These changes need to be made until 2022.

The new European In Vitro Diagnostic Regulation (IVDR - 2017/746), or the IVDR, became effective as of May 25, 2017, marking the start of a transition period for manufacturers selling IVD devices into Europe. The IVDR, which replaces IVD Directive (98/79/EC), or the Directive, has a transition period of five years, after which the IVDR will apply in full, and no new applications pursuant to the Directive will be accepted. Manufacturers have the duration of the five-year transition period to update their technical documentation and processes to meet the new, more stringent EU regulatory requirements. We believe that the most challenging areas under the IVDR will be regarding the classification of products and the performance evaluation of IVDs, which will not only include the classic clinical performance and analytical performance but also scientific validity, the role and responsibilities of the economic actors of the supply chain, the traceability and the transparency of the devices with, in particular, the introduction of the UDI-system and an expanded EUDAMED database.

During the 2019, we plan to commence updating our technical files in accordance with the new IVDR.

Israel

In Israel, medical devices are regulated by the Israeli Ministry of Health (MoH) medical device department. On January 23, 2019, we applied to the MoH for approval for our products. We expect to complete the process and obtain MoH approval within 6 months.

U.S.

United States federal and state governmental agencies subject the health care industry to intense regulatory scrutiny, including heightened civil and criminal enforcement efforts. The federal government scrutinizes, among other things, the marketing, labeling, promotion, manufacturing and export of diagnostic health care products. Our cancer screening products fall within the IVD medical device category and are subject to FDA clearance or approval in the United States.

The federal government has increased funding in recent years to fight health care fraud, and various agencies, such as the United States Department of Justice, the Office of Inspector General of the Department of Health and Human Services, or OIG, and state Medicaid fraud control units, are coordinating their enforcement efforts.

In the United States, we anticipate that our cancer screening products will have to be cleared through the FDA's premarket notification or 510(k), process or its premarket approval, or PMA, process. The determination of whether a 510(k) or a PMA is necessary will depend in part on the proposed indications for use and the FDA's assessment of the risk associated with the use of the IVD for a particular indication.

Research and Development

For information regarding our clinical studies, please see above under the caption "New Clinical Studies in Process."

For the years ended December 31, 2018, 2017 and 2016, we incurred \$509,184, \$720,527, and \$317,907, respectively, of net research and development expense.

Our research and development efforts are financed in part through grants received from the IIA. As of December 31, 2018, we have received the aggregate amount of \$272,237 from the IIA. Aside from payment of royalties to the IIA, we are required to comply with the requirements of the Research Law. Under the Research Law, royalties of 3% to 3.5% on the revenues derived from sales of products or services developed in whole or in part using these IIA grants are payable to the Israeli government. We developed our technologies, at least in part, with funds from these grants, and accordingly we would be obligated to pay these royalties on sales of any of our product candidates that achieve regulatory approval. The maximum aggregate royalties paid generally cannot exceed 100% of the grants made to us, plus annual interest equal to the 12-month LIBOR applicable to dollar deposits, as published on the first business day of each calendar year.

Production and Manufacturing

We are revising our production line for kits for laboratories and physicians. All of our product production is conducted under ISO 13485 and by conforming to CE instructions, we aim to reduce risks and be more prepared for commercialization of our assays.

We currently have several third-party suppliers, from various geographic locations, that provide us with raw materials. While we are currently relying on these suppliers, we plan to locate other suppliers upon strict inspection. We plan to have a minimum of two suppliers for each component in our system and it is our intention to eventually produce the raw material internally. However, because we are in a highly specialized industry, there can be no assurance that we will be able to achieve that.

Listed below are our current material suppliers. There is no assurance that they will be able to continue supply of our raw materials or that, if necessary, we will be able to find replacement vendors on a timely basis on favorable terms.

List of the raw material suppliers for kits

SUPPLIER	MATERIAL
BD	PUSH BUTTON SET 21G GREEN
BD	Vacutainer® K2EDTA 6 mL Blood collection tube
Eppendorf	Pipette tips 100-1000 ml
Eppendorf	Pipette tips 0.1-10 ml
Eppendorf	Centrifuge tube 50 ml
Eppendorf	Eppendorf tubes 1.5 ml
Grenier	Freezing vials 2.0 ml
Grenier	Leucosep® 50 ml tube

Sales and Marketing

We currently do not sell our products. Our goal is to have a diversified pool of customers worldwide, including the United States. However, we plan to focus initially on the Western EU nations, Singapore and Israel since we have the CE mark, whereas entering the U.S. market will require more time, effort and substantial funding in order to obtain FDA approval. Assuming we successfully raise additional funding, over the next 12 months we plan to commence clinical trials in Israel, Austria, and Romania in order to complete the trials and validation stages prior to commencement of sales. Furthermore, once the clinical trials tests are successfully completed, we may decide to apply to obtain regulatory approvals in Singapore to sell our products there. Our plans depend on us financing our operations through the sale of equity, incurring debt, or other financing alternatives.

C. Organizational Structure

We currently have one wholly owned subsidiary: Todos Medical Singapore Pte. Ltd., which is incorporated in Singapore.

D. Property, Plant and Equipment

We do not own any real property. Our offices, research and development facility and in-house laboratory are located at our headquarters at 1 Hamada Street, Rehovot, Israel, where we currently occupy approximately 108 square meters for a monthly consideration of NIS 7,400 (approximately \$2,000). The lease automatically renewed for an additional one year on February 1, 2019. Lease payments are linked to the Israeli Consumer Price Index, or CPI, based on the CPI published on February 15, 2015. We own lab equipment, including a spectroscopy, with an aggregate value of approximately \$157,000, which is being allocated as a depreciation expense over the useful life of the equipment.

We consider our current office space sufficient to meet our anticipated needs for the foreseeable future and is suitable for the conduct of our business.

ITEM 4A. UNRESOLVED STAFF COMMENTS

None.

ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

The following discussion and analysis should be read in conjunction with our financial statements and related notes included elsewhere in this annual report on Form 20-F. This discussion and other parts of this annual report on Form 20-F contain forward-looking statements based upon current expectations that involve risks and uncertainties. Our actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of several factors, including those set forth under "Risk Factors" and elsewhere in this annual report in Form 20-F. We report financial information under US GAAP and our financial statements were prepared in accordance with generally accepted accounting principles in the United States.

Overview

We are an IVD for cancer diagnosis company, engaged in the development of a series of patient-friendly blood tests for the detection of a variety of cancers based on our TBIA, a proprietary method for detection of solid tumors using peripheral blood analysis. The method incorporates biochemistry, physics and signal processing. The TBIA detection method is based on the cancer's influence on the immune system which triggers biochemical changes in PBMC, and plasma. Our core technology, TBIA, is based on research conducted and technology invented by the research teams at BGU and Soroka, whose intellectual property has been licensed to us in consideration of our contractual obligation to pay certain licensing fees. On December 9, 2013, our TBIA test obtained the CE mark approval.

We believe that our clinical results conducted to date demonstrate the capability to simply and rapidly detect malignant breast and colon tumors in comparison to a controlled healthy group. We anticipate that future broad clinical studies should reveal the full potential of our technology. We believe our proprietary innovation is conducive to constant improvement in the algorithm as we ascend the learning curve, thereby perfecting our test performances and expand the intended population with each test. Accordingly, we will be required to continue to devote substantial resources and efforts to research and development activities in order to potentially achieve and maintain a competitive position in this field. We plan to increase our products portfolio and improve the existing products by improving the algorithms and optimizing and automating the process. As of March 20, 2019, our unaudited cash holdings were \$310,000.

One of our objectives in the next two years is to make our products known in the medical and scientific fields by publishing peer reviewed, high impact articles in medical journals about our TBIA test. During this period, we plan to begin selling our products in Israel, Europe and the Far East and to prepare the groundwork for FDA approval in the United States. We will also focus on enhancing our TBIA proprietary automation and algorithms in order to obtain a higher level of accuracy and reproducibility for the results of the blood tests. In addition, we believe that automating the process will reduce the relevant costs for the general public. We believe that proper robots and optimized spectrometers will enhance our method to the higher productivity levels needed for the TBIA detection tool to be able to perform a higher volume of tests.

Prior to selling our products, we first need to complete the automation process. This process includes several steps including qualifying a robust new test protocol, making our test measurement more automated in order to reduce our dependency on the skills of lab technicians, installing the proper web cloud data warehouse, and integrating a full business to business network. We plan to protect the confidentiality of patient medical data and personally identifiable information by means of: (i) having a secure facility where the data and information we hold will be stored; and (ii) requiring our third-party providers of data storage to comply with HIPAA and applicable state privacy and security laws and regulations. These changes will enable our customers to run the tests with lower costs while obtaining faster results. To the knowledge of our management, these changes will not impact the previously obtained CE mark approval of the TBIA test. At this point there can be no assurance that our plan will be implemented in accordance with what we currently envision, and future clinical results may lead to different conclusions about our products.

We are an IVD company, developing proprietary technology which will analyze a blood test to detect the presence of various cancers. As we are not developing a drug, we believe that we will not need to submit an investigational new drug application to the FDA prior to conducting clinical trials in the U.S. We believe that we will only need IRB approval prior to conducting clinical trials in the U.S.

Operating Results

A. Operating Expenses

Our current operating expenses consist of two components - research and development expenses, and general and administrative expenses.

Research and Development Expenses

Our research and development expenses consist primarily of salaries and related personnel expenses, subcontracted work and consulting, liabilities for royalties and other related research and development expenses.

The following table discloses the breakdown of research and development expenses:

	Year ended December 31		
	2018	2017	2016
Salaries and related expenses	\$ 178,486	\$ 144,250	\$ 145,997
Stock-based compensation	12,077	22,883	48,056
Professional fees	22,271	18,888	37,426
Laboratory and materials	70,779	143,644	109,299
Patent expenses	82,367	65,654	24,956
Rent and maintenance	40,146	58,381	41,289
Liability for minimum royalties expenses	-	238,000	50,000
Depreciation	25,650	24,083	20,695
Travel expenses	3,804	2,152	2,942
Insurance and other expenses	23,604	2,592	3,293
	<u>459,184</u>	<u>720,527</u>	<u>483,953</u>
Less: Grants from the OCS and others	-	-	(166,046)
	<u>\$ 459,184</u>	<u>\$ 720,527</u>	<u>\$ 317,907</u>

We expect that our research and development expenses will materially increase as we plan to rapidly recruit more employees in order to accelerate our research and development efforts.

General and administrative

General and administrative expenses consist primarily of salaries, share-based compensation expense, professional service fees (for accounting, legal, bookkeeping, intellectual property and facilities), directors fee and insurance and other general and administrative expenses.

The following table discloses the breakdown of general and administrative expenses:

	Year ended December 31		
	2018	2017	2016
Salaries and related expenses	\$ 190,207	\$ 67,541	\$ 29,254
Stock-based compensation	35,595	90,875	162,124
Communication and investor relations	230,194	83,836	5,121
Professional fees	269,980	224,407	150,341
Insurance and other expenses	193,718	150,428	64,142
	<u>\$ 919,694</u>	<u>\$ 617,087</u>	<u>\$ 410,982</u>

Comparison of the year ended December 31, 2018 to the year ended December 31, 2017

Results of Operations

Research and Development Expenses. Our net research and development expenses for the year ended December 31, 2018 were \$459,184, compared to \$720,527 for the year ended December 31, 2017, representing a net decrease of \$261,343, or 36.23%. The decrease is primarily due to liabilities to minimum royalties that posted in 2017 to reflect the present value of the liability we have to Ben Gurion University.

General and Administrative Expenses. Our expenses for the year ended December 31, 2018 were \$919,694, compared to \$617,087 for the year ended December 31, 2017, providing an increase of \$302,607 or 51%. The increase is primarily due to the increase from communication and investor relations expenses.

Finance Income and Expenses. Our net finance (Income) expenses for the year ended December 31, 2018 was (\$921,337), compared to expenses of \$1,337,758 for the year ended December 31, 2017, providing a decrease of \$2,259,095. The decrease is primarily due to the change in the fair value of warrants liability in the amount of \$2,027,908 and inducement related to warrants exercised in the amount of \$166,500, and the impact of exchange rate transaction of \$114,687. We issued warrants that are classified as liability instruments. As such, the fair value of these warrants is re-measured at the end of each accounting period with changes in this fair value reflected in the financial statement caption “Long Term Liabilities.” The exchange rate differentials affected the balances appearing on the balance sheet.

Net Loss. Our net loss for the year ended December 31, 2018 was \$457,541, compared to \$2,675,372 for the year ended December 31, 2017, providing a \$2,217,831 decrease in the amount of the loss or an 82.9% decrease. The decrease is primarily due to the change in the fair value of warrants liability, inducement related to warrants exercised, and research and development expenses.

Comparison of the year ended December 31, 2017 to the year ended December 31, 2016

Results of Operations

Research and Development Expenses. Our net research and development expenses for the year ended December 31, 2017 were \$720,527, compared to \$317,907 for the year ended December 31, 2016, representing a net increase of \$402,620, or 126%. The increase is primarily due to research and development grants we have received from the IIA and Horizon 2020 (the EU Framework Program for Research and Innovation) of \$166,000 in 2016 that are included as an offset to research and development expenses in 2016, and royalty expenses to BGU.

General and Administrative Expenses. Our expenses for the year ended December 31, 2017 were \$617,087, compared to \$410,982 for the year ended December 31, 2016, providing an increase of \$206,105 or 50.1%. The increase is primarily due to the increase from professional services expenses.

Finance Income and Expenses. Our net finance expenses for the year ended December 31, 2017 was \$1,337,758, compared to income of \$75,428 for the year ended December 31, 2016, providing an increase of \$1,413,186. The increase is primarily due to the change in the fair value of warrants liability in the amount of \$1,101,229 and inducement related to warrants exercised in the amount of 166,500. We issued warrants that are classified as liability instruments. As such, the fair value of these warrants is re-measured at the end of each accounting period with changes in this fair value reflected in the financial statement caption “Long Term Liabilities.” The exchange rate differentials affected the balances appearing on the balance sheet.

Net Loss. Our net loss for the year ended December 31, 2017 was \$2,675,372, compared to \$653,461 for the year ended December 31, 2016, providing a \$2,021,911 increase in the amount of the loss or a 309% increase. The increase is primarily due to the change in the fair value of warrants liability, inducement related to warrants exercised and research and development expenses.

Critical Accounting Policies and Estimate

We describe our significant accounting policies more fully in Note 2 to our financial statements for the year ended December 31, 2018, included elsewhere in this annual report on Form 20-F. We believe that the accounting policies below are critical in order to fully understand and evaluate our financial condition and results of operations.

We prepare our financial statements in accordance with accounting principles generally accepted in the United States, or U.S. GAAP. At the time of the preparation of the financial statements, our management is required to use estimates, evaluations, and assumptions which affect the application of the accounting policy and the amounts reported for assets, obligations, income, and expenses. Any estimates and assumptions are continually reviewed. The changes to the accounting estimates are credited during the period in which the change to the estimate is made.

Subject to certain conditions set forth in the JOBS Act, as an “emerging growth company,” we elected to rely on other exemptions, including without limitation, (i) providing an auditor’s attestation report on our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act and (ii) complying with any requirement that may be adopted by the PCAOB regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements (auditor discussion and analysis). These exemptions will apply until on or before the last day of the 2021 fiscal year (the fifth anniversary of the date of the first sale of our common equity securities pursuant to an effective registration statement under the Securities Act).

Going Concern Uncertainty

We devoted substantially all of our efforts to research and development and raising capital and have not yet generated any revenues. The development and commercialization of our products are expected to require substantial further expenditures. We have not yet generated any revenues from operations, and therefore we are dependent upon external sources for financing our operations. Since inception, we have incurred substantial accumulated losses, negative working capital, and negative operating cash flow, and have a significant shareholders' deficit. These factors raise substantial doubt about our ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of this uncertainty. As of March 20, 2019, our unaudited cash holdings were \$310,000. We plan to finance our operations through the sale of equity and, to the extent available, short term and long-term loans. There can be no assurance that we will succeed in obtaining the necessary financing to continue our operations. See also Item 3.D - Risk Factors under the caption "The report of our independent registered public accounting firm expresses substantial doubt about our ability to continue as a going concern."

B. Liquidity and Capital Resources

Overview

To date, we have funded our operations primarily with loans, grants from the IIA, and issuing Ordinary Shares and warrants.

The table below presents our cash flows:

STATEMENTS OF CASH FLOWS

U.S. dollars in thousands

	For the Year ended December 31,		
	2018	2017	2016
Cash flows from operating activities:			
Loss for the year	\$ (458)	\$ (2,675)	\$ (653)
Adjustments to reconcile loss for the year to net cash used in operating activities:			
Depreciation	26	24	21
Liability for minimum royalties	50	238	50
Change in fair value of warrants liability	(926)	1,101	(118)
Stock-based compensation	48	114	210
Inducement related to warrants exercised	-	167	-
Financing expenses of long term loans & other Shekel denominated balances	(48)	67	8
Changes in operating assets and liabilities:			
Decrease (increase) in other current assets	(13)	1	6
Increase (decrease) in accounts payable	163	(22)	14
(Decrease) increase in other current liabilities	102	81	(8)
Net cash used in operating activities	(1,056)	(904)	(469)
Cash flows from investing activities			
Purchase of property and equipment	(15)	(4)	(35)
Net cash used in investing activities	(15)	(4)	(35)
Cash flows from financing activities			
Proceeds allocated to short term loan	27	-	-
Proceeds allocated to Ordinary Shares, net	80	563	567
Proceeds allocated to warrants	20	-	244
Proceeds allocated from exercise of warrants	324	599	-
Proceeds from exercise of stock options	-	0.226	0.273
Repayments of shareholders loans	-	-	(24)
Proceeds from shareholders loans	-	-	-
Net cash provided by financing activities	451	1,162	788
(Decrease) Increase in cash and cash equivalents	(620)	254	283
Cash and cash equivalents at beginning of the year	693	439	156
Cash and cash equivalents at end of the year	\$ 73	\$ 693	\$ 439

Operating Activities

Net cash used in operating activities for the year ended December 31, 2018 was \$1,056,296, compared to \$904,410 in the year ended December 31, 2017, and \$469,389 in the year ended December 31, 2016. The increase in the cash flow used in operating activities in 2018 compared to 2017 is primarily due to increase from operating loss.

Investing Activities

Net cash used in investing activities for the for the year ended December 31, 2018 was \$15,370, compared to net cash used in the year ended December 31, 2017 of \$3,596, compared to net cash used in the year ended December 31, 2016 of \$34,971.

Financing Activities

Net cash provided by financing activities for the year ended December 31, 2018 was \$451,258, compared to net cash provided by financing activities for the year ended December 31, 2017 of \$1,162,230, compared to net cash provided by financing activities for the year ended December 31, 2016 of \$787,759. This decrease is primarily due to a cash received from the exercise of warrants, proceeds from private placement and proceeds from convertible loan.

Current Outlook

As of March 20, 2019, our unaudited cash holdings were \$310,000.

We cannot assure that our cancer detection kits will be commercialized, work as indicated, or that they will receive regulatory approval and that we will earn revenues sufficient to support our operations or that we will ever be profitable. Furthermore, since we have no committed source of financing, we cannot assure that we will be able to raise money as and when we need it to continue our operations. If we cannot raise funds as and when we need them, we may be required to severely curtail, or even to cease, our operations.

We have limited experience with IVD. As such, these budget estimates may not be accurate. In addition, the actual work to be performed is not known at this time, other than a broad outline, as is normal with any scientific work. As further work is performed, additional work may become necessary or change in plans or workload may occur. Such changes may have an adverse impact on our estimated budget. Such changes may also have an adverse impact on our projected timeline of drug development

If we are unable to raise additional funds, we will need to do one or more of the following:

- delay, scale-back or eliminate some or all of our research and product development programs;
- provide licenses to third parties to develop and commercialize products or technologies that we would otherwise seek to develop and commercialize ourselves;
- seek strategic alliances or business combinations;

- attempt to sell our company;
- cease operations; or
- declare bankruptcy.

Any debt financing secured by us in the future could involve restrictive covenants relating to our capital raising activities and other financial and operational matters, which may make it more difficult for us to obtain additional capital and to pursue business opportunities, including potential acquisitions. We may not be able to secure additional debt or equity financing in a timely manner, or at all, which could require us to scale back our business plan and operations.

The above conditions raise substantial doubt about our ability to continue as a going concern. The financial statements included elsewhere herein were prepared under the assumption that we would continue our operations as a going concern. Our financial statements do not include any adjustments that may result from the outcome of this uncertainty. Without additional funds from debt or equity financing, sales of our intellectual property or technologies, or from a business combination or a similar transaction, we will soon exhaust our resources and will be unable to continue operations. If we cannot continue as a viable entity, our shareholders may lose some or all of their investment in us.

Our management intends to attempt to secure additional required funding primarily through additional equity or debt financings. We may also seek to secure required funding through sales or out-licensing of intellectual property assets, seeking partnerships with other pharmaceutical companies or third parties to co-develop and fund research and development efforts, or similar transactions. However, there can be no assurance that we will be able to obtain required funding. If we are unsuccessful in securing funding from any of these sources, we will defer, reduce or eliminate certain planned expenditures in our research protocols. If we do not have sufficient funds to continue operations, we could be required to seek bankruptcy protection or other alternatives that could result in our shareholders losing some or all of their investment in us.

C. Off-Balance Sheet Arrangements

We currently do not have any off-balance sheet arrangements.

D. Tabular Disclosure of Contractual Obligations

The following table summarizes our contractual obligations as of December 31, 2018:

	Payments due by period			
	(US\$)			
	Total	Less than 1 year	1-3 years	More than 5 years
Shareholders' loans (1)	611,925	611,925	-	-
Royalties to BGU (2)	373,000	185,000	-	188,000
Total (3)	<u>984,925</u>	<u>796,925</u>	<u>-</u>	<u>188,000</u>

- (1) Between the years 2011 and 2014, we received loans from two shareholders. The loans are denominated in NIS, mature on December 31, 2019 and bear no interest. The loans are linked to the Israeli CPI as of January 1, 2015. The loans may be repaid by us from time to time according to our cash availability.
- (2) This balance was measured based on the future cash payments discounted using an interest rate of 21%, which represents, according to management's estimate, the applicable rate of risk for us.
- (3) This does not include the repayment of approximately \$272,000 of grants we received from the IIA and interest thereon, which shall be repaid as royalties upon the commercialization of our products.

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

The following table sets forth information regarding our executive officers, directors, and our key employees as of March 25, 2019:

Name	Age	Position(s)
Dr. Herman Weiss	48	Chief Executive Officer and Director
Rami Zigdon	56	Chief Business Officer and Director
Udi Zelig	40	Chief Technology Officer
David Ben Naim	50	Chief Financial Officer
Alon Ostrovitzky	34	Director
Moshe Schlisser	30	Director
Moshe Abramovitz	37	Director
Colin Bier	72	Director
Alon Shalev	47	External Director
Ronit Even-Zahav Meitin	53	External Director

Executive Officers, Directors, and Key Employees**Dr. Herman Weiss**, CEO and Director

Dr. Herman Weiss has been a director since June 22, 2017. Dr. Weiss was appointed CEO of the Company on July 30, 2018. Dr. Weiss previously served as the vice president of medical affairs and clinical development at Juniper Pharmaceuticals Inc. in Boston, MA. Before that, Dr. Weiss previously served as the Global Medical Director of women's health and bone health at Teva Pharmaceutical Industries, Ltd. in Petah Tikve, Israel. Dr. Weiss has served as a consultant to multiple medical device and pharmaceutical companies, including American medical systems and venture capital firms in New York City, and also founded and served as the chief medical officer of FibroControl, a biotech medical device company in Herzliya, Israel. Dr. Weiss owns multiple patents and is the author of numerous publications in the area of women's health and gynecology. Dr. Weiss holds an M.B.A. from the George Washington University, Washington DC, an M.D. from the Ohio State University College of Medicine, and a B.A. in Philosophy (summa cum laude) from the Ramapo College of New Jersey.

Rami Zigdon, Chief Business Officer and Director

Mr. Rami Zigdon was appointed CBO of the Company on July 30, 2018. Before to that, served as our Chief Executive Officer since our inception in 2010 and also served as a director on our board from May 12, 2011 until June 3, 2015. On May 10, 2016, he was elected again to serve as a director. As of January 2016, Mr. Zigdon has also served as a director on the board of our subsidiary, Todos Singapore. Mr. Zigdon is an experienced business manager of technology-based companies. From 2003 to 2009, Mr. Zigdon served as the Israeli country manager of Renesas Technology, a leading Japanese semiconductors corporation. Prior to his position at Renesas, Mr. Zigdon served as the manager of Hitachi Semiconductors Israel and as the embedded systems group manager at RDT. Mr. Zigdon has held various technical and management positions at Scitex Belgium, NI Medical and Spectronix. Mr. Zigdon graduated with honors from the Hebrew University of Jerusalem and holds a B.S in Biology from the Hebrew University of Jerusalem, a B.S. in Electrical Engineering from the Ben Gurion University of the Negev and an MBA from the Heriot-Watt University, Edinburgh.

Udi Zelig, Chief Technology Officer

Dr. Udi Zelig has served as our full-time Chief Technology Officer since January 1, 2012. Prior to that, Dr. Zelig served as our non-employee Chief Technology Officer from our inception through November 15, 2009, while concurrently being employed by Crow Technologies 1977, Ltd. Dr. Zelig is a nuclear and biomedical engineer with more than a decade of research experience in conducting and managing of in-vitro and clinical experiments. His main field of research concerns various applications of infrared spectroscopy for blood cancer detection and investigation of chemotherapeutic drug influence on blood cells. Dr. Zelig is the author of numerous scientific publications in leading biophysics and medicinal journals. Dr. Zelig holds a B.S. in Nuclear Engineering, a Master of Science and a Ph.D. in bio-medical engineering, all from the Ben-Gurion University of the Negev.

David Ben Naim, Chief Financial Officer

Mr. David Ben Naim has served as our Chief Financial Officer since January 2018. Since 2014, Mr. Ben Naim has been the owner and manager of DBN Finance, a company that provides full outsourcing financial services to companies located in Israel. From 2012 until 2014, Mr. Ben Naim served as the chief financial officer of Inuline Medical Inc., which is traded on the Tel Aviv Stock Exchange, or TASE, under the symbol INSL. Mr. Ben Naim served as the chief financial officer for Crow Technologies 1977, Ltd. (OTCQB - CRWTF) from 2008 until 2011 and for Ilex Medical Limited (TASE) from 2007 until 2008. Other positions held by Mr. Ben Naim include, in connection with his ownership of DBN Finance, chief financial officer since 2016 of Microbot Medical (Nasdaq - MBOT) and Vonetize PLC (TASE - VNTZ). Additionally, Mr. Ben Naim served as the Corporate Controller of Tadiran Telecom Limited from 2003 until 2007. Mr. Ben Naim holds an MBA from Ono Academic College as well as a C.P.A. license from the Ramat Gan College.

Alon Ostrovitzky, Director

Mr. Alon Ostrovitzky has been a director since December 5, 2013. Since 2008, Mr. Ostrovitzky has acted as the President of Ostrovitzky Holdings Company, a company which has developed a variety of real estate projects in the Czech Republic, Germany, and Israel. As President, Mr. Ostrovitzky supervised sub-contractors and service providers among other things. Mr. Ostrovitzky has also developed and spearheaded renewable energy projects in Greece, planned and oversaw construction of photovoltaic parks in Greece, and provided management for a medical center (Dialysis and specialists) in the Czech Republic. Mr. Ostrovitzky holds a B.A. in business administration from the Interdisciplinary Center Herzliya, where he specialized in finance, and also studied economics at Tel Aviv University.

Moshe Schlisser, Director

Mr. Moshe Schlisser has been a director since February 27, 2016. Mr. Schlisser currently also serves as a director at SmartGreen Ltd, Tanel Group Ltd and III Pte Ltd. Mr. Schlisser is a General Partner at Shefa Capital Ltd a Growth Venture Fund with a focus on mid to later stage deep technology investments. Mr. Schlisser held managerial positions in various investment firms and has experience with investments, structured finance and mergers and acquisitions. In 2010, Mr. Schlisser co-founded and currently serves as a director of a soup kitchen in Jerusalem that serves to over 50 homeless and underprivileged individuals a hot prepared dinner every night and that delivers weekend food packages to over 250 underprivileged families.

Moshe Abramovitz, Director

Mr. Moshe Abramovitz has been a director since February 27, 2016. Mr. Abramovitz has held managerial positions in various organizations (Israeli companies and charities) including serving as the deputy chief executive officer of A.S. Mehadrin Ltd. Mr. Abramovitz holds a B.A. in business administration, specializing in information systems, from Ono Academic College and an MBA in business administration specializing in business strategy from Ono Academic College. Mr. Abramovitz received training and a certificate to serve as a mediator from Bar Ilan University.

Colin Bier, Director

Dr. Colin Bier was added to the Board of Directors on March 25, 2019. Dr. Bier currently serves as Managing Director of ABA BioResearch, Inc.. From September 2013 until 2018, he served as a Corporate Advisor of Amaranthus Bioscience Holdings, Inc. He also served as a Senior Advisor of TVM V Life Science Ventures and NGN Capital. From November 2001 to June 15, 2002, Dr. Bier served as Chairman of the Board and Chief Executive Officer of Soligenix, Inc. From 1996 through 2008, Dr. Bier was a Director of Neurochem Inc. Dr. Bier serves as a Director of Lomir Biomedical Inc., a private company, of Mount Sinai Hospital Montreal, and of Receptagen, a publicly traded company. He has published more than twenty-five scientific articles in his field in peer-reviewed journals. Dr. Bier received his Ph.D. in Experimental Pathology from Colorado State University in 1978 and then pursued additional training in experimental pathology and toxicology as a Medical Research Council Postdoctoral Fellow and the Dr. Douglas James Fellow in the Department of Pathology, McGill University. He received his M.Sc. from Long Island University in 1974, and his B.A. from Sir George Williams University in 1967.

Alon Shalev, Director

Mr. Alon Shalev has been a director since June 22, 2017. Mr. Shalev led BrainsGate from its inception phase, into its European clinical trials with a highly innovative technological and clinical platform. Subsequently, he led Nicast from initial exploratory work in different fields through a process of application definition, prioritization and selection, and into its First-In-Man clinical trials as well as the CE approval process. Under his direction, Nicast has become the first medical device company to introduce an implantable medical device based on polymer electrospinning. In 2008, Mr. Shalev started generating the core IP upon which Endospan was later founded. Mr. Shalev has been the chief executive officer of Endospan since 2013 and also serves on its board of directors. Mr. Shalev is an inventor of numerous patents in the medical field. Mr. Shalev holds an MS in Solid State Electronics, Physical Electronics (cum laude) and a B.S. in Electrical Engineering both from Tel Aviv University.

Ronit Even-Zahav Meitin, Director

Ms. Ronit Even-Zahav Meitin has been a director since June 22, 2017. Since 2014, Ms. Even Zahav Meitin has provided financial consulting services to various companies. Previously, Ms. Even Zahav Meitin served as chief financial officer with the Afcon Group (a public company traded on the TASE). Ms. Even-Zahav Meitin also serves as a director and chairperson of the finance committee for Cross Israeli Highway (a governmental company), and as an independent director in Inter Green Ltd. (a public company traded on the TASE). Until 2012, Ms. Even-Zahav Meitin served, among other positions, as chief financial officer of Paz Industries and Services (Oil) and a director of its subsidiaries. Ms. Even-Zahav Meitin is a certified accountant in Israel and holds a BA in Accounting and Economics from Tel Aviv University and an MBA in Finance from Bar Ilan University.

Family Relationships

There are no family relationships between any of our executive officers and our directors.

B. Compensation

Compensation

The following table presents in the aggregate all compensation we paid to all of our directors and executive officers as a group for work during or with respect to the year ended December 31, 2018. The table does not include any amounts we paid to reimburse any of such persons for costs incurred in providing us with services during this period.

All amounts reported in the tables below reflect the cost to our Company, in thousands of U.S. Dollars, for the year ended December 31, 2018. Amounts paid in NIS are translated into U.S. dollars at the rate of NIS 3.6 is equal to \$1.00, based on the average representative rate of exchange between the NIS and the U.S. dollar as reported by the Bank of Israel in the year ended December 31, 2018.

	Salary and Related Benefits, including Pension, Retirement and Other Similar Benefits	Share Based Compensation
All directors and executive officers as a group, consisting of nine persons	\$ 351,000	\$ 48,000

In accordance with the Companies Law, the table below reflects the compensation granted to our four most highly compensated officers during or with respect to the year ended December 31, 2018.

Annual Compensation - in thousands of USD - convenience translation

Executive Officers	Salary and Related Benefits, including Pension, Retirement and Other Similar Benefits	Share Based Compensation	Total
Herman Weiss, M.D., CEO	\$ 83 ⁽¹⁾	\$ -	\$ 83
Rami Zigdon, CBO	\$ 72	\$ 36	\$ 108
Udi Zelig, CTO	\$ 81	\$ 12	\$ 93
David Ben Naim, CFO	\$ 50	\$ -	\$ 50
	\$ 286	\$ 48	\$ 334

(1) This amount has not been paid to the CEO; rather the Company has made a provision in its financial statements to reflect a compensation liability to Dr. Weiss.

Employment Agreements with Executive Officers

We have entered into written employment agreements with each of our executive officers, except for our CEO. The Company's Compensation Committee and Board of Directors have approved the following compensation package for our CEO, to be retroactive to August 1, 2018, which will be presented to the shareholders of the Company for approval at the annual meeting of shareholders scheduled for April 29, 2019.

- *Salary:* NIS 47,840 per month
- *Bonus:* Annual performance bonus of up to 35% of annual salary + 1% additional options, linked to the achievement of performance goals to be established by the Board of Directors each year.
- *Equity:* The Company will grant the CEO options to purchase 5% of the Company's issued and outstanding shares as of March 25, 2019, at an exercise price equal to the fair market value of the Company's shares on the date of grant, in accordance with the following vesting schedule:
 - o 25% will vest on grant
 - o 25% will vest on the consummation of the Company's planned public offering (the "Public Offering Date")
 - o 25% will vest quarterly in the first year following the Public Offering Date
 - o 25% will vest quarterly in the second year following the Public Offering Date
- *Notice Period:* 3 months
- *Severance Payments:* 6 months' salary following effective date of termination

- *Change in Control Payment* In the event the CEO is terminated due to a change of control, the Company will pay the CEO 12 months' salary (instead of the 6 months' salary) following the effective date of termination.
- *Change in Control Acceleration* In the event of a change of control transaction following the Public Offering Date vesting will be accelerated, and all of the options will become fully vested.

All of the Company's employment agreements contain customary provisions regarding noncompetition, confidentiality of information and assignment of inventions. However, the enforceability of the noncompetition provisions may be limited under applicable law. In addition, we have entered into agreements with each executive officer and director, pursuant to which, we have agreed to indemnify each of them up to a certain amount and to the extent that these liabilities are not covered by directors and officers insurance.

For a description of the terms of our options and option plans, see "Item 6.E. Share Ownership" below.

Todos Medical Ltd. 2015 Share Option Plan

The Todos Medical Ltd. 2015 Share Option Plan, or the Option Plan, was adopted by our Board of Directors on November 2015. The Option Plan generally permits the reservation, allocation and issuance of share options to our employees, directors or consultants. As of December 31, 2018, 1,758,315 options to purchase our Ordinary Shares have been granted under the Option Plan and 4,241,685 Ordinary Shares were available for future option grants under the Option Plan. As of March 20, 2019, 1,137,731 options have been exercised. Unless terminated earlier by our Board of Directors, the Option Plan will terminate ten years from its date of adoption.

Directors' Service Contracts

Other than with respect to our directors who are also executive officers, we do not have written agreements with any director providing for benefits upon the termination of his employment with our company.

C. Board Practices

According to the Companies Law, the management of our business is vested in our Board of Directors. Our Board of Directors may exercise all powers and may take all actions that are not specifically granted to our shareholders. Our executive officers are responsible for our day-to-day management and have individual responsibilities established by our Board of Directors. Executive officers are appointed by and serve at the discretion of our Board of Directors, subject to any applicable employment agreements we have entered into with the executive officers.

Under the Companies Law, we are not required to have a majority of independent directors. We are required to appoint at least two external directors. According to our Amended Articles, our Board of Directors must consist of at least five and not more than nine directors, including external directors. Currently, our Board of Directors consists of seven directors. Pursuant to our Amended Articles, other than the external directors, for whom special election requirements apply under the Companies Law, our directors are elected at an annual or special general meeting of our shareholders and serve on our Board of Directors until the next annual general meeting at which one or more directors are elected or until they are removed by the majority of our shareholders at an annual or special general meeting of our shareholders or upon the occurrence of certain events, in accordance with the Companies Law and our Amended Articles. In addition, our Amended Articles allow our Board of Directors to appoint directors, other than external directors, to fill vacancies on our Board of Directors to serve until the next annual meeting or special general meeting, or earlier if required by our Amended Articles or applicable law. For additional information concerning external directors, see "-External Directors" below.

Under the Companies Law, our Board of Directors must determine the minimum number of directors who are required to have financial and accounting expertise. Under applicable regulations, a director with financial and accounting expertise is a director who, by reason of his or her education, professional experience and skill, has a high level of proficiency in and understanding of business accounting matters and financial statements. He or she must be able to thoroughly comprehend the financial statements of the listed company and initiate debate regarding the manner in which financial information is presented. In determining the number of directors required to have such expertise, a company's board of directors must consider, among other things, the type and size of the company and the scope and complexity of its operations. Our Board of Directors has determined that we require at least one director with the requisite financial and accounting expertise.

The term office holder is defined in the Companies Law as a general manager, chief business manager, deputy general manager, vice general manager, executive vice president, vice president, or any other person assuming the responsibilities of any of the foregoing positions, without regard to such person's title, or a director or any other manager directly subordinate to the general manager.

External Directors

Under the Companies Law, a public company is required to appoint at least two external directors to serve on its board of directors. External directors must meet stringent standards of independence. As of the date hereof, our external directors are Ms. Ronit Even-Zahav Meitin and Mr. Alon Shalev.

The provisions of the Companies Law set forth special approval requirements for the election of external directors. External directors must be elected by a majority vote of the shares present and voting on the matter at a shareholders meeting, provided that either:

- such majority includes at least a majority of the shares held by all shareholders who are non-controlling shareholders and shareholders who do not have a personal interest in the election of the external director (other than a personal interest not deriving from a relationship with a controlling shareholder) that are voted at the meeting, excluding abstentions, which we refer to as a disinterested majority; or
- the total number of shares held by shareholders who are non-controlling shareholders and shareholders who do not have a personal interest in the election of the external director (other than a personal interest not derived from a relationship with a controlling shareholder) voted against the election of the external director does not exceed 2% of the aggregate voting rights in the company.

The term "controlling shareholder" is defined in the Companies Law as a shareholder with the ability to direct the activities of a company, other than by virtue of being an office holder. A shareholder is deemed to be a controlling shareholder if the shareholder holds 50% or more of the voting rights in the company or has the right to appoint 50% or more of the directors of a company or its general manager. With respect to certain matters, a controlling shareholder is deemed to include any shareholder that holds 25% or more of the voting rights in a public company if no other shareholder holds more than 50% of the voting rights in the company, but excludes a shareholder whose power derives solely from his or her position as a director of the company or from any other position with the company.

The term "personal interest" is defined in the Companies Law as a person's or entity's personal interest in an act or a transaction of a company, (i) including the personal interest of (a) any spouse, sibling, parent, grandparent or descendant of the persons, any descendant, sibling or parent of a spouse of the person and the spouse of any of the foregoing; and (b) an entity in which the person or entity or any of the foregoing relatives of the person serves as a director or the chief executive officer, owns at least 5% of its issued share capital or voting rights or has the right to appoint one or more directors or the chief executive officer, but (ii) excluding a personal interest arising solely from the ownership of shares. In the case of a person voting by proxy, "personal interest" includes the personal interest of the proxy holder or the shareholder granting the proxy (even if the proxy holder has no personal interest in the matter), whether or not the proxy holder has discretion how to vote.

The initial term of an external director is three years. Thereafter, an external director may be reelected by shareholders to serve in that capacity for up to two additional three-year terms, provided that either:

- his or her service for each such additional term is recommended by one or more shareholders holding at least 1% of the company's voting rights and is approved at a shareholders meeting by a disinterested majority, where the total number of shares held by non-controlling, disinterested shareholders voting for such reelection exceeds 2% of the aggregate voting rights in the company, and provided further that the external director is not an affiliated or competing shareholder, as defined in the Companies Law, or a relative of such a shareholder at the time of the appointment, and is not affiliated with such a shareholder at the time of appointment or within the two years preceding the date of appointment; or
- his or her service for each such additional term is recommended by the board of directors and is approved at a shareholders meeting by the same majority required for the initial election of an external director (as described above).

External directors may be removed only by a special general meeting of shareholders called by the board of directors after the board has determined that circumstances allow such dismissal, at the same special majority of shareholders required for their election or by a court, and in both cases only if the external directors cease to meet the statutory qualifications for their appointment or if they violate their duty of loyalty to our company. In the event of a vacancy created by an external director which causes the company to have fewer than two external directors, the board of directors is required under the Companies Law to call a shareholders meeting as soon as possible to appoint such number of new external directors in order that the company thereafter has two external directors.

Each committee of the board of directors that exercises the powers of the board of directors must include at least one external director, except that the audit committee and the compensation committee must include all external directors then serving on the board of directors. Under the Companies Law, external directors of a company are prohibited from receiving, directly or indirectly, any compensation for their services as external directors other than pursuant to the Companies Law and the regulations promulgated thereunder. Compensation of an external director is determined prior to his or her appointment and may not be changed during any three-year term subject to certain exceptions.

The Companies Law provides that a person is not qualified to serve as an external director if (i) the person is a relative of a controlling shareholder of the company, or (ii) if that person or his or her relative, partner, employer, another person to whom he or she was directly or indirectly subordinate, or any entity under the person's control, has or had, during the two years preceding the date of appointment as an external director: (a) any affiliation with the company, with any person or entity controlling the company or a relative of such person at the time of appointment, or with any entity controlled by or under common control with the company at the time of appointment or during the two years preceding the appointment; or (b) in the case of a company with no controlling shareholder or a shareholder holding 25% or more of its voting rights, had at the date of appointment as an external director, any affiliation with a person then serving as chairman of the board or chief executive officer, a holder of 5% or more of the issued share capital or voting power in the company or the most senior financial officer.

The term "relative" is defined as a spouse, sibling, parent, grandparent or descendant; spouse's sibling, parent or descendant; and the spouse of each of the foregoing persons.

The term "affiliation" includes (subject to certain exceptions): an employment relationship; a business or professional relationship even if not maintained on a regular basis (excluding insignificant relationships); control; and service as an office holder, excluding service as a director in a private company prior to the initial public offering of its shares if such director was appointed as a director of the private company in order to serve as an external director following the initial public offering.

In addition, no person may serve as an external director if that person's positions or professional or other activities create, or may create, a conflict of interest with that person's responsibilities as a director or otherwise interfere with that person's ability to serve as a director or if the person is an employee of the Israel Securities Authority or of an Israeli stock exchange. A person may furthermore not continue to serve as an external director if he or she received direct or indirect compensation other than as permitted by the Companies Law and the regulations promulgated thereunder.

Following the termination of an external director's service on a board of directors, such former external director and his or her spouse and children and other relatives may not be provided a direct or indirect benefit by the company, its controlling shareholder or any entity under its controlling shareholder's control. This includes engagement as an officer or director of the company or a company controlled by its controlling shareholder or employment by, or provision of services to, any such company for consideration, either directly or indirectly, including through a corporation controlled by such person. This restriction extends for a period of two years with regard to the former external director and his or her spouse or child and for one year with respect to other relatives of the former external director.

If at the time at which an external director is appointed all members of the board of directors who are not controlling shareholders or relatives of controlling shareholders of the company are of the same gender, the external director to be appointed must be of the other gender. A director of one company may not be appointed as an external director of another company if a director of the other company is acting as an external director of the first company at such time.

According to the Companies Law and regulations promulgated under the Companies Law, a person may be appointed as an external director only if he or she has professional qualifications or if he or she has accounting and financial expertise (each, as defined below). At least one of the external directors must be determined by our Board of Directors to have accounting and financial expertise. We have determined that Ms. Ronit Even-Zahav has accounting and financial expertise.

A director with accounting and financial expertise is a director who, due to his or her education, experience and skills, possesses an expertise in, and an understanding of, financial and accounting matters and financial statements, such that he or she is able to understand the financial statements of the company and initiate a discussion about the presentation of financial data. A director is deemed to have professional qualifications if he or she has any of (i) an academic degree in economics, business management, accounting, law or public administration, (ii) an academic degree or has completed another form of higher education in the primary field of business of the company or in a field which is relevant to his/her position in the company, or (iii) at least five years of experience serving in one of the following capacities, or at least five years of cumulative experience serving in two or more of the following capacities: (a) a senior business management position in a company with a significant volume of business; (b) a senior position in the company's primary field of business; or (c) a senior position in public administration or service. The board of directors is charged with determining whether a director possesses financial and accounting expertise or professional qualifications.

Audit Committee

Israeli Companies Law Requirements

Under the Companies Law, a public company is required to appoint an audit committee. The audit committee must be comprised of at least three directors, including all of the external directors, one of whom must serve as chairman of the committee. The audit committee may not include the chairman of the board, a controlling shareholder of the company or 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.

In addition, under the Companies Law, the audit committee of a publicly traded company must consist of a majority of unaffiliated directors, within the meaning of the Companies Law. In general, an "unaffiliated director" under the Companies Law is defined as either an external director or a director who meets the following criteria:

- the audit committee has determined that he or she meets the qualifications for being appointed as an external director, except for (i) the requirement that the director be an Israeli resident (which does not apply to companies such as ours whose securities have been offered outside of Israel or are listed outside of Israel); and (ii) the requirement for accounting and financial expertise or professional qualifications; and
- he or she has not served as a director of the company for a period exceeding nine consecutive years. For this purpose, a break of less than two years in the service shall not be deemed to interrupt the continuation of the service.

Audit Committee Role

Our Board of Directors will adopt an audit committee charter that will set forth the responsibilities of the audit committee consistent with the regulations of the SEC, as well as the requirements for audit committees under the Companies Law, including the following:

- oversight of our independent registered public accounting firm and recommending the engagement, compensation or termination of engagement of our independent registered public accounting firm to the board of directors or shareholders for their approval, as applicable, in accordance with the requirements of the Companies Law;
- recommending the engagement or termination of the person filling the office of our internal auditor; and;
- recommending the terms of audit and non-audit services provided by the independent registered public accounting firm for pre-approval by the board or shareholders for their approval, as applicable, in accordance with the requirements of the Companies Law.

Our audit committee provides assistance to our Board of Directors in fulfilling its legal and fiduciary obligations in matters involving our accounting, auditing, financial reporting, internal control and legal compliance functions by pre-approving the services performed by our independent accountants and reviewing their reports regarding our accounting practices and systems of internal control over financial reporting. Our audit committee also oversees the audit efforts of our independent accountants and takes those actions that it deems necessary to satisfy itself that the accountants are independent of management.

Under the Companies Law, our audit committee is responsible for:

- determining whether there are deficiencies in the business management practices of our company, including in consultation with our internal auditor or the independent auditor, and making recommendations to the board of directors to improve such practices;
- determining whether to approve certain related party transactions (including transactions in which an office holder has a personal interest) and whether such transaction is extraordinary or material under Companies Law (see “- Approval of Related Party Transactions under Israeli Law”);
- determining whether a competitive process must be implemented for the approval of certain transactions with controlling shareholders or its relative or in which a controlling shareholder has a personal interest (whether or not the transaction is an extraordinary transaction), under the supervision of the audit committee or other party determined by the audit committee and in accordance with standards determined by the audit committee, or whether a different process determined by the audit committee should be implemented for the approval of such transactions;
- determining the process for the approval of certain transactions with controlling shareholders or in which a controlling shareholder has a personal interest that the audit committee has determined are not extraordinary transactions but are not immaterial transactions;
- where the board approves the working plan of the internal auditor, to examine such working plan before its submission to the board and proposing amendments thereto;
- examining our internal controls and internal auditor’s performance, including whether the internal auditor has sufficient resources and tools to dispose of its responsibilities;
- examining the scope of our auditor’s work and compensation and submitting a recommendation with respect thereto to our Board of Directors or shareholders, depending on which of them is considering the compensation of our auditor; and
- establishing procedures for the handling of employees’ complaints as to the management of our business and the protection to be provided to such employees.

Our audit committee consists of Ms. Ronit Even-Zahav Meitin, who serves as the chairperson, Mr. Alon Shalev and Mr. Moshe Abramovitz. Our audit committee may not approve any actions requiring its approval (see “- Approval of Related Party Transactions under Israeli Law”), unless at the time of the approval a majority of the committee’s members are present, which majority consists of unaffiliated directors including at least one external director.

Financial Statement Examination Committee

Under the Companies Law, the board of directors of a public company must appoint a financial statement examination committee, which consists of members with accounting and financial expertise or the ability to read and understand financial statements. Our audit committee holds the responsibilities and duties of a financial statement examination committee, as permitted under the relevant regulations promulgated under the Companies Law. From time to time, as necessary and required in order to approve our financial statements, the audit committee will hold separate meetings prior to the scheduled meetings of the board in respect of the financial statements. The function of a financial statement examination committee is to discuss and provide recommendations to the board of directors (including reporting any deficiencies found) with respect to the following issues: (a) estimations and assessments made in connection with the preparation of financial statements; (b) internal controls related to the financial statements; (c) completeness and appropriateness of the disclosure in the financial statements; (d) the accounting policies adopted and the accounting treatment implemented in material matters of the Company; and (e) value evaluation, including the assumptions and assessments on which evaluations are based and the supporting data in the financial statements.

Compensation Committee and Compensation Policy

A public company in Israel is required to have a compensation committee as required by the Companies Law. The compensation committee must be comprised of at least three directors, including all of the external directors, who must constitute a majority of the members of the compensation committee. Each compensation committee member that is not an external director must be a director whose compensation does not exceed an amount that may be paid to an external director under regulations promulgated under the Companies Law. The compensation committee is subject to the same Companies Law restrictions as the audit committee as to who may not be a member of the committee. See “- Audit Committee - Israeli Companies Law Requirements.”

Our compensation committee consists of Ms. Ronit Even-Zahav Meitin, who serves as the chairperson, Mr. Alon Shalev and Mr. Moshe Abramovitz.

Compensation Committee Role

Our Board of Directors will adopt a compensation committee charter. Responsibilities of the compensation committee consistent with the requirements for compensation committees under the Companies Law which includes the following:

- recommending to the board of directors for its approval (i) a compensation policy; (ii) whether a compensation policy should continue in effect, if the then-current policy has a term of greater than three years (approval of either a new compensation policy or the continuation of an existing compensation policy must in any case occur every three years); and (iii) periodic updates to the compensation policy. See “- Compensation Policy.” In addition, the compensation committee is required to periodically examine the implementation of the compensation policy;
- the approval of the terms of employment and service of office holders (including determining whether the compensation terms of a candidate for chief executive officer of the company need not be brought to approval of the shareholders); and
- reviewing and approving grants of options and other incentive awards to persons other than office holders to the extent such authority is delegated by our Board of Directors, subject to the limitations on such delegation as provided in the Companies Law.

Compensation Policy

Under the Companies Law, the duties of the compensation committee include the recommendation to the company's board of directors of a policy regarding the terms of engagement of office holders, as such term is defined in the Companies Law, to which we refer to as a compensation policy, and any extensions and updates thereto. The compensation policy must be adopted by the company's board of directors, after considering the recommendations of the compensation committee, and will need to be brought for approval by the company's shareholders, which approval requires a Special Approval for Compensation (as defined below under "- Approval of Related Party Transactions under Israeli Law - Disclosure of Personal Interests of an Office Holder").

Under the Companies Law, we were required to adopt an office holder compensation policy within nine months following our listing on the OTCQB. As of the date hereof, we have not yet approved the compensation policy and we intend to have our compensation policy approved by our shareholders in the next general meeting.

The compensation policy must serve as the basis for decisions concerning the financial terms of employment or engagement of office holders, including exculpation, insurance, indemnification or any monetary payment or obligation of payment in respect of employment or engagement. The compensation policy must relate to certain factors, including advancement of the company's objectives, the company's business plan and its long-term strategy, and creation of appropriate incentives for office holders, and must consider (among other things) the company's risk management, size and the nature of its operations. The compensation policy must also consider the following additional factors:

- the knowledge, skills, expertise and accomplishments of the relevant office holder;
- the office holder's roles and responsibilities and prior compensation agreements with him or her;
- the relationship between the terms offered and the average compensation of the other employees of the company (including any employees employed through manpower companies);
- the impact of disparities in salary upon work relationships in the company;
- the possibility of reducing variable compensation at the discretion of the board of directors, and the possibility of setting a limit on the exercise value of non-cash variable equity-based compensation; and
- as to severance compensation, the period of employment or service of the office holder, the terms of his or her compensation during such period, the company's performance during such period, the person's contribution towards the company's achievement of its goals and the maximization of its profits, and the circumstances under which the person is leaving the company.

The compensation policy must also include the following principles:

- the link between variable compensation and long-term performance and measurable criteria;
- the relationship between variable and fixed compensation, and the ceiling for the value of variable compensation;
- the conditions under which an office holder would be required to repay compensation paid to him or her if it was later shown that the data upon which such compensation was based was inaccurate and was required to be restated in the company's financial statements;
- the minimum holding or vesting period for variable, equity-based compensation; and
- maximum limits for severance compensation.

Internal Auditor

Under the Companies Law, the board of directors of an Israeli public company must appoint an internal auditor recommended by the audit committee. An internal auditor may not be:

- a person (or a relative of a person) who holds more than 5% of the company's outstanding shares or voting rights;
- a person (or a relative of a person) who has the power to appoint a director or the general manager of the company;
- an office holder, within the meaning of the Companies Law (including a director and the general manager) of the company (or a relative thereof); or
- a member of the company's independent accounting firm, or anyone on his or her behalf.

The role of the internal auditor is to examine, among other things, our compliance with applicable law and orderly business procedures. The audit committee is required to oversee the activities and to assess the performance of the internal auditor as well as to review the internal auditor's work plan.

On December 20, 2018, we retained Mr. Doron Levin to serve as our internal auditor instead of Mr. Adi Yarim, who resigned effective December 20, 2018.

Approval of Related Party Transactions under Israeli Law

Fiduciary Duties of Office Holders

The Companies Law codifies the fiduciary duties that office holders owe to a company.

An office holder's fiduciary duties consist of a duty of care and a duty of loyalty. The duty of care requires an office holder to act with the level of care with which a reasonable office holder in the same position would have acted under the same circumstances. The duty of care includes a duty to use reasonable means to obtain:

- information on the advisability of a given action brought for his or her approval or performed by virtue of his or her position; and
- all other important information pertaining to any such action.

The duty of loyalty requires an office holder to act in good faith and in the best interests of the company, and includes, among other things, the duty to:

- refrain from any conflict of interest between the performance of his or her duties to the company and his or her other duties or personal affairs;
- refrain from any activity that is competitive with the company;
- refrain from exploiting any business opportunity of the company to receive a personal gain for himself or herself or others; and
- disclose to the company any information or documents relating to the company's affairs which the office holder received as a result of his or her position as an office holder.

We may approve an act specified above which would otherwise constitute a breach of the office holder's duty of loyalty, provided that the office holder acted in good faith, the act or its approval does not harm the company and the office holder discloses his or her personal interest a sufficient amount of time before the date for discussion of approval of such act.

Disclosure of Personal Interests of an Office Holder

The Companies Law requires that an office holder promptly disclose to the company any “personal interest” that he or she may be aware of and all related material information or documents concerning any existing or proposed transaction with the company. An interested office holder’s disclosure must be made promptly and in any event no later than the first meeting of the board of directors at which the transaction is considered. A personal interest includes an interest of any person in an act or transaction of a company, including a personal interest of such person’s relative or of a corporate entity in which such person or a relative of such person holds 5% or more of the outstanding shares or voting rights, is a director or general manager or in which he or she has the right to appoint at least one director or the general manager, but excluding a personal interest arising from one’s ownership of shares in the company. A personal interest includes the personal interest of a person for whom the office holder holds a voting proxy or the personal interest of the office holder with respect to his or her vote on behalf of a person for whom he or she holds a proxy even if such shareholder has no personal interest in the matter. An office holder is not, however, obliged to disclose a personal interest if it derives solely from the personal interest of his or her relative in a transaction that is not considered an extraordinary transaction. Under the Companies Law, an extraordinary transaction is defined as any of the following: a transaction other than in the ordinary course of business; a transaction that is not on market terms; or a transaction that may have a material impact on a company’s profitability, assets or liabilities.

Generally, a person who has a personal interest in a matter which is considered at a meeting of the board of directors or the audit committee may not be present at such a meeting or vote on that matter unless, with respect to an office holder, the chairman of the audit committee or board of directors (as applicable) determines that the office holder should be present in order to present the transaction that is subject to approval. If a majority of the members of the audit committee or the board of directors (as applicable) has a personal interest in the approval of a transaction, then all directors may participate in discussions of the audit committee or the board of directors (as applicable) on such transaction and the voting on approval thereof. If a majority of the members of the board of directors has a personal interest in the approval of a transaction, shareholder approval is also required for such transaction.

Approval of Transactions with Officer Holders

If it is determined that an office holder has a personal interest in a transaction that is not an extraordinary transaction, approval by the board of directors is required for the transaction, unless the company’s articles of association provide for a different method of approval. Further, so long as an office holder has disclosed his or her personal interest in a transaction, the board of directors may approve an act by the office holder that would otherwise be deemed a breach of his or her duty of loyalty, provided that the transaction is in the company’s best interest and the office holder acted in good faith. An extraordinary transaction in which an office holder has a personal interest requires approval first by the company’s audit committee and subsequently by the board of directors.

Disclosure of Personal Interests of Controlling Shareholders and Approval of Certain Transactions

Pursuant to Israeli law, the disclosure requirements regarding personal interests that apply to directors and executive officers also apply to a controlling shareholder of a public company. In the context of a transaction involving a shareholder of the company, a controlling shareholder also includes a shareholder who holds 25% or more of the voting rights in the company if no other shareholder holds more than 50% of the voting rights in the company. For this purpose, the holdings of all shareholders who have a personal interest in the same transaction will be aggregated. Extraordinary transactions with a controlling shareholder or in which a controlling shareholder has a personal interest, including a private placement in which a controlling shareholder has a personal interest, and the terms of engagement with a controlling shareholder or a relative thereof, directly or indirectly (including through a corporation controlled by a controlling shareholder), for the provision of services to the company and his or her terms of employment or service as an office holder or employment as other than an office holder, require the approval of each of (i) the audit committee or the compensation committee with respect to the terms of service or employment by the company as an office holder, an employee or service provider; (ii) the board of directors; and (iii) the shareholders, in that order. The shareholder approval requires one of the following, which we refer to as a Special Majority:

- at least a majority of the shares held by all shareholders who do not have a personal interest in the transaction and who are present and voting on the matter approves the transaction, excluding abstentions; or

- the shares voted against the transaction by shareholders who have no personal interest in the transaction and who are present and voting at the meeting do not exceed 2% of the voting rights in the company.

Each shareholder voting on the approval of an extraordinary transaction with a controlling shareholder must inform the company prior to voting whether or not he or she has a personal interest in the approval of the transaction, otherwise, the shareholder is not eligible to vote on the proposal and his or her vote will not be counted for purposes of the proposal.

To the extent that any such transaction with a controlling shareholder is for a period of more than three years, approval is required once every three years, unless, with respect to any such extraordinary transactions, the audit committee determines that the duration of the transaction is reasonable given the related circumstances.

The compensation committee and board approval for arrangements regarding the terms of service or employment of a controlling shareholder must be in accordance with the company's compensation policy. In special circumstances the compensation committee and board of directors may approve a compensation arrangement that is inconsistent with the company's compensation policy, provided that they have considered the same considerations and matters required for the approval of a compensation policy in accordance with the Companies Law and that shareholder approval was obtained by the Special Majority.

Pursuant to regulations promulgated under the Companies Law, certain transactions with a controlling shareholder or his or her relative, or with directors, relating to terms of service or employment that would otherwise require approval of a company's shareholders may be exempt from shareholder approval upon certain determinations of the audit committee and board of directors. Under these regulations, a shareholder holding at least 1% of the issued share capital or voting power of the company may require, within 14 days of the publication or announcement of such determinations, that despite such determinations by the audit committee and the board of directors, such transaction will require shareholder approval under the same majority requirements that would otherwise apply to such transactions.

In addition, disclosure of a personal interest in a private placement of a public company (including disclosure of any material fact or document) is required by (i) a shareholder holding 5% or more of the company's issued and outstanding capital or its voting rights whose holdings will increase as result of the private placement and a shareholder who will hold 5% or more of the company's issued and outstanding capital or its voting rights as a result of the private placement, if 20% or more of the company's outstanding share capital prior to the private placement is issued in the private placement and the payment for which is not only in cash or listed securities or the transaction is not on market terms; and (ii) a person or entity that will become a controlling shareholder as a result of the private placement.

Shareholder Duties

Pursuant to the Companies Law, a shareholder has a duty to act in good faith and in a customary manner toward the company and other shareholders and to refrain from abusing his or her power in the company, including, among other things, in voting at a meeting of shareholder with respect to the following matters:

- an amendment to the company's articles of association;
- an increase of the company's authorized share capital;

- a merger; and
- the approval of related party transactions and acts of office holders that require shareholder approval.

In addition, a shareholder has a general duty to refrain from discriminating against other shareholders.

Certain shareholders have a duty of fairness toward the company. These shareholders include any controlling shareholder, any shareholder who knows that he or she has the power to determine the outcome of a shareholder vote and any shareholder who has the power to appoint or to prevent the appointment of an office holder of the company or other power towards the company. The Companies Law does not define the substance of the duty of fairness, except to state that the remedies generally available upon a breach of contract will also apply in the event of a breach of the duty to act with fairness.

Exculpation, Insurance and Indemnification of Directors and Officers

Under the Companies Law, a company may not exculpate an office holder from liability for a breach of the duty of loyalty. An Israeli company may exculpate an office holder in advance from liability to the company, in whole or in part, for damages caused to the company as a result of a breach of duty of care, but only if a provision authorizing such exculpation is included in its articles of association. Our Articles include such a provision, to the fullest extent permitted by law. The company may not exculpate in advance a director from liability arising out of a prohibited dividend or other distribution to shareholders.

Under the Companies Law and the Israeli Securities Law, 5728-1968, or the Israeli Securities Law, a company may indemnify an office holder in respect of the following liabilities and expenses incurred for acts performed by him or her as an office holder, either pursuant to an undertaking made in advance of any such event or following an event, provided its articles of association include a provision authorizing such indemnification:

- a financial liability imposed on him or her in favor of another person pursuant to a judgment, including a settlement or arbitrator's award approved by a court. However, if an undertaking to indemnify an office holder with respect to such liability is provided in advance, then such an undertaking must be limited to events which, in the opinion of the board of directors, can be foreseen based on the company's activities when the undertaking to indemnify is given, and to an amount or according to criteria determined by the board of directors as reasonable under the circumstances, and such undertaking shall detail the abovementioned foreseen events and amount or criteria;
- reasonable litigation expenses, including attorneys' fees, incurred by the office holder (1) as a result of an investigation or proceeding instituted against him or her by an authority authorized to conduct such investigation or proceeding, provided that (i) no indictment was filed against such office holder as a result of such investigation or proceeding; and (ii) no financial liability was imposed upon him or her as a substitute for the criminal proceeding as a result of such investigation or proceeding or, if such financial liability was imposed, it was imposed with respect to an offense that does not require proof of criminal intent; and (2) in connection with a monetary sanction;
- reasonable litigation expenses, including attorneys' fees, incurred by the office holder or imposed by a court in proceedings instituted against him or her by the company, on its behalf, or by a third party, or in connection with criminal proceedings in which the office holder was acquitted, or as a result of a conviction for an offense that does not require proof of criminal intent; and
- expenses, including reasonable litigation expenses and legal fees, incurred by an office holder in relation to an administrative proceeding instituted against such office holder, or certain compensation payments made to an injured party imposed on an office holder by an administrative proceeding, pursuant to certain provisions of the Israeli Securities Law.

Under the Companies Law and the Israeli Securities Law, a company may insure an office holder against the following liabilities incurred for acts performed by him or her as an office holder if and to the extent provided in the company's articles of association:

- a breach of the duty of loyalty to the company, provided that the office holder acted in good faith and had a reasonable basis to believe that the act would not harm the company;
- a breach of the duty of care to the company or to a third party, to the extent such a breach does not arise out of the negligent conduct of the office holder;
- a financial liability imposed on the office holder in favor of a third party; and
- expenses, including reasonable litigation expenses and legal fees, incurred by an office holder in relation to an administrative proceeding instituted against such office holder or certain compensation payments to an injured party imposed on an office holder by an administrative proceeding, pursuant to certain provisions of the Securities Law.

Under the Companies Law, a company may not indemnify, exculpate or enter into an insurance contract for office holder liability, for any of the following:

- a breach of the duty of loyalty, except for indemnification and insurance for a breach of the duty of loyalty to the company to the extent that the office holder acted in good faith and had a reasonable basis to believe that the act would not prejudice the company;
- a breach of the duty of care committed intentionally or recklessly, excluding a breach arising out of the negligent conduct of the office holder;
- an act or omission committed with intent to derive illegal personal benefit; or
- a fine, monetary sanction or forfeit levied against the office holder.

Under the Israeli Companies Law, exculpation, indemnification and insurance of office holders in a public company must be approved by the compensation committee and the board of directors and, with respect to the chief executive officer or a director or under certain circumstances, also by the shareholders.

Our Amended Articles permits us to exculpate, indemnify and insure our office holders to the fullest extent permitted under the Companies Law. We have entered into indemnification and exculpation agreements with each of our directors. This indemnification is limited to events determined as foreseeable by our Board of Directors based on our activities, as set forth in the indemnification agreements.

We have obtained directors' and officers' liability insurance for the benefit of our office holders and intend to continue to maintain such coverage and pay all premiums thereunder to the fullest extent permitted by the Companies Law, with coverage of \$5 million in the aggregate.

Remuneration of Directors

Under the Companies Law, remuneration of directors is subject to the approval of the compensation committee (until recently of the audit committee), thereafter by the board of directors and thereafter by the general meeting of the shareholders. In case the remuneration of the directors is in accordance with regulation applicable to remuneration of the external directors then such remuneration shall be exempt from the approval of the general meeting.

D. Employees.

As of December 31, 2018, we had four full-time employees and two part-time employees, all located in Israel.

In addition, we engage specialists and consultants in fields such as optics, physics, medicine, mathematical algorithms, biochemistry, regulatory and patents from time to time as required by our operations. Furthermore, Mr. David Ben Naim, our Chief Financial Officer, is engaged by us as an external consultant.

E. Share Ownership.

For information concerning the overall beneficial ownership of our ordinary shares by our executive officers and directors, please see the table in Item 7. “Major Shareholders and Related Party Transactions—Major Shareholders” below.

Todos Medical Ltd. 2015 Share Option Plan

Our Board of Directors administers the Option Plan, including (i) designating participants in the Option Plan; (ii) determining the terms and provisions of respective option agreements, including the number of shares to be covered by each option, exercisability, transferability, and other terms and conditions of the option; (iii) accelerating the right of an option-holder to exercise any previously granted option; (iv) determining the fair market value of the shares; and (v) interpreting the provisions and supervising the administration of the Option Plan. Our Board of Directors may amend or discontinue the Option Plan at any time, except that generally no amendment may impair the rights of an option-holder without his or her written consent.

Share options granted to Israeli employees under the Option Plan may be granted pursuant to the provisions of Section 102 of the Israeli Income Tax Ordinance. Any options granted pursuant to such provision will be issued to a trustee and be held by the trustee for at least two years from the date of grant of the options, as required under the Israeli tax ordinance.

Upon termination of employment or service for any reason, other than for cause or death or disability, the option-holder may exercise his or her vested options within 90 days of the date of termination. If we terminate an option-holder’s employment or service for cause, all of the employee’s options, whether vested or unvested, expire on the termination date. Upon termination of employment or service due to death or disability, the option-holder or his or her estate may exercise his or her vested options within twelve months from the date of death or disability. An option may not, however, be exercised after the option’s expiration date.

Options are non-transferable except in the event of an option holder’s death.

If we are party to a merger or consolidation, outstanding options and shares acquired under the Option Plan will be subject to the agreement of merger or consolidation, which will provide for one or more of the following: (i) the continuation of such options by us, (ii) the assumption of such options by the surviving corporation or its parent, (iii) the substitution by the surviving corporation or its parent of new options, (iv) the cancellation of the such options in exchange for payment equaling the market value of the shares subject to the option less the exercise price, or (v) full exercisability of the option and full vesting of the shares subject to the option.

In the event of any variation in our share capital, including a share dividend, share split, combination or exchange of shares, recapitalization, or any other like event, the number, class and kind of shares subject to the Option Plan and outstanding options, and the exercise prices of the options, will be appropriately and equitably adjusted so as to maintain the proportionate number of shares without changing the aggregate exercise price of the options.

As of March 20, 2019, 1,137,731 options under the Option Plan are vested and unexercised.

ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

A. Major Shareholders

The following table sets forth information regarding beneficial ownership of our Ordinary Shares as of March 20, 2019 by:

- each person, or group of affiliated persons, known to us to be the beneficial owner of more than 5% of our outstanding ordinary shares;
- each of our directors and executive officers; and
- all of our directors and executive officers as a group.

The beneficial ownership of our ordinary shares is determined in accordance with the rules of the SEC and generally includes any shares over which a person exercises sole or shared voting or investment power, or the right to receive the economic benefit of ownership. For purposes of the table below, we deem ordinary shares issuable pursuant to options and warrants that are currently exercisable or exercisable within 60 days of March 20, 2019 to be outstanding and to be beneficially owned by the person holding the options for the purposes of computing the percentage ownership of that person, but we do not treat them as outstanding for the purpose of computing the percentage ownership of any other person.

The percentage of shares beneficially owned has been computed on the basis of 90,386,931 ordinary shares outstanding as of March 20, 2019.

Unless otherwise noted below, the address of each shareholder, director and executive officer is c/o Todos Medical Ltd., 1 HaMada St., Rehovot, Israel.

Except as indicated in footnotes to this table, we believe that the shareholders named in this table have sole voting and investment power with respect to all shares shown to be beneficially owned by them, based on information provided to us by such shareholders. The shareholders listed below do not have any different voting rights from any of our other shareholders.

	No. of Shares Beneficially Owned	Percentage Owned ⁽¹⁾
Holders of more than 5% of our voting securities:		
Amarantus Bioscience Holdings, Inc.	17,986,999	19.99%
Assaf Gold ⁽²⁾	9,225,000	9.83%
D.P.H. Investments Ltd. ⁽³⁾	8,280,000	9.16%
Adeline Holdings Limited ⁽⁴⁾	7,395,976	8.18%
Shmuel Melman	7,260,976	8.03%
S.B. Nihul Merkakein Ltd. ⁽⁵⁾	6,500,000	6.92%
Directors and executive officers:		
Dr. Herman Weiss, CEO and Director	0	*
Rami Zigdon, CBO and Director ⁽⁶⁾	3,423,850	3.78%
Moshe Abramovitz, Director	0	*
Alon Ostrovitzky, Director	0	*
Moshe Schlisser, Director	0	*
Colin Bier	0	*
Ronit Even-Zahav Meitin, Director	0	*
Alon Shalev, Director	0	*
Udi Zelig, CTO	927,375	1.03%
David Ben Naim, CFO	0	*
All directors and executive officers as a group (10 persons)	4,351,225	4.81%

* Indicates beneficial ownership of less than 1% of the total ordinary shares outstanding

(1) The percentages shown are based on 90,386,931 Ordinary Shares issued and outstanding as of March 20, 2019. In addition, the percentages shown assume that the shareholders of the Company approve the assignment and loan conversion agreement among the Company, Adeline Holdings Ltd., Yitzhak Ostrovitzky, Sorry Doll Ltd., and S.B. Nihul Mekarkein Ltd., dated November 28, 2018, described in the Related Party Transactions section below.

- (2) Assuming the shareholders of the Company approve the assignment and loan conversion agreement among the Company, Adeline Holdings Ltd., Yitzhak Ostrovitzky, Sorry Doll Ltd., and S.B. Nihul Mekarkein Ltd., dated November 28, 2018, described in the Related Party Transactions section below. Assaf Gold is the owner of Horizon Design Investment Ltd., which is the owner of Sorry Doll Ltd., which owns 7,000,000 Ordinary Shares, including options to purchase 3,500,000 Ordinary Shares. Mr. Gold also owns fifty percent of Care G.B. Plus Ltd., which owns 2,225,000 Ordinary Shares, with the other fifty percent of these shares owned by Ramot Gilad Ltd, a company owned by Eyal Yona. Mr. Gold and Mr. Yona jointly control the shares of the Company that are held by Care.
- (3) D.P.H. Investments Ltd., or DPH, is an entity that has 18 shareholders, none of whom own more than 17% of DPH. Moshe Abramovitz, a member of our Board of Directors since February 27, 2016, is also a shareholder of DPH. At least five shareholders need to agree before any action with regard to these shares can be taken by DPH. Pursuant to its February 2016 investment, DPH had the right to appoint two members to our Board of Directors. Moshe Schlisser and Moshe Abramovitz were appointed as DPH's representatives on our Board of Directors. Since March 16, 2017 (the date of approval of the Amended Articles), none of our shareholders maintain rights different from the rights of other shareholders and DPH no longer has the right to appoint two members to our Board of Directors. Messrs. Schlisser and Abramovitz remain Board members.
- (4) Mr. Yitzhak Ostrovitzky, the father of Board member Alon Ostrovitzky, has sole voting and sole investment control of the shares held by Adeline Holdings.
- (5) Assuming the shareholders of the Company approve the assignment and loan conversion agreement among the Company, Adeline Holdings Ltd., Yitzhak Ostrovitzky, Sorry Doll Ltd., and S.B. Nihul Mekarkein Ltd., dated November 28, 2018, described in the Related Party Transactions section below. S.B. Nihul's shareholding includes options to purchase 3,500,000 Ordinary Shares. S.B. Nihul is owned by Barouch Saar.
- (6) Includes 1,000 shares underlying a warrant which is currently exercisable and 284,436 employee options which are currently exercisable. Out of the 1,241,163 employee option shares that had been granted to Mr. Zigdon in January 2016, 103,428 vested options were exercised by Mr. Zigdon and are currently held by ESOP Management & Trust Services Ltd. for the benefit of Mr. Zigdon. As of March 20, 2019, 284,436 (22.9%) of these employee option shares have vested and are unexercised.

Changes in Percentage Ownership by Major Shareholders

As part of the Company's joint venture with Amarantus, the Company was granted an option, in effect for sixty (60) days, to acquire the remaining 80.01% of Breakthrough held by Amarantus in exchange for the issuance to Amarantus of Ordinary Shares of the Company representing an additional thirty percent (30%) of the Company, such that upon consummation of the transaction the Company will own 100% of Breakthrough and Amarantus will own 49.99% of the Company. At the annual meeting of shareholders of the Company scheduled for April 29, 2019, the Company's shareholders will vote on a resolution approving the Company's exercise of this option.

Record Holders

Based upon a review of the information provided to us by our transfer agent, as of March 20, 2019, there were a total of 59 holders of record of our shares, of which three record holders who hold 1,759,075 shares, or approximately 1.91% of our outstanding shares, had a registered address in the U.S., thirty-five (35) holders had registered addresses in Israel, 14 holders had registered addresses in Singapore, three holders had registered addresses in Canada, two holders had registered addresses in the United Kingdom, one holder had a registered address in German, and one holder had a registered address in Cyprus.

B. Related Party Transactions

Other than the transactions discussed below and in the section titled Recent Developments above, since January 1, 2018, we have not entered into any transaction nor are there any proposed transactions in which any of our Directors, executive officers, 5% shareholders, or any member of the immediate family of any of the foregoing had or is to have a direct or indirect material interest.

Reseller Agreement with Care G.B. Plus

On December 28, 2018 we entered into a Marketing and Reseller Agreement with Care G.B. Plus Ltd. for the resale of our breast cancer screening products in Israel. Care is fifty-percent owned by Assaf Gold, who was the beneficial owner of 5.49% of our issued and outstanding shares at the time the Care agreement was signed by the Company. Pursuant to the agreement, we appointed Care as our exclusive distributor in Israel, and Care undertook to establish at least one laboratory in Israel to support the assay protocol and to run a fifty (50) patient pilot trial to evaluate the performance of the laboratory and Care's support team. At the annual meeting of shareholders of the Company scheduled for April 29, 2010, the Company's shareholders will vote on a resolution approving the Company's entry into this reseller agreement.

Loans from Shareholders

Sorry Doll Ltd. and S.B. Nihul Mekarkein Ltd.

Mr. Yitzhak Ostrovitzky, the father of one of the Company's directors, Alon Ostrovitzky, granted the Company a loan in order to fund the Company's ongoing operations. This loan had not been memorialized in a written document. Rather, the lender was present during meetings of the Board of Directors, at which the terms of repayment were approved and agreed upon.

By agreement dated November 28, 2018, Yitzhak Ostrovitzky assigned the unpaid balance of his loan in the amount of approximately \$350,000 to Sorry Doll Ltd. ("Sorry Doll") and S.B. Nihul Mekarkein Ltd. ("S.B. Nihul") (together, the "Assignees"). Sorry Doll is owned by Assaf Gold, who was the beneficial owner of 5.49% of our issued and outstanding shares at the time the assignment agreement was signed. S.B. Nihul, while not a related party at the time of the assignment of the loan, will become a related in the event the loan is converted into shares, as described below.

The Company and the Assignees have agreed that, subject to shareholder approval, instead of having the Company repay the loan to the Assignees, the Company will convert the outstanding balance of the Assignees' loan in the amount of approximately \$350,000 into 3,500,000 Ordinary Shares of the Company, par value NIS 0.01, at a conversion price of ten cents (US\$0.10) per share, and grant to each of the Assignees an option to purchase 3,500,000 Ordinary Shares of the Company, par value NIS 0.01, at an exercise price of twenty cents (US\$0.20) per share. The option shall be in effect for five years from November 28, 2018.

If the loan conversion transaction is approved, following the conversion of the loan and the grant of the options, Assaf Gold, will own 9,225,000 Ordinary Shares, representing 9.82% of the Company (assuming exercise of the options) and S.B. Nihul will hold 6,500,000 Ordinary Shares, representing 6.92% of the Company (assuming exercise of the options).

At the annual meeting of shareholders of the Company scheduled for April 29, 2019, the Company's shareholders will vote on a resolution approving the Company's entry into this loan conversion agreement.

DPH Investment Ltd. Loan

On February 27, 2019, we entered into a convertible bridge loan agreement, and issued notes and warrants relating thereto, to obtain an aggregate loan of \$1,350,500 from several private lenders, including DPH Investment Ltd., a holder of 11.5% of our shares (as of such date), to finance the Company's activities through the consummation of a proposed public offering and our planned uplisting to the NASDAQ Capital Market. The loan, which had an original issue discount of ten percent (10%), bears interest at a flat rate of ten percent (10%) and has a maturity date six months after receipt of the loan funds. The loan is convertible into ordinary shares of the Company after the maturity date at a conversion price equal to 70% of the average closing bid price of the Company's Ordinary Shares in the five days prior to the conversion. In the event the Company's defaults under the loan agreement, the conversion price will be reduced to 60% of the average closing bid price of the Company's Ordinary Shares in the 15 days prior to the conversion. In addition, DPH received 25% warrant coverage, with the warrant exercise price to be equal to the offering price in the proposed public offering, or, in the event the loan is converted into shares, the warrant exercise price will be equal to the applicable closing bid price of the Company's shares at the time of the conversion of the loan. The warrant may be exercised upon the lapse of six months following the determination of the warrant exercise price and the number of warrant shares, and for a period of three years thereafter.

On March 10, 2019, we entered into an amendment to the bridge loan agreement. The amendment provides for a 10% penalty if we repay the loan prior to the maturity date. In addition, we agreed to grant DPH an additional 25% warrant coverage, under the same terms as the original warrant, but with a warrant exercise price equal to 150% of the closing bid price of our shares on the day prior to the closing of the bridge loan transaction.

At the annual meeting of shareholders of the Company scheduled for April 29, 2019, the Company's shareholders will vote on a resolution ratifying the Company's entry into this bridge loan agreement with DPH.

Employment Agreements

We have entered into written employment agreements with each of our executive officers, except for our CEO. The Company's Compensation Committee and Board of Directors have approved of a compensation package for our CEO, which will be presented to the shareholders of the Company for approval at the annual meeting of shareholders scheduled for April 29, 2019. A description of the CEO's compensation package appears above in Item 6.B. Compensation -- *Employment Agreements with Executive Officers*. All of these agreements contain customary provisions regarding noncompetition, confidentiality of information and assignment of inventions. However, the enforceability of the noncompetition provisions may be limited under applicable law. In addition, we have entered into agreements with each executive officer and director pursuant to which we have agreed to indemnify each of them up to a certain amount and to the extent that these liabilities are not covered by directors and officers insurance. See "Item 6.B. Compensation" for compensation to our directors and officers.

Options

Since our inception we have granted options to purchase our Ordinary Shares to our officers and our directors. Such option agreements may contain acceleration provisions upon certain merger, acquisition, or change of control transactions. We describe our option plans under "Share Ownership." If the relationship between us and an executive officer or a director is terminated, except for cause (as defined in the various option plan agreements), options that are vested will generally remain exercisable for six months after such termination.

Royalty Payments from BG Negev to our Chief Technology Officer

Dr. Udi Zelig, our Chief Technical Officer, is one of the inventors of the know-how licensed under the agreement, and to the best of our knowledge, is entitled to receive from BG Negev between 10% to 15% of all payments that BG Negev is entitled to receive from us under the license agreement.

Share Transfer from Crow Technologies

On May 2011, Crow Technologies 1977, Ltd. (a company in which Mr. Shmuel Melman, one of our principal shareholders, is one of the controlling shareholders), or Crow, and Mr. Rami Zigdon entered into a share transfer agreement, whereby Mr. Zigdon acquired from Crow 100% of our share capital. Pursuant to the share transfer agreement, Crow was granted the exclusive right to produce our products at a price which will be 50% higher than the fair market value of such production in Israel. We believe that the exclusive right held by Crow is immaterial to the ultimate price for which we will sell our products or the overall cost of producing our products since the exclusive right to manufacture components applies only to electronic components, of which there are not any in our products.

Iberica Investments LLC Consulting Agreement

In February 2015, we entered into a consulting agreement with Iberica Investments LLC, or Iberica, and A.S. Iber Israel Ltd., or Iber, in which, Mr. Moshe Schlisser, who serves as our director, and Mr. Ephraim Schlisser (the father of Mr. Moshe Schlisser and a member of the Wasserman Group) hold managerial positions. Pursuant to the agreement, Iberica agreed to provide assistance with our fundraising efforts, in consideration for up to 10% of the total value of the benefit derived by us, and Iberica assigned its rights and obligations to Iber. From January 1, 2015 through December 31, 2018, we have paid Iber and Iberica approximately \$317,000, pursuant to this consulting agreement. On November 29, 2018, we terminated this agreement.

Employment Agreement with Dr. Wee Yue Chew

On March 16, 2017, our subsidiary, Todos Singapore entered into an employment agreement with Dr. Wee Yue Chew to serve as the managing director of Todos Singapore. The agreement is effective for a term of three years, unless terminated earlier with six months' notice, or shorter notice in the event of special circumstances. Under the agreement, Dr. Wee is entitled to an annual performance bonus at the rate of 4% of Todos Singapore's net profit before tax, if such profit in said year exceeds SGD3,000,000 (approximately \$ 2,150,000). Payment of the bonus is to be made within thirty (30) days from the approval of the financial statements. Todos Singapore is inactive and has not realized any profits. In addition, Dr. Wee received fully vested warrants to purchase 1,000,000 Ordinary Shares, for an exercise price of \$0.10 per share. None of the warrants were exercised and they all expired on June 16, 2017.

Warrants Granted to Dr. Schmitt

On January 17, 2017, we granted Dr. Schmitt, one of the advisors on our Advisory Board, warrants to purchase 620,521 Ordinary Shares at an exercise price of NIS 0.01 per share. As of March 20, 2019, all of these warrants are fully vested. The warrants granted to Dr. Schmitt were issued in consideration of consultancy services provided to us under a consulting agreement dated October 18, 2016. The agreement's initial two-year term has expired, and the parties are negotiating an extension of the term.

C. Interests of Experts and Counsel

Not applicable.

ITEM 8. FINANCIAL INFORMATION.

A. Consolidated Statements and Other Financial Information.

See "Item 18. Financial Statements."

Legal Proceedings

From time to time, we are involved in various routine legal proceedings incidental to the ordinary course of our business. We do not believe that the outcomes of these legal proceedings have had in the recent past, nor will have (with respect to any pending proceedings), significant effects on our financial position or profitability. As of March 20, 2019, we were not a party to any legal proceedings.

Dividends

We have never declared or paid any cash dividends on our Ordinary Shares and do not anticipate paying any cash dividends in the foreseeable future. Payment of cash dividends, if any, in the future will be at the discretion of our Board of Directors and will depend on then-existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects and other factors our Board of Directors may deem relevant.

Payment of dividends may be subject to Israeli withholding taxes. See "Item 10.E. Taxation," for additional information.

B. Significant Changes

No significant change, other than as otherwise described in this annual report on Form 20-F, has occurred in our operations since the date of our consolidated financial statements and the date of the filing of this annual report on Form 20-F.

ITEM 9. THE OFFER AND LISTING

A. Offer and Listing Details

Please see our response to Item 9.C below.

B. Plan of Distribution

Not applicable.

C. Markets

Our Ordinary Shares have been quoted on the OTCQB under the symbol "TOMDF" since March 7, 2017. There has been minimal trading in the Ordinary Shares on the OTCQB. Prior to March 7, 2017, there was no public trading market for the Ordinary Shares.

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. Articles of Association

Our registration number with the Israeli Registrar of Companies is 51-443712-8.

Purposes and Objects of the Company

Our purpose is set forth in Section 2 of the Amended Articles and includes engaging in any type of lawful business.

The Powers of the Directors

Our Board of Directors shall direct our policy and shall supervise the performance of our chief executive officer and his actions. Our Board of Directors may exercise all powers that are not required under the Companies Law or under our Amended Articles to be exercised or taken by our shareholders.

Borrowing Powers

Pursuant to the Israeli Companies Law and our amended and restated articles of association, our Board of Directors may exercise all powers and take all actions that are not required under law or under our amended and restated articles of association to be exercised or taken by our shareholders or other corporate bodies, including the power to borrow money for company purposes.

Rights Attached to Shares

Our Ordinary Shares shall confer upon the holders thereof:

- equal right to attend and to vote at all of our general meetings, whether regular or special, with each Ordinary Share entitling the holder thereof, which attend the meeting and participate at the voting, either in person or by a proxy or by a written ballot, to one vote;
- equal right to participate in distribution of dividends, if any, whether payable in cash or in bonus shares, in distribution of assets or in any other distribution, on a per share pro rata basis; and
- equal right to participate, upon our dissolution, in the distribution of our assets legally available for distribution, on a per share pro rata basis.

Election of Directors

Pursuant to our Amended Articles, our directors are elected at an annual general meeting and/or a special meeting of our shareholders and serve on our Board of Directors until the next annual general meeting (except for external directors) or until they resign or until they cease to act as Board members pursuant to the provisions of our amended and restated articles of association or any applicable law, upon the earlier. In addition, our Amended Articles allow our Board of Directors to appoint directors to fill vacancies and/or as an addition to our Board of Directors (subject to the maximum number of directors) to serve until the next annual general meeting or earlier if required by our Amended Articles or applicable law, upon the earlier. External directors are elected for an initial term of three years and may be removed from office pursuant to the terms of the Companies Law. See "Item 6.C. Board Practices - External Directors."

Annual and Special Meetings

Under the Israeli law, we are required to hold an annual general meeting of our shareholders once every calendar year, at such time and place which shall be determined by our Board of Directors that must be no later than 15 months after the date of the previous annual general meeting. All meetings other than the annual general meeting of shareholders are referred to as special general meetings. Our Board of Directors may call special meetings whenever it sees fit and upon the written request of: (a) any two of our directors or such number of directors equal to one quarter of the directors present at such a meeting; and/or (b) one or more shareholders holding, in the aggregate, 5% of our outstanding voting power.

Notices

The Companies Law requires that a notice of any annual or special shareholders meeting be provided at least 21 days prior to the meeting, and if the agenda of the meeting includes the appointment or removal of directors, the approval of transactions with office holders or interested or related parties, or an approval of a merger, notice must be provided at least 35 days prior to the meeting.

Quorum

As permitted under the Companies Law, the quorum required for our general meetings consists of at least two shareholders present in person, by proxy or written ballot, who hold or represent between them at least 25% of the total outstanding voting rights. If within half an hour of the time appointed for the general meeting a quorum is not present, the general meeting shall stand adjourned the same day of the following week, at the same hour and in the same place, or to such other date, time and place as prescribed in the notice to the shareholders and in such adjourned meeting, if no quorum is present within half an hour of the time arranged, any two shareholders participating in the meeting, shall constitute a quorum.

Adoption of Resolutions

Our Amended Articles provide that all resolutions of our shareholders require a simple majority vote, unless otherwise required under the Companies Law or our Amended Articles. A shareholder may vote in a general meeting in person, by proxy or by a written ballot.

Changing Rights Attached to Shares

Unless otherwise provided by the terms of the shares and subject to any applicable law, in order to change the rights attached to any class of shares, such change must be adopted by the board of directors and at a general meeting of the affected class or by a written consent of all the shareholders of the affected class.

Resolutions regarding the following matters must be passed at a general meeting of our shareholders:

- amendments to our Amended Articles;
- the exercise of our Board of Director's powers if our Board of Directors is unable to exercise its powers
- appointment or termination of our auditors;
- appointment of directors, including external directors;
- approval of acts and transactions requiring general meeting approval pursuant to the provisions of the Companies Law and any other applicable law
- increases or reductions of our authorized share capital; and
- a merger (as such term is defined in the Companies Law).

The enlargement of an existing class of shares or the issuance of additional shares thereof, shall not be deemed to modify the rights attached to the previously issued shares of such class or of any other class, unless otherwise provided by the terms of the shares.

Limitations on the Right to Own Securities in Our Company

There are no limitations on the right to own our securities.

Provisions Restricting Change in Control of Our Company

There are no specific provisions of our Amended Articles 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 our Subsidiary). 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 (1) 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 (2) 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 (1) the purchaser would become a 25% or greater shareholder of the company, unless there is already another 25% or greater shareholder of the company or (2) the purchaser would become a 45% or greater shareholder of the company, unless there is already a 45% or greater shareholder of the company. These requirements do not apply if, in general, the acquisition (1) was made in a private placement that received shareholder approval, (2) was from a 25% or greater shareholder of the company which resulted in the acquirer becoming a 25% or greater shareholder of the company, or (3) was from a 45% or greater shareholder of the company which resulted in the acquirer becoming a 45% or greater shareholder of 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 tender offer may be consummated only if (1) at least 5% of the company’s outstanding shares will be acquired by the offeror and (2) the number of shares tendered in the offer exceeds the number of shares whose holders objected to the offer.

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 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. 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.

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.

Changes in Our Capital

The general meeting may, by a simple majority vote of the shareholders attending the general meeting:

- increase our registered share capital by the creation of new shares from the existing class or a new class, as determined by the general meeting;
- cancel any registered share capital which have not been taken or agreed to be taken by any person;
- consolidate and divide all or any of our share capital into shares of larger nominal value than our existing shares;
- subdivide our existing shares or any of them, our share capital or any of it, into shares of smaller nominal value than is fixed;
- reduce our share capital and any fund reserved for capital redemption in any manner, and with and subject to any incident authorized, and consent required, by the Companies Law; and
- reduce shares from our issued and outstanding share capital, in such manner that those shares shall be cancelled and the nominal par value paid for those shares will be registered on our books as capital fund, which shall be deemed as a premium paid on those shares which shall remain in our issued and outstanding share capital.

Access to Corporate Records

Under the Companies Law, all shareholders of a company generally have the right to review minutes of the company's general meetings, its shareholders register and principal shareholders register, articles of association, financial statements and any document it is required by law to file publicly with the Israeli Registrar of Companies and the Israeli Securities Authority. Furthermore, any of our shareholders may request access to review any document in our possession that relates to any action or transaction with a related party, interested party or office holder that requires shareholder approval under the Companies Law. However, we may deny such a request to review a document if we determine that the request was not made in good faith, that the document contains a commercial secret or a patent or that the document's disclosure may otherwise prejudice our interests.

C. Material Contracts

For a description of the Company's material contracts not entered into in the ordinary course of business, please refer to "Item 7.B. Related Party Transactions."

D. Exchange Controls

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 that are in a state of war with Israel, is not restricted in any way by our Amended Articles or by the laws of the State of Israel.

E. Taxation.

Israeli Tax Considerations and Government Programs

The following is a description of the material Israeli income tax consequences of the ownership of our Ordinary Shares. The following also contains a description of material relevant provisions of the current Israeli income tax structure applicable to companies in Israel, with reference to its effect on us. To the extent that the discussion is based on new tax legislation which has not been subject to judicial or administrative interpretation, there can be no assurance that the tax authorities will accept the views expressed in the discussion in question. The discussion is not intended, and should not be taken, as legal or professional tax advice and is not exhaustive of all possible tax considerations.

The following description is not intended to constitute a complete analysis of all tax consequences relating to the ownership or disposition of our Ordinary Shares. Shareholders should consult their own tax advisors concerning the tax consequences of their particular situation, as well as any tax consequences that may arise under the laws of any state, local, foreign or other taxing jurisdiction.

General Corporate Tax Structure in Israel

Israeli companies are generally subject to corporate tax. As of January 2016, the corporate tax rate was 25%. As of January 1, 2017, the corporate tax rate was reduced to 24% and as of January 1, 2018, the corporate tax rate has been further reduced to 23%. Capital gains derived by an Israeli company are generally subject to the prevailing corporate tax rate.

Tax Benefits and Grants for Research and Development

Tax Benefits for Research and Development

In general, Israeli tax law allows, under certain conditions, a tax deduction for expenditures for scientific research and development projects, for the year in which they are incurred. Expenditures related to scientific research and development projects, would be reduced by the sum of any funds received through government grants for the finance of such scientific research and development projects. No deduction under these research and development deduction rules is allowed if such expenditure was invested in an asset depreciable under the general depreciation rules of the income Tax Ordinance, 1961. In addition, expenditures for scientific research and development projects not approved as deductions under the rules described above are generally deductible in equal amounts over three years, as of the year in which they were paid. From time to time we may apply to the IIA for approval to allow a tax deduction for all research and development expenses during the year incurred. There can be no assurance that such application will be accepted.

Taxation of our Shareholders

In general, under an Israeli tax law an individual would be subject to capital gain tax rate of 25% or 30% if the is a substantial shareholder as defined below (in 2017 and 2018). In addition, an individual would be subject to an “Additional Tax” of 3% on his income exceeding NIS 640,000 (in 2017) or exceeding NIS 641,880 (in 2018). A corporation would be subject to capital gain at a rate of 24% (in 2017) or 23% (in 2018).

Capital Gains Taxes Applicable to Non-Israeli Resident Shareholders. In general, under Israeli tax law, a non-Israeli resident who derives capital gains from the sale of shares in an Israeli resident company will be exempt from Israeli tax so long as the shares were not held through a permanent establishment that the non-resident maintains in Israel and if additional conditions are met. However, non-Israeli corporations will not be entitled to the foregoing exemption if Israeli residents: (i) have a controlling interest of more than 25% in such non-Israeli corporation, whether directly or indirectly, by themselves or with others or (ii) are the beneficiaries of, or are entitled to, 25% or more of the revenues or profits of such non-Israeli corporation, whether directly or indirectly.

Additionally, a sale of securities by a non-Israeli resident may be exempt from Israeli capital gains tax under the provisions of an applicable tax treaty. For example, under Convention Between the Government of the United States of America and the Government of the State of Israel with respect to Taxes on Income, as amended, or the U.S.-Israel Tax Treaty, the sale, exchange or other disposition of shares by a shareholder who is a U.S. resident (for purposes of the U.S.-Israel Tax Treaty) holding the shares as a capital asset, is generally exempt from Israeli capital gains tax if certain conditions are met, unless: (i) the capital gain arising from such sale, exchange or disposition is attributed to real estate located or situated in Israel; (ii) the capital gain arising from such sale, exchange or disposition is attributed to royalties; (iii) the capital gain arising from the such sale, exchange or disposition of business profits as industrial or commercial profits attributed to a permanent establishment of the shareholder in Israel, under certain terms; (iv) such Treaty U.S. Resident holds, directly or indirectly, shares representing 10% or more of the voting capital during any part of the 12-month period preceding the disposition, subject to certain conditions; or (v) such U.S. resident (for purposes of the US-Israel Tax Treaty), holds, directly or indirectly, shares representing 10% or more of the voting capital during any part of the 12-month period preceding the disposition, subject to certain conditions.

In some instances where our shareholders may be liable for Israeli tax on the sale of their Ordinary Shares, the payment of the consideration may be subject to the withholding of Israeli tax at source. Shareholders may be required to demonstrate in advance that they are exempt from tax on their capital gains in order to avoid withholding at source at the time of sale.

Taxation of Non-Israeli Shareholders on Receipt of Dividends. Non-Israeli residents are generally subject to Israeli income tax on the receipt of dividends paid on our Ordinary Shares at the rate of 25% (in 2017 and 2018), which tax will be withheld at source, unless relief is provided in an applicable treaty between Israel and the shareholder’s country of residence. With respect to a person who is a “substantial shareholder” at the time of receiving the dividend or on any time during the preceding twelve months, the applicable tax rate would be 30% (in 2017 and 2018). A “substantial shareholder” is generally defined as a person who alone, or together with his or her relative or another person who collaborates with such person on a regular basis, holds, directly or indirectly, at least 10% of any of the “means of control” of the corporation. “Means of control” generally include the right to vote in a general meeting of the shareholders, the right to receive profits, the right to nominate a director or an executive officer, the right to receive assets upon liquidation, or (after settling the debts) the right to instruct someone who holds any of the aforesaid rights regarding the manner in which he or she is to exercise such right(s), and whether by virtue of shares, rights to shares or other rights, or in any other manner, including by means of voting agreements or trusteeship agreements. In addition, an individual would be subject to an “Additional Tax” of 3% on his income exceeding NIS 640,000 (in 2017) or exceeding NIS 641,880 (in 2018).

U.S. Tax Considerations

The following is a general summary of certain material U.S. federal income tax consequences relating to the purchase, ownership and disposition of our Ordinary Shares by U.S. Holders (as defined below). This summary is based on the Internal Revenue Code, or the Code, the regulations of the U.S. Department of the Treasury issued pursuant to the Code (the “Treasury Regulations”), the U.S.-Israel Tax Treaty, and administrative and judicial interpretations thereof, all as in effect on the date hereof and all of which are subject to change, possibly with retroactive effect, or to different interpretation. No ruling has been sought from the Internal Revenue Service, or the IRS, with respect to any U.S. federal income tax consequences described below, and there can be no assurance that the IRS or a court will not take a contrary position. This summary is no substitute for consultation by prospective investors with their own tax advisors and does not constitute tax advice. This summary does not address all of the tax considerations that may be relevant to specific U.S. Holders in light of their particular circumstances or to U.S. Holders subject to special treatment under U.S. federal income tax law (including, without limitation, banks, insurance companies, tax-exempt entities, retirement plans, regulated investment companies, partnerships, dealers in securities, brokers, real estate investment trusts, certain former citizens or residents of the U.S., persons who acquire our Ordinary Shares as part of a straddle, hedge, conversion transaction or other integrated investment, persons who acquire our Ordinary Shares through the exercise or cancellation of employee stock options or otherwise as compensation for their services, persons that have a “functional currency” other than the U.S. dollar, persons that own (or are deemed to own, indirectly, or by attribution) 10% or more of our shares, or persons that mark their securities to market for U.S. federal income tax purposes). This summary does not address any U.S. state or local or non-U.S. tax considerations, any U.S. federal estate, gift or alternative minimum tax considerations, or any U.S. federal tax consequences other than U.S. federal income tax consequences.

As used in this summary, the term “U.S. Holder” means a beneficial owner of our Ordinary Shares that is, for U.S. federal income tax purposes, (i) an individual citizen or resident of the United States, (ii) a corporation, or other entity taxable as a corporation for U.S. federal income tax purposes, created or organized in or under the laws of the United States, any state thereof, or the District of Columbia, (iii) an estate the income of which is subject to U.S. federal income tax regardless of its source, or (iv) a trust with respect to which a court within the United States is able to exercise primary supervision over its administration and one or more U.S. persons have the authority to control all of its substantial decisions, or that has a valid election in effect under applicable Treasury Regulations to be treated as a “United States person.”

If an entity treated as a partnership for U.S. federal income tax purposes holds our Ordinary Shares, the tax treatment of such entity treated as a partnership and each person treated as a partner thereof generally will depend upon the status and activities of the entity and such person. A holder that is treated as a partnership for U.S. federal income tax purposes should consult its own tax advisor regarding the U.S. federal income tax considerations applicable to it and its partners of the purchase, ownership and disposition of our Ordinary Shares.

Prospective investors should be aware that this summary does not address the tax consequences to investors who are not U.S. Holders. Prospective investors should consult their own tax advisors as to the particular tax considerations applicable to them relating to the purchase, ownership and disposition of our Ordinary Shares, including the applicability of U.S. federal, state and local tax laws and non-U.S. tax laws.

Taxation of U.S. Holders

Distributions. Subject to the discussion below under “Passive Foreign Investment Company,” a U.S. Holder, other than certain U.S. Holders that are U.S. corporations, that receives a distribution with respect to an Ordinary Share generally will be required to include the amount of such distribution in gross income as a dividend (without reduction for any Israeli tax withheld from such distribution) when actually or constructively received to the extent of the U.S. Holder’s pro rata share of our current and/or accumulated earnings and profits (as determined under U.S. federal income tax principles). Any distributions in excess of our earnings and profits will be applied against and will reduce (but not below zero) the U.S. Holder’s tax basis in its Ordinary Shares, and, to the extent they exceed that tax basis, will be treated as gain from the sale or exchange of our Ordinary Shares.

For U.S. Holders that are corporations, the Tax Cuts and Jobs Act, or the TCJA, passed into law on December 20, 2017, provides a 100% deduction for the foreign-source portion of dividends received from “specified 10-percent owned foreign corporations” by U.S. corporate holders, subject to a one-year holding period. No foreign tax credit, including Israeli withholding tax (or deduction for foreign taxes paid with respect to qualifying dividends) would be permitted for foreign taxes paid or accrued with respect to a qualifying dividend. Deduction would be unavailable for “hybrid dividends.”

As noted above, we do not anticipate paying any cash dividends in the foreseeable future. If we were to pay dividends, we expect to pay such dividends in NIS. A dividend paid in NIS, including the amount of any Israeli taxes withheld, will be includible in a U.S. Holder’s income at a U.S. dollar amount calculated by reference to the exchange rate in effect on the date such dividend is received, regardless of whether the payment is in fact converted into U.S. dollars. If the dividend is converted to U.S. dollars on the date of receipt, a U.S. Holder generally will not recognize a foreign currency gain or loss. However, if the U.S. Holder converts the NIS into U.S. dollars on a later date, the U.S. Holder must include, in computing its income, any gain or loss resulting from any exchange rate fluctuations. The gain or loss will be equal to the difference between (i) the U.S. dollar value of the amount included in income when the dividend was received and (ii) the amount received on the conversion of the NIS into U.S. dollars. Such gain or loss generally will be ordinary income or loss and will be U.S. source income or loss for U.S. foreign tax credit purposes. U.S. Holders should consult their own tax advisors regarding the tax consequences to them if we pay dividends in NIS or any other non-U.S. currency.

Subject to certain significant conditions and limitations, any Israeli taxes paid on or withheld from distributions from us and not refundable to a U.S. Holder may be credited against the U.S. Holder’s U.S. federal income tax liability or, alternatively, may be deducted from the U.S. Holder’s taxable income. The election to deduct, rather than credit, foreign taxes, is made on a year-by-year basis and applies to all foreign taxes paid by a U.S. Holder or withheld from a U.S. Holder that year. Dividends paid on the Ordinary Shares generally will constitute income from sources outside the United States and be categorized as “passive category income” or, in the case of some U.S. Holders, as “general category income” for U.S. foreign tax credit purposes. Because the rules governing foreign tax credits are complex, U.S. Holders should consult their own tax advisors regarding the availability of foreign tax credits in their particular circumstances.

Dividends paid on the Ordinary Shares will not be eligible for the “dividends-received” deduction generally allowed to corporate U.S. Holders with respect to dividends received from U.S. corporations, unless the U.S. Holder is a corporation that owns 10 percent or more of our Ordinary Shares.

Certain distributions treated as dividends that are received by an individual U.S. Holder from a “qualified foreign corporation” generally qualify for a 20% reduced maximum tax rate so long as certain holding period and other requirements are met. A non-U.S. corporation (other than a corporation that is treated as a passive foreign investment company, or a PFIC, for the taxable year in which the dividend is paid or the preceding taxable year) generally will be considered to be a qualified foreign corporation (i) if it is eligible for the benefits of a comprehensive tax treaty with the United States which the Secretary of Treasury of the United States determines is satisfactory for purposes of this provision and which includes an exchange of information program, or (ii) with respect to any dividend it pays on stock which is readily tradable on an established securities market in the United States. Dividends paid by us in a taxable year in which we are not a PFIC and with respect to which we were not a PFIC in the preceding taxable year are expected to be eligible for the 20% reduced maximum tax rate, although we can offer no assurances in this regard. However, any dividend paid by us in a taxable year in which we are a PFIC or were a PFIC in the preceding taxable year will be subject to tax at regular ordinary income rates (along with any applicable additional PFIC tax liability, as discussed below).

The additional 3.8% “net investment income tax” (described below) may apply to dividends received by certain U.S. Holders who meet certain modified adjusted gross income thresholds.

Sale, Exchange or Other Taxable Disposition of Ordinary Shares. Subject to the discussion under “Passive Foreign Investment Company” below, a U.S. Holder generally will recognize capital gain or loss upon the sale, exchange, or other taxable disposition of our Ordinary Shares in an amount equal to the difference between the amount realized on the sale, exchange, or other taxable disposition and the U.S. Holder’s adjusted tax basis (determined under U.S. federal income tax rules) in such Ordinary Shares. This capital gain or loss will be long-term capital gain or loss if the U.S. Holder’s holding period in our Ordinary Shares exceeds one year. Preferential tax rates for long-term capital gain (currently, with a maximum rate of 20%) will apply to individual U.S. Holders. The deductibility of capital losses is subject to limitations. The gain or loss generally will be income or loss from sources within the United States for U.S. foreign tax credit purposes, subject to certain possible exceptions under the U.S.-Israel Tax Treaty. The additional 3.8% “net investment income tax” (described below) may apply to gains recognized upon the sale, exchange, or other taxable disposition of our Ordinary Shares by certain U.S. Holders who meet certain modified adjusted gross income thresholds.

U.S. Holders should consult their own tax advisors regarding the U.S. federal income tax consequences of receiving currency other than U.S. dollars upon the disposition of their Ordinary Shares.

Passive Foreign Investment Company. In general, a non-U.S. corporation will be treated as a PFIC for U.S. federal income tax purposes in any taxable year in which either (i) at least 75% of its gross income is “passive income,” or (ii) on average at least 50% of its assets by value produce passive income or are held for the production of passive income. Passive income for this purpose generally includes, among other things, certain dividends, interest, royalties, rents and gains from commodities and securities transactions and from the sale or exchange of property that gives rise to passive income. Passive income also includes amounts derived by reason of the temporary investment of funds, including those raised in a public offering. Assets that produce or are held for the production of passive income include cash, even if held as working capital or raised in a public offering, marketable securities and other assets that may produce passive income. In determining whether a non-U.S. corporation is a PFIC, a proportionate share of the income and assets of each corporation in which it owns, directly or indirectly, at least a 25% interest (by value) is taken into account.

A foreign corporation’s PFIC status is an annual determination that is based on tests that are factual in nature, and our status for any year will depend on our income, assets, and activities for such year. We have not performed an analysis of our PFIC status for our taxable year ended December 31, 2016. In addition, our actual PFIC status for our current taxable year (2017) or any subsequent taxable year is uncertain and will not be determinable until after the end of such taxable year. Accordingly, there can be no assurance with respect to our status as a PFIC for our taxable year ended December 31, 2016 or any subsequent taxable year.

U.S. Holders should be aware of certain tax consequences of investing directly or indirectly in us due to our classification as a PFIC. A U.S. Holder is subject to different rules depending on whether the U.S. Holder makes an election to treat us as a “qualified electing fund,” or a QEF election, for the first taxable year that the U.S. Holder holds Ordinary Shares, makes a “mark-to-market” election with respect to the Ordinary Shares, or makes neither election. An election to treat us as a QEF will not be available if we do not provide the information necessary to make such an election. It is not expected that a U.S. Holder will be able to make a QEF election because we do not intend to provide U.S. Holders with the information necessary to make a QEF election.

QEF Election. One way in which certain of the adverse consequences of PFIC status can be mitigated is for a U.S. Holder make a QEF election. Generally, a shareholder making the QEF election is required for each taxable year to include in income a pro rata share of the ordinary earnings and net capital gain of the QEF, subject to a separate election to defer payment of taxes, which deferral is subject to an interest charge. An election to treat us as a QEF will not be available if we do not provide the information necessary to make such an election. It is not expected that a U.S. Holder will be able to make a QEF election because we do not intend to provide U.S. Holders with the information necessary to make a QEF election.

Mark-to-Market Election. Alternatively, if our Ordinary Shares are treated as “marketable stock,” a U.S. Holder would be allowed to make a “mark-to-market” election with respect to our Ordinary Shares, provided the U.S. Holder completes and files IRS Form 8621 in accordance with the relevant instructions and related Treasury Regulations. If that election is made, the U.S. Holder generally would include as ordinary income in each taxable year the excess, if any, of the fair market value of our Ordinary Shares at the end of the taxable year over such holder’s adjusted tax basis in such Ordinary Shares. The U.S. Holder would also be permitted an ordinary loss in respect of the excess, if any, of the U.S. Holder’s adjusted tax basis in our Ordinary Shares over their fair market value at the end of the taxable year, but only to the extent of the net amount previously included in income as a result of the mark-to-market election. A U.S. Holder’s tax basis in our Ordinary Shares would be adjusted to reflect any such income or loss amount. Gain realized on the sale, exchange or other disposition of our Ordinary Shares would be treated as ordinary income, and any loss realized on the sale, exchange or other disposition of our Ordinary Shares would be treated as ordinary loss to the extent that such loss does not exceed the net mark-to-market gains previously included in income by the U.S. Holder, and any loss in excess of such amount will be treated as capital loss. Amounts treated as ordinary income will not be eligible for the favorable tax rates applicable to qualified dividend income or long-term capital gains.

Generally, stock will be considered marketable stock if it is “regularly traded” on a “qualified exchange” within the meaning of applicable Treasury Regulations. A class of stock is regularly traded on an exchange during any calendar year during which such class of stock is traded, other than in de minimis quantities, on at least 15 days during each calendar quarter. To be marketable stock, our Ordinary Shares must be regularly traded on a qualifying exchange (i) in the United States that is registered with the SEC or a national market system established pursuant to the Exchange Act or (ii) outside the United States that is properly regulated and meets certain trading, listing, financial disclosure and other requirements. Our Ordinary Shares are not currently “marketable stock.”

A mark-to-market election will not apply to our Ordinary Shares held by a U.S. Holder for any taxable year during which we are not a PFIC, but will remain in effect with respect to any subsequent taxable year in which we become a PFIC. Such election will not apply to any PFIC subsidiary that we own. Each U.S. Holder is encouraged to consult its own tax advisor with respect to the availability and tax consequences of a mark-to-market election with respect to our Ordinary Shares.

Each U.S. Holder should consult its own tax adviser with respect to the applicability of the “net investment income tax” (discussed below) where a mark-to-market election is in effect.

Default PFIC Rules. A U.S. Holder who does not make a timely QEF election, or a Non-Electing U.S. Holder, (we do not currently intend to prepare or provide the information that would enable a U.S. Holder to make a QEF election) or a mark-to-market election, will be subject to special rules with respect to (i) any “excess distribution” (generally, the portion of any distributions received by the Non-Electing U.S. Holder on the Ordinary Shares in a taxable year in excess of 125% of the average annual distributions received by the Non-Electing U.S. Holder in the three preceding taxable years, or, if shorter, the Non-Electing U.S. Holder’s holding period for the Ordinary Shares), and (ii) any gain realized on the sale or other disposition of such Ordinary Shares. Under these rules:

- the excess distribution or gain would be allocated ratably over the Non-Electing U.S. Holder’s holding period for such Ordinary Shares;
- the amount allocated to the current taxable year and any year prior to us becoming a PFIC would be taxed as ordinary income; and
- the amount allocated to each of the other taxable years would be subject to tax at the highest rate of tax in effect for the applicable class of taxpayer for that year, and an interest charge for the deemed deferral benefit would be imposed with respect to the resulting tax attributable to each such other taxable year.

If a Non-Electing U.S. Holder who is an individual dies while owning our Ordinary Shares, the Non-Electing U.S. Holder’s successor would be ineligible to receive a step-up in tax basis of such Ordinary Shares. Non-Electing U.S. Holders should consult their tax advisors regarding the application of the “net investment income tax” (described below) to their specific situation.

To the extent a distribution on our Ordinary Shares does not constitute an excess distribution to a Non-Electing U.S. Holder, such Non-Electing U.S. Holder generally will be required to include the amount of such distribution in gross income as a dividend to the extent of our current or accumulated earnings and profits (as determined for U.S. federal income tax purposes) that are not allocated to excess distributions. The tax consequences of such distributions are discussed above under “Taxation of U.S. Holders-Distributions.” Each U.S. Holder is encouraged to consult its own tax advisor with respect to the appropriate U.S. federal income tax treatment of any distribution on our Ordinary Shares.

If we are treated as a PFIC for any taxable year during the holding period of a Non-Electing U.S. Holder, we will continue to be treated as a PFIC for all succeeding years during which the Non-Electing U.S. Holder is treated as a direct or indirect Non-Electing U.S. Holder even if we are not a PFIC for such years. A U.S. Holder is encouraged to consult its tax advisor with respect to any available elections that may be applicable in such a situation, including the “deemed sale” election of Code Section 1298(b)(1) (which will be taxed under the adverse tax rules described above).

We may invest in the equity of foreign corporations that are PFICs or may own subsidiaries that own PFICs. If we are classified as a PFIC, under attribution rules, U.S. Holders will be subject to the PFIC rules with respect to their indirect ownership interests in such PFICs, such that a disposition of the Ordinary Shares of the PFIC or receipt by us of a distribution from the PFIC generally will be treated as a deemed disposition of such Ordinary Shares or the deemed receipt of such distribution by the U.S. Holder, subject to taxation under the PFIC rules. There can be no assurance that a U.S. Holder will be able to make a QEF election or a mark-to-market election with respect to PFICs in which we invest. Each U.S. Holder is encouraged to consult its own tax advisor with respect to tax consequences of an investment by us in a corporation that is a PFIC.

In addition, U.S. Holders should consult their tax advisors regarding the IRS information reporting and filing obligations that may arise as a result of the ownership of Ordinary Shares in a PFIC, including IRS Form 8621, Information Return by a Shareholder of a Passive Foreign Investment Company or Qualified Electing Fund.

The U.S. federal income tax rules relating to PFICs, QEF elections, and mark-to market elections are complex. U.S. Holders are urged to consult their own tax advisors with respect to the purchase, ownership and disposition of our Ordinary Shares, any elections available with respect to such Ordinary Shares and the IRS information reporting obligations with respect to the purchase, ownership and disposition of our Ordinary Shares.

Certain Reporting Requirements

Certain U.S. Holders must report information on IRS Form 8938, Statement of Specified Foreign Financial Assets, with respect to their investments in certain “foreign financial assets,” which would include an investment in our Ordinary Shares, if the aggregate value of all of those assets exceeds certain thresholds. This reporting requirement applies to individuals and certain U.S. entities.

U.S. Holders who fail to report required information could become subject to substantial penalties. U.S. Holders should consult their tax advisors regarding the possible implications of these reporting requirements arising from their investment in our Ordinary Shares.

Backup Withholding Tax and Information Reporting Requirements

Payments in respect of Ordinary Shares may be subject to information reporting to the IRS and to U.S. backup withholding tax at the rate (currently) of 28%. Backup withholding will not apply, however, if you (i) are a corporation or fall within certain exempt categories, and demonstrate the fact when so required, or (ii) furnish a correct taxpayer identification number and make any other required certification.

Backup withholding is not an additional tax. Amounts withheld under the backup withholding rules may be credited against a U.S. Holder’s U.S. tax liability. A U.S. Holder may obtain a refund of any excess amounts withheld under the backup withholding rules by filing the appropriate claim for refund with the IRS.

Medicare Tax on Investment Income

Certain U.S. persons, including individuals, estates and trusts, will be subject to an additional 3.8% Medicare tax, or “net investment income tax,” on unearned income. For individuals, the additional net investment income tax applies to the lesser of (i) “net investment income” or (ii) the excess of “modified adjusted gross income” over \$200,000 (\$250,000 if married and filing jointly or \$125,000 if married and filing separately). “Net investment income” generally equals the taxpayer’s gross investment income reduced by the deductions that are allocable to such income. Investment income generally includes, among other things, passive income such as interest, dividends, annuities, royalties, rents, and capital gains. U.S. Holders are urged to consult their own tax advisors regarding the implications of the additional net investment income tax resulting from their ownership and disposition of our Ordinary Shares.

THE DISCUSSION ABOVE IS A GENERAL SUMMARY. IT DOES NOT COVER ALL TAX MATTERS THAT MAY BE OF IMPORTANCE TO A PROSPECTIVE INVESTOR. EACH PROSPECTIVE INVESTOR IS URGED TO CONSULT ITS OWN TAX ADVISOR ABOUT THE TAX CONSEQUENCES RELATING TO THE PURCHASE, OWNERSHIP AND DISPOSITION OF OUR ORDINARY SHARES IN LIGHT OF THE INVESTOR'S OWN CIRCUMSTANCES, INCLUDING THE CONSEQUENCES OF ANY PROPOSED CHANGE IN APPLICABLE LAWS.

F. Dividends and Paying Agents

Not applicable.

G. Statement by Experts

Not applicable.

H. Documents on Display

We are subject to certain information reporting requirements of the Exchange Act, applicable to foreign private issuers and under those requirements will file reports with the SEC. You may read and copy the annual report on Form 20-F, including the related exhibits and schedules, and any document we file with the SEC without charge at the SEC's public reference room at 100 F Street, N.E., Room 1580, Washington, DC 20549. You may also obtain copies of the documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street, N.E., Room 1580, Washington, DC 20549. Please call the SEC at 1-800-SEC-0330 for further information on the public reference room. The SEC also maintains an Internet website that contains reports and other information regarding issuers that file electronically with the SEC. Our filings with the SEC will also be available to the public through the SEC's website at www.sec.gov.

As a foreign private issuer, we are exempt from the rules under the Exchange Act related to the furnishing and content of proxy statements, and our officers, directors and principal shareholders will be exempt from the reporting and 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 annual, quarterly and current reports and financial statements with the SEC as frequently or as promptly as U.S. domestic companies whose securities are registered under the Exchange Act. However, we will file with the SEC, within 120 days after the end of each fiscal year, or such applicable time as required by the SEC, an annual report on Form 20-F containing financial statements audited by an independent registered public accounting firm.

We maintain a corporate website <http://www.todosmedical.com>. Information contained on, or that can be accessed through, our website and the other websites referenced above do not constitute a part of this annual report on Form 20-F. We have included these website addresses in this annual report on Form 20-F solely as inactive textual references.

I. Subsidiary Information.

Not Applicable.

ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

In the ordinary course of our operations, we are exposed to certain market risks, primarily changes in foreign currency exchange rates and interest rates.

Quantitative and Qualitative Disclosure About Market Risk

We are exposed to market risks in the ordinary course of our business. Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates. Our current investment policy is to invest available cash in bank deposits with banks that have a credit rating of at least A-minus. Accordingly, a substantial majority of our cash and cash equivalents is held in deposits that bear interest.

Given the current low rates of interest we receive, we will not be adversely affected if such rates are reduced. Our market risk exposure is primarily a result of NIS/U.S. dollar exchange rates, which is discussed in detail in the following paragraph.

Foreign Currency Exchange Risk

Our results of operations and cash flow are subject to fluctuations due to changes in NIS/U.S. dollar currency exchange rates. The vast majority of our liquid assets is held in U.S. dollars, and a certain portion of our expenses is denominated in NIS. We expect that the percentage of our NIS denominated expenses will materially decrease in the near future, therefore reducing our exposure to exchange rate fluctuations. We do not hedge our foreign currency exchange risk. In the future, we may enter into formal currency hedging transactions to decrease the risk of financial exposure from fluctuations in the exchange rates of our principal operating currencies. These measures, however, may not adequately protect us from the material adverse effects of such fluctuations.

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

Not applicable.

PART II

ITEM 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES

None.

ITEM 14. MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS AND USE OF PROCEEDS

In March 2017, our shareholders approved our Amended Articles, pursuant to which all shareholders have equal rights. As a result, our preferred shares were converted into Ordinary Shares. In addition, DPH's rights to appoint two directors to our Board of Directors expired and any additional veto rights in respect of other decisions also expired.

ITEM 15. CONTROLS AND PROCEDURES

(a) Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of December 31, 2018, or the Evaluation Date. Based on such evaluation, those officers have concluded that, as of the Evaluation Date, our disclosure controls and procedures are effective in recording, processing, summarizing and reporting, on a timely basis, information required to be included in periodic filings under the Exchange Act and that such information is accumulated and communicated to management, including our principal executive and financial officers, as appropriate to allow timely decisions regarding required disclosure.

(b) Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Exchange Act. Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based principally on the framework and criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission as of the end of the period covered by this report. Based on that evaluation, we have identified a material weakness related to our internal control over financial reporting as of December 31, 2018. As defined in Regulation 12b-2 under the Securities Exchange Act, a "material weakness" is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented, or detected on a timely basis. Specifically, we determined that that in 2018 we didn't have sufficient segregation of duties in the procurement process, and ineffective control environment.

We continue to evaluate the impact of internal control over financial reporting and disclosure controls and procedures. As of December 31, 2018, the ineffectiveness of the Company's internal control over financial reporting was due to the following material weaknesses: lack of segregation of duties in the procurement process, and ineffective control environment.

We have taken action toward remediating this material weakness by segregate duties in the procurement process and by strengthen our control environment. However, the implementation of these initiatives may not fully address any material weakness or other deficiencies that we may have in our internal control over financial reporting.

(c) Attestation Report of the Registered Public Accounting Firm

This annual report on form 20-F does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting due to an exemption for emerging growth companies provided in the JOBS Act.

(d) Changes in Internal Control over Financial Reporting

During the year ended December 31, 2018, there were no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 16A. AUDIT COMMITTEE FINANCIAL EXPERT

Our Board of Directors determined that Mrs. Ronit Even-Zahav shall serve as our audit committee financial expert following the establishment of our audit committee by our Board of Directors.

ITEM 16B. CODE OF ETHICS

We have adopted a written code of ethics that applies to our officers and employees, including our principal executive officer, principal financial officer, principal controller and persons performing similar functions as well as our directors. Our Code of Business Conduct and Ethics is posted on our website at www.todosmedical.com. Information contained on, or that can be accessed through, our website does not constitute a part of this annual report on form 20-F and is not incorporated by reference herein. If we make any amendment to the Code of Business Conduct and Ethics or grant any waivers, including any implicit waiver, from a provision of the code, we will disclose the nature of such amendment or waiver on our website to the extent required by the rules and regulations of the SEC including the instructions to Item 16B of Form 20-F. We have not granted any waivers under our Code of Business Conduct and Ethics.

ITEM 16C. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Fahn Kanne & Co. Grant Thornton Israel has served as our principal independent registered public accounting firm for each of the two years ended December 31, 2017 and 2018. The following table provides information regarding fees paid by us to Fahn Kanne & Co. Grant Thornton Israel for all services, including audit services, for the years ended December 31, 2017 and 2018:

	Year Ended December 31,	
	2018	2017
Audit Fees (1)	\$ 42,000	\$ 42,000
Audit Related Fees	0	0
Tax Fees (2)	0	0
All other Fees	0	0
Total:	\$ 42,000	\$ 42,000

(1) "Audit fees" are aggregate fees for audit services, including fees associated with the annual audit, annual tax report, reviews of our quarterly financial results submitted in Reports of Foreign Private Issuer on Form 6-K, consultation on various accounting issues and audit services provided in connection with other statutory or regulatory filings.

(2) "Tax fees" are fees for tax services rendered by our auditors for tax compliance and for general tax consulting.

Pre-Approval of Auditors' Compensation

Our Board of Directors pre-approves the engagement of our independent registered public accounting firm to perform certain audit and non-audit services.

ITEM 16D. EXEMPTIONS FROM THE LISTING STANDARDS FOR AUDIT COMMITTEES

Not Applicable

ITEM 16E. PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS

Not Applicable

ITEM 16F. CHANGE IN REGISTRANT'S CERTIFYING ACCOUNTANT

Not applicable.

ITEM 16G. CORPORATE GOVERNANCE

Not applicable.

ITEM 16H. MINE SAFETY DISCLOSURE

Not applicable

PART III

ITEM 17. FINANCIAL STATEMENTS

We have elected to provide financial statements and related information pursuant to Item 18.

ITEM 18. FINANCIAL STATEMENTS

The consolidated financial statements and the related notes required by this Item are included in this annual report on Form 20-F beginning on page F-1.

ITEM 19. EXHIBITS.

Exhibit	Description
1.1	Amended and Restated Articles of Association of Todos Medical Ltd. (filed as Exhibit 99.1 to the Company’s current report on Form 6-K (File No. 333-209744) filed on March 30, 2017, and incorporated herein by reference).
2.1	Form of Warrant (filed as Exhibit 4.1 to the Company’s registration statement on Form F-1 (File No. 333-209744) filed on February 26, 2016, and incorporated herein by reference).
4.1	Research and License Agreement with B.G. Negev Technologies and Applications Ltd. and Mor Research Applications Ltd., dated April 26, 2010, as amended June 25, 2012 (filed as Exhibit 10.1 to the Company’s registration statement on Form F-1 (File No. 333-209744) filed on February 26, 2016, and incorporated herein by reference).
4.2	Addendum No. 2 to Research and License Agreement Dated March 19, 2017, as amended on June 25, 2012 with B.G. Negev Technologies and Applications Ltd. and Mor Research Applications Ltd. (filed as Exhibit 4.2 to Form 20-F (File No. 333-209744) filed on May 1, 2017, and incorporated herein by reference).
4.3	Summary English Translation of Lease Agreement for Corporate Offices in Rehovot, Israel (filed as Exhibit 10.4 to the Company’s registration statement on Form F-1 (File No. 333-209744) filed on February 26, 2016, and incorporated herein by reference).
4.4	Todos Medical Ltd. 2015 Israeli Share Option Plan (filed as Exhibit 10.7 to the Company’s registration statement on Form F-1 (File No. 333-209744) filed on February 26, 2016, and incorporated herein by reference).
4.5	Employment Agreement, dated March 16, 2017, between Todos Medical Singapore Pte Ltd. and Dr. Wee Yue Chew and warrant agreement, dated March 16, 2017, between Todos Medical Ltd. and Dr. Wee Yue Chew (filed as Exhibit 4.12 to Form 20-F (File No. 333-209744) filed on May 1, 2017, and incorporated herein by reference).
4.6	Convertible Bridge Loan Agreement, dated February 27, 2019, filed as Exhibit 4.1 to the Company’s Form 6-K filed on February 28, 2019
4.7	Amendment to Convertible Bridge Loan Agreement, dated February 27, 2019, filed as Exhibit 4.1 to the Company’s Form 6-K filed on March 12, 2019
4.8	Share Purchase and Assignment of License Agreement among Todos Medical Ltd., Amarantus Bioscience Holdings, Inc., and Breakthrough Diagnostics, Inc., dated February 27, 2019, filed as Exhibit 4.4 to the Company’s Form 6-K filed on February 28, 2019
4.9	Assignment and Loan Conversion Agreement among the Company, Adeline Holdings Ltd., Yitzhak Ostrovitsky, and Sorry Doll Ltd. and S.B. Nihul Merkakein Ltd., dated November 28, 2018
4.10	Marketing and Reseller Agreement, between the Company and Care G.B. Plus Ltd., dated December 20, 2018
8.1	List of Subsidiaries, filed as Exhibit 21.1 to Company’s amended registration statement on Form F-1/A (File No. 333-209744) filed on July 27, 2016, and incorporated herein by reference.
12.1	Certification of the Chief Executive Officer pursuant to rule 13a-14(a) of the Securities Exchange Act of 1934 furnished herewith.
12.2	Certification of the Principal Financial and Accounting Officer pursuant to rule 13a-14(a) of the Securities Exchange Act of 1934 furnished herewith.
13.1	Certification of the Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. 1350, furnished herewith.
101.INS	XBRL 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

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 Form 20-F filed on its behalf.

Date: March 27, 2019

TODOS MEDICAL LTD.

By: /s/ Herman Weiss
Herman Weiss, M.D.
Chief Executive Officer and Director

TODOS MEDICAL LTD.
FINANCIAL STATEMENTS
AS OF DECEMBER 31, 2018

TODOS MEDICAL LTD.
FINANCIAL STATEMENTS
AS OF DECEMBER 31, 2018
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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Shareholders
Todos Medical Ltd.

Fahn Kanne & Co.

Head Office
32 Hamasger Street
Tel-Aviv 6721118, ISRAEL
PO Box 36172, 6136101

T +972 3 7106666
F +972 3 7106660
www.gtfk.co.il

Opinion on the financial statements

We have audited the accompanying balance sheets of Todos Medical Ltd. (the "Company") as of December 31, 2018 and 2017, the related statements of loss, changes in shareholders' deficit, and cash flows for each of the three years in the period ended December 31, 2018, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1A to the financial statements, the Company has incurred net losses since its inception, and has not yet generated any revenues. As of December 31, 2018, there is an accumulated deficit of \$5,693,353 and shareholders' deficit of \$1,215,934, and current liabilities exceed current assets by \$1,092,651. These conditions, along with other matters as set forth in Note 1A, raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regards to these matters are also described in Note 1A. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's 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 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 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 supporting the amounts and disclosures in the 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 financial statements. We believe that our audits provide a reasonable basis for our opinion.

FAHN KANNE & CO. GRANT THORNTON ISRAEL

We have served as the Company's auditor since 2015.
Tel Aviv, Israel
March 27, 2019

Certified Public Accountants

Fahn Kanne & Co. is the Israeli member firm of Grant Thornton International Ltd

TODOS MEDICAL LTD.
BALANCE SHEETS
(U.S. dollars except share and per share amounts)

	Note	As of December 31,	
		2018	2017
ASSETS			
Current assets:			
Cash and cash equivalents		\$ 63,550	\$ 683,202
Restricted cash		9,343	10,099
Other current assets	3	32,990	19,754
Total current assets		<u>105,883</u>	<u>713,055</u>
Property and equipment, net	4	<u>93,242</u>	<u>103,374</u>
Total assets		<u>\$ 199,125</u>	<u>\$ 816,429</u>
LIABILITIES AND SHAREHOLDERS' DEFICIT			
Current liabilities:			
Short-term loans from third party, net	5	\$ 18,012	\$ -
Fair value of derivative liability related to conversion feature	5	9,000	
Liability for minimum royalties	6, 10B	185,000	135,000
Accounts payable		163,174	-
Short-term loans from shareholders	8	611,925	-
Other current liabilities	7	211,423	109,791
Total current liabilities		<u>1,198,534</u>	<u>244,791</u>
Non-current liabilities:			
Long-term loans from shareholders	8	-	659,526
Liability for minimum royalties – long-term	6, 10B	188,000	188,000
Derivative warrant liability	9	28,525	1,063,745
Total non-current liabilities		<u>216,525</u>	<u>1,911,271</u>
Commitments and contingent liabilities	10		
Shareholders' deficit:			
Ordinary Shares of NIS 0.01 par value each:	11	-	-
Authorized: 1,000,000,000 shares at December 31, 2018 and 2017. Issued and outstanding: 72,230,162 shares and 70,087,141 shares at December 31, 2018 and 2017, respectively		190,679	184,961
Additional paid-in capital		4,286,740	3,711,218
Accumulated deficit		(5,693,353)	(5,235,812)
Total shareholders' deficit		<u>(1,215,934)</u>	<u>(1,339,633)</u>
Total liabilities and shareholders' deficit		<u>\$ 199,125</u>	<u>\$ 816,429</u>

The accompanying notes are an integral part of these financial statements.

TODOS MEDICAL LTD.
STATEMENTS OF LOSS
(U.S. dollars except share and per share amounts)

	Note	Year ended December 31,		
		2018	2017	2016
Research and development expenses, net	13	\$ 459,184	\$ 720,527	\$ 317,907
General and administrative expenses	14	919,694	617,087	410,982
Operating loss		(1,378,878)	(1,337,614)	(728,889)
Financing income (expenses), net	15	921,337	(1,337,758)	75,428
Net loss		<u>\$ (457,541)</u>	<u>\$ (2,675,372)</u>	<u>\$ (653,461)</u>
Basic and diluted net loss per share	17	<u>\$ (0.006)</u>	<u>\$ (0.04)</u>	<u>\$ (0.01)</u>
Basic and diluted weighted average number of ordinary shares outstanding		<u>70,869,924</u>	<u>68,587,261</u>	<u>62,467,556</u>

The accompanying notes are an integral part of these financial statements.

TODOS MEDICAL LTD.
STATEMENTS OF CHANGES IN SHAREHOLDERS' DEFICIT
(U.S. dollars except share and per share amounts)

	Preferred shares, NIS 0.01 Par Value		Ordinary shares, NIS 0.01 Par Value		Additional paid-in capital	Accumulated deficit	Total Shareholders' deficit
	Shares	Amount	Shares	Amount			
BALANCE AT DECEMBER 31, 2015	3,096,195	8,810	59,125,670	154,781	1,215,878	(1,906,979)	(527,510)
CHANGES DURING THE YEAR ENDED DECEMBER 31, 2016:							
Stock-based compensation	237,276	614	-	-	160,816	-	161,430
Issuance of ordinary shares, net of issuance expenses	-	-	4,518,406	11,669	554,900	-	566,569
Exercise of stock options	-	-	103,428	273	-	-	273
Stock-based compensation for consulting services	-	-	-	-	48,750	-	48,750
Net loss for the year	-	-	-	-	-	(653,461)	(653,461)
BALANCE AT DECEMBER 31, 2016	3,333,471	9,424	63,747,504	166,723	1,980,344	(2,560,440)	(403,949)
CHANGES DURING THE YEAR ENDED DECEMBER 31, 2017:							
Exercise of warrants, net of issuance expenses and amount classified to equity upon exercise (see Note 9)	-	-	1,665,000	4,625	1,058,475	-	1,063,100
Issuance of ordinary shares, net of issuance expenses	-	-	1,061,125	3,015	559,538	-	562,553
Exercise of stock options	-	-	81,432	226	-	-	226
Stock-based compensation	18,379	51	-	-	109,957	-	110,008
Conversion of preferred shares into ordinary shares	(3,351,850)	(9,475)	3,351,850	9,475	-	-	-
Stock-based compensation for consulting services	-	-	350,000	897	2,904	-	3,801
Net loss for the year	-	-	-	-	-	(2,675,372)	(2,675,372)
BALANCE AT DECEMBER 31, 2017	- \$	-	70,256,911 \$	184,961 \$	3,711,218 \$	(5,235,812) \$	(1,339,633)
Exercise of warrants, net of issuance expenses and amount classified to equity upon exercise (see Note 9)	-	-	722,500	1,928	451,295	-	453,223
Issuance of ordinary shares	-	-	800,000	2,134	78,211	-	80,345
Exercise of stock options	-	-	620,521	1,656	(1,656)	-	-
Stock-based compensation	-	-	-	-	47,672	-	47,672
Net loss for the year	-	-	-	-	-	(457,541)	(457,541)
BALANCE AT DECEMBER 31, 2018	-	-	72,399,932 \$	190,679 \$	4,286,740 \$	(5,693,353) \$	(1,215,934)

The accompanying notes are an integral part of these financial statements.

TODOS MEDICAL LTD.
STATEMENTS OF CASH FLOWS
(U.S. dollars except share and per share amounts)

	Year ended December 31		
	2018	2017(*)	2016
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	\$ (457,541)	\$ (2,675,372)	\$ (653,461)
Adjustments required to reconcile net loss to net cash used in operating activities:			
Depreciation	25,502	24,083	20,695
Liability for minimum royalties	50,000	238,000	50,000
Changes in fair value of warrants liability and fair value of warrants expired (see Note 9)	(925,910)	1,101,229	(117,577)
Stock-based compensation	47,672	113,758	210,180
Inducement related to warrants exercised (see Note 9)	-	166,500	-
Financing expenses of long-term loans and other NIS denominated balances	(47,589)	66,658	7,962
Decrease (increase) in other current assets	(13,236)	1,120	6,143
Increase (decrease) in accounts payables	163,174	(21,874)	14,491
Increase (decrease) in other current liabilities	101,632	81,488	(7,822)
Net cash used in operating activities	<u>(1,056,296)</u>	<u>(904,410)</u>	<u>(469,389)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of property and equipment	(15,370)	(3,596)	(34,971)
Net cash used in investing activities	<u>(15,370)</u>	<u>(3,596)</u>	<u>(34,971)</u>
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds received from issuance of convertible bridge loan	27,000	-	-
Proceeds allocated to ordinary shares	80,345	562,604	566,569
Proceeds allocated to warrants	19,655	-	244,446
Proceeds from exercise of warrants, net	324,258	599,400	-
Proceeds from exercise of stock options	-	226	273
Repayments of shareholders loans	-	-	(23,529)
Net cash provided by financing activities	<u>451,258</u>	<u>1,162,230</u>	<u>787,759</u>
INCREASE (DECREASE) IN CASH, CASH EQUIVALENTS, AND RESTRICTED CASH	(620,408)	224,254	283,399
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH AT BEGINNING OF YEAR	693,301	439,077	155,678
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH AT END OF YEAR	<u>\$ 72,893</u>	<u>\$ 693,301</u>	<u>\$ 439,077</u>
Supplemental disclosure of non-cash activities:			
Fair value of warrants liability classified to equity in connection with warrants exercised during the period (see Note 9)	<u>\$ 128,965</u>	<u>\$ 297,200</u>	<u>\$ -</u>
During the reported period, the entire balance of preferred shares were converted into ordinary shares (see Note 11)	<u>\$ -</u>	<u>\$ 9,424</u>	<u>\$ -</u>

(*) See Note 2D

The accompanying notes are an integral part of these financial statements.

**TODOS MEDICAL LTD.
NOTES TO FINANCIAL STATEMENTS**

NOTE 1 – GENERAL

A. Operations

Todos Medical Ltd. (the “Company”) was incorporated under the laws of Israel and commenced its operations on April 22, 2010. The Company engages in the development of a series of patient-friendly blood tests for the purpose of early detection of a variety of cancers. The method incorporates biochemistry, physics and signal processing and is based on the cancer’s influence on the immune system which triggers biochemical changes in peripheral blood mononuclear cells. These changes are measured by spectroscopy and examined through a processing algorithm.

The Company’s products in development currently consist of individual kits being developed for blood test detection of breast cancer (TB), and colorectal cancer (TC). Since inception, the Company’s operations have been limited to developing the products and raising capital to fund this development. The Company has not generated any revenues to date.

On January 27, 2016, the Company incorporated a wholly owned subsidiary in Singapore under the name: Todos Medical (Singapore) Pte Ltd. (“Todos Singapore”) for the purpose of conducting clinical trials in the future in Singapore and to obtain possible Singapore government grants to partially finance the conducting of such operations. As of December 31, 2018, Todos Singapore has not yet commenced its business operations and as a result, consolidated financial statements were not prepared.

In August 2016, the Company’s registration statement on Form F-1 was declared effective by the U.S. Securities & Exchange Commission, and as of March 2017, the Company’s shares began to be quoted on the OTCQB under the symbol “TOMDF”.

Going concern uncertainty

The Company has devoted substantially all of its efforts to research and development and raising capital and has not yet generated any revenues. The development and commercialization of the Company’s products are expected to require substantial further expenditures. The Company has not yet generated any revenues from operations, and therefore it is dependent upon external sources for financing its operations. Since inception through December 31, 2018, the Company has incurred accumulated losses of \$5,693,353, current liabilities exceed current assets by \$1,092,651, and shareholders’ deficit of \$1,215,934 and negative operating cash flow for all periods. As of March 20, 2019, the total cash and cash equivalent balance (individual restricted cash) is approximately \$310,000, such balance is expected to be sufficient for at least three months. Management has considered the significance of such condition in relation to the Company’s ability to meet its current obligations and to achieve its business targets and determined that these conditions raise substantial doubt about the Company’s ability to continue as a going concern. The Company plans to finance its operations through the sale of equity and to the extent available, short-term and long-term loans. There can be no assurance that the Company will succeed in obtaining the necessary financing to continue its operations as a going concern. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

B. Risk factors

The Company has a limited operating history and faces various risks, including uncertainties regarding finalization of the development process, demand and market acceptance of the Company’s products, the effects of technological changes, competition and the development of products by competitors. Additionally, other risk factors also exist, such as the ability to manage growth and the effect of planned expansion of operations on the Company’s future results. In addition, the Company expects to continue incurring significant operating costs and losses in connection with the development of its products and marketing efforts. As previously discussed, the Company has not yet generated any revenues from its operations to fund its activities and therefore the Company is dependent on the receipt of additional funding in order to continue its operations.

TODOS MEDICAL LTD.
NOTES TO FINANCIAL STATEMENTS (cont.)

NOTE 2– SIGNIFICANT ACCOUNTING POLICIES

The financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (US GAAP).

A. Use of estimates in the preparation of financial statements

The preparation of the financial statements in conformity with US GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the dates of the financial statements, and the reported amounts of expenses during the reporting periods. Actual results could differ from those estimates. As applicable to these financial statements, the most significant estimates and assumptions relate to the fair value measurement of the derivative warrants liability stock-based compensation and the going concern assumptions.

B. Functional currency

The currency of the primary economic environment in which the operations of the Company are conducted is the U.S dollar (“\$” or “dollar”). Thus, the functional currency of the Company is the dollar (which is also the reporting currency of the Company).

C. Cash and cash equivalents

Cash equivalents are short-term highly liquid investments which include short term bank deposits (up to three months from date of deposit), that are not restricted as to withdrawals or use that are readily convertible to cash with maturities of three months or less as of the date acquired.

D. Restricted Cash

Restricted cash is invested in certificates of deposit, which are used to secure the Company’s line of credit. For presentation of statement of cash flows purposes, restrict cash balances are included with cash and cash equivalents, when reconciling the reported period total amounts.

	<u>December 31</u> <u>2018</u>	<u>December 31</u> <u>2017</u>
Cash and cash equivalents	\$ 63,550	\$ 683,202
Restricted cash	9,343	10,099
Total cash, cash equivalents, and restricted cash shown in the statement of cash flows	<u>\$ 72,893</u>	<u>\$ 693,301</u>

There were no restricted cash amounts as of December 31, 2016.

E. Property, plant and equipment

Property and equipment are stated at cost, net of accumulated depreciation. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets. When an asset is retired or otherwise disposed of, the related cost and accumulated depreciation are removed from the respective accounts and the net difference less any amount realized from disposition is reflected in the Statements of Comprehensive Loss.

<u>Rate of depreciation</u>	<u>%</u>
Laboratory equipment	15
Furniture and equipment	7-15
Computers	33
Vehicle	15

F. Impairment of long-lived assets

The Company’s long-lived assets are reviewed for impairment in accordance with Accounting Standards Codification (“ASC”) Topic 360, “Property, Plant and Equipment”, whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to the future undiscounted cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the asset exceeds its fair value. To date the Company has not incurred any impairment losses.

TODOS MEDICAL LTD.
NOTES TO FINANCIAL STATEMENTS (cont.)

NOTE 2– SIGNIFICANT ACCOUNTING POLICIES (cont.)

G. Deferred income taxes

The Company accounts for income taxes in accordance with ASC Topic 740, “Income Taxes”. Accordingly, deferred income taxes are determined utilizing the asset and liability method based on the estimated future tax effects of differences between the financial accounting and the tax bases of assets and liabilities under the applicable tax law. Deferred tax balances are computed using the enacted tax rates expected to be in effect when these differences reverse. Valuation allowance in respect of deferred tax assets are provided for, if necessary, to reduce deferred tax assets in amounts more likely than not to be realized.

H. Convertible Bridge Loan

The Company has considered the provisions of ASC 815-40, “Derivatives and Hedging - Contracts in Entity’s Own Equity” and determined that the embedded conversion feature of the convertible bridge loan should be bifurcated from the host instrument, as the embedded conversion feature is not considered indexed to the company’s own stock (since the “fixed-for-fixed” concept is not met). accordingly, upon initial recognition, the embedded conversion feature was measured at fair value and the remaining proceeds were allocated to the loan component (Host). In subsequent periods the derivative liability related to the conversion feature is remeasured at fair value through profit or loss (with changes presented within financing income or expense, as applicable) and the remaining bridge loan component is measured at amortized cost. The amount that was allocated to the embedded conversion feature upon initial recognition, created a discount on the loan component. Such discount is amortized as interest expense to profit or loss over the term of the loan until its stated maturity.

I. Deferred income taxes

The Company accounts for uncertain tax positions in accordance with ASC Topic 740-10, which prescribes detailed guidance for the financial statement recognition, measurement and disclosure of uncertain tax positions recognized in an enterprise’s financial statements. According to ASC Topic 740-10, tax positions must meet a more-likely-than-not recognition threshold. The Company’s accounting policy is to classify interest and penalties relating to uncertain tax positions under income taxes, however the Company did not recognize such items in its fiscal 2018, 2017 and 2016 financial statements and did not recognize any liability with respect to an unrecognized tax position in its balance sheets.

J. Liability for employee rights upon retirement

Israeli employees are entitled to severance pay of one month’s salary for each year of employment, or a portion thereof. The Company satisfies its full obligation with respect to its Israeli employees by contributing one month of the employees’ salary for each year of service into a fund managed by a third party. Neither the obligation, nor the amounts deposited on behalf of the employees for such obligation are recorded on the Balance Sheet, as the Company is legally released from the obligation to the employees once the amounts have been deposited. All deposits required through December 31, 2018 have been made.

K. Research and development expenses

Research and development expenses are charged to operations as incurred. Grants received by the Company from the Government of Israel through the Office of the Chief Scientist of the Ministry of Industry, Trade and Labor (the “OCS”) for the development of approved projects are recognized as a reduction of expenses against the related costs incurred.

L. Royalty-bearing grants

Royalty-bearing grants from the OCS for funding approved research and development projects are recognized at the time the Company is entitled to such grants (i.e. at the time that there is reasonable assurance that the Company will comply with the conditions attached to the grant and that there is reasonable assurance that the grant will be received), on the basis of the costs incurred and reduce research and development costs - see Note 10A. and Note 13. The cumulative research and development grants received by the Company from inception through December 2018 amounted to \$272,237.

As of December 31, 2018, and 2017, the Company did not accrue for or pay any royalties to the OCS as no revenue has yet been generated.

TODOS MEDICAL LTD.
NOTES TO FINANCIAL STATEMENTS (cont.)

NOTE 2– SIGNIFICANT ACCOUNTING POLICIES (cont.)

M. Basic and diluted net loss per ordinary share

Basic net loss per ordinary share is computed by dividing the net loss for the period applicable to ordinary shareholders, by the weighted average number of ordinary shares outstanding during the period. Securities that may participate in dividends with the ordinary shares (such as the convertible preferred shares that were outstanding until March 16, 2017) are considered in the computation of basic loss per share under the two-class method. However, in periods of net loss, only the convertible preferred shares were considered, since such shares had a contractual obligation to share in the losses of the Company, in accordance with the guidance in ASC Topic 260-10.

Diluted loss per share gives effect to all potentially dilutive common shares outstanding during the year using the treasury stock method with respect to stock options and stock warrants and using the if-converted method with respect to convertible loans. In computing Diluted loss per share, the average stock price for the period is used in determining the number of shares assumed to be purchased from the exercise of stock options or warrants. Diluted loss per share excludes all potentially dilutive shares if their effect is anti-dilutive.

N. Stock-based compensation

The Company measures and recognizes the compensation expense for all equity-based payments to employees based on their estimated fair values in accordance with ASC 718, “Compensation-Stock Compensation”. Share-based payments including grants of stock options are recognized in the statement of net loss as an operating expense based on the fair value of the award at the date of grant. The fair value of stock options granted is estimated using the Black-Scholes option-pricing model. The Company has expensed compensation costs, net of estimated forfeitures, applying the accelerated vesting method, over the requisite service period or over the implicit service period when a performance condition affects the vesting, and it is considered probable that the performance condition will be achieved.

Share-based payments awarded to consultants (non-employees) are accounted for in accordance with ASC Topic 505-50, “Equity-Based Payments to Non-Employees”.

O. Fair Value Measurements

The Company measures and discloses fair value in accordance with the Financial Accounting Standards Board (“FASB”), Accounting Standards Codification 820, Fair Value Measurements and Disclosures (“ASC Topic 820”). ASC Topic 820 defines fair value, establishes a framework and gives guidance regarding the methods used for measuring fair value, and expands disclosures about fair value measurements. Fair value is an exit price, representing the amount 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. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions there exists a three-tier fair-value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1 - unadjusted quoted prices are available in active markets for identical assets or liabilities that the Company has the ability to access as of the measurement date

Level 2 – pricing inputs are other than quoted prices in active markets that are directly observable for the asset or liability or indirectly observable through corroboration with observable market data.

Level 3 – pricing inputs are unobservable for the non-financial asset or liability and only used when there is little, if any, market activity for the non-financial asset or liability at the measurement date. The inputs into the determination of fair value require significant management judgment or estimation. Level 3 inputs are considered as the lowest priority within the fair value hierarchy. The valuation of the short-term liability relating to the warrants issued to the unit owners (see Note 2N and Note 9) falls under this category.

This hierarchy requires the Company to use observable market data, when available, and to minimize the use of unobservable inputs when determining fair value.

The fair value of cash and cash equivalents is based on its demand value, which is equal to its carrying value. Additionally, the carrying value of all other short term monetary assets and liabilities are estimated to be equal to their fair value due to the short-term nature of these instruments.

TODOS MEDICAL LTD.
NOTES TO FINANCIAL STATEMENTS (cont.)

NOTE 2– SIGNIFICANT ACCOUNTING POLICIES (cont.)

P. Warrants Liability

During 2018, 2016 and 2015, the Company issued 600,000, 4,518,406 and 3,106,000 warrants, respectively, to purchase shares of the Company’s ordinary-stock in connection with a Private Placement Memorandum (“PPM”). The Company accounted for these warrants as a liability measured at fair value due to a provision included in the warrants agreement that provides the warrants holders with an option to require the Company to purchase their warrants for cash in an amount equal to their Black-Scholes Option Pricing Model value (the Black-Scholes Model), in the event that certain fundamental transactions (which some of them are not considered solely within the control of the Company) as defined in the warrant agreement, occur. The fair value of the warrants liability is estimated using the Black-Scholes Model which requires inputs such as the expected term of the warrants, share price volatility and risk-free interest rate. These assumptions are reviewed on a regular basis and changes in the estimated fair value of the outstanding warrants are recognized each reporting period as part of in the “Financing Expense, net” line in operations in the accompanying statement of loss.

Q. Concentrations of credit risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents as well as certain other current assets that do not amount to a significant amount. Cash and cash equivalents, which are primarily held in Dollars and New Israeli Shekels, are deposited with major banks in Israel. Management believes that such financial institutions are financially sound and, accordingly, minimal credit risk exists with respect to these financial instruments. The Company does not have any significant off-balance-sheet concentration of credit risk, such as foreign exchange contracts, option contracts or other foreign hedging arrangements.

R. Contingencies

The Company records accruals for loss contingencies arising from claims, litigation and other sources when it is probable that a liability has been incurred and the amount can be reasonably estimated. These accruals are adjusted periodically as assessments change or additional information becomes available. Legal costs incurred in connection with loss contingencies are expensed as incurred.

S. Recent Accounting Pronouncements

1. Commencing January 1, 2018, the Company early adopted ASU 2016-18, Statement of Company’s consolidated financial statements Cash Flows (Topic 230): “Restricted Cash”, which requires companies to include amounts generally described as restricted cash and restricted cash equivalents in cash and cash equivalents when reconciling beginning-of-period and end-of-period total amounts shown on the statement of cash flows. The amendments in this update are effective for public business entities for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years.

ASU 2016-18 requires application using a retrospective transition method. The Company adopted ASU 2016-18, January 1, 2018 using the retrospective transition method, as required by its provisions. As a result, the Company has retrospectively applied this guidance to the accompanying consolidated statement of cash flows for the year ended December 31, 2017. There were no restricted cash balances during 2016.

2. In May 2017, the FASB issued ASU 2017-09, “Compensation-Stock Compensation”. The amendment provides guidance about which changes to terms or conditions of a share-based payment award require an entity to apply modification accounting. The guidance became effective for the fiscal year beginning on January 1, 2018, including interim periods within that year.

This guidance had no material impact on the Company’s consolidated financial statements.

TODOS MEDICAL LTD.
NOTES TO FINANCIAL STATEMENTS (cont.)

NOTE 2– SIGNIFICANT ACCOUNTING POLICIES (cont.)

S. Recent Accounting Pronouncements (cont.)

3. In February 2016, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update No. 2016-02 (Topic 842) “Leases”. Topic 842 supersedes the lease requirements in ASC Topic 840, “Leases”. Under Topic 842, lessees are required to recognize assets and liabilities on the balance sheet for most leases and provide enhanced disclosures. ASU No. 2016-02 is effective for interim and annual reporting periods beginning after December 15, 2018. In July 2018, the FASB issued amendments in ASU 2018-11, which provide a transition election to not restate comparative periods for the effects of applying the new standard. This transition election permits entities to change the date of initial application to the beginning of the earliest comparative period presented, or retrospectively at the beginning of the period of adoption through a cumulative-effect adjustment.

The company is not involved in any financing leases as a lessor. Based on the current operating leases of the company as a lessee, the company believes that the provisions of ASU 2016-02 will not have a material impact on the financial statements.

4. In June 2018, the Financial Accounting Standards Board (“FASB”) issued ASU 2018-07, “Improvements to Nonemployee Share-Based Payment Accounting”, which simplifies the accounting for share-based payments granted to nonemployees for goods and services. Under the ASU, most of the guidance on such payments to nonemployees would be aligned with the requirements for share-based payments granted to employees. The changes take effect for public companies for fiscal years starting after December 15, 2018, including interim periods within that fiscal year. For all other entities, the amendments are effective for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020. Early adoption is permitted, but no earlier than an entity’s adoption date of Topic 606.

The Company is currently evaluating the impact of adopting this standard on its financial statements and related disclosures, if any.

NOTE 3 – OTHER CURRENT ASSETS

	As of December 31,	
	2018	2017
Prepaid expenses	\$ 21,000	\$ -
Governmental institutions	6,117	8,444
Others	5,873	11,310
	\$ 32,990	\$ 19,754

NOTE 4 – PROPERTY AND EQUIPMENT, NET

	As of December 31,	
	2018	2017
Laboratory equipment & other	\$ 151,065	\$ 139,093
Computers	7,180	3,782
Vehicle	5,204	5,204
Furniture and equipment	13,046	13,046
	176,495	161,125
Less - accumulated depreciation	(83,253)	(57,751)
Total property and equipment, net	\$ 93,242	\$ 103,374

Related depreciation expense was \$25,502 in 2018, \$24,083 in 2017, and \$20,695 in 2016.

TODOS MEDICAL LTD.
NOTES TO FINANCIAL STATEMENTS (cont.)

NOTE 5 – SHORT-TERM LOANS FROM THIRD PARTY

On December 30, 2018, the Company signed a bridge loan agreement with an investor for a total amount of Thirty Thousand U.S. Dollars (US\$30,000). The loan principal will bear interest at a flat rate of ten percent (10%) of the loan principal over the period of 6 months (the initial term of the loan). In addition, 10% of the loan principal was deducted upfront as an original issue discount. The loan principal plus the interest shall be due six (6) months after the date of the loan (the “Maturity Date”).

The investor shall have at any time after the Maturity Date the option to convert the loan principal plus the unpaid interest into Ordinary Shares of the Company, at a conversion price equal to 70% of the lowest closing price of the Company’s Ordinary Shares in the five (5) days prior to the conversion as quoted by Bloomberg, LP. In the event of default by the Company, the investor shall have the option to convert the loan principal plus the interest into Ordinary Shares of the Company, at a conversion price equal to 60% of the lowest closing price of the Company’s Ordinary Shares in the fifteen (15) days prior to the conversion as quoted by Bloomberg, LP.

Upon the consummation of the Company’s proposed public offering and upon listing to the NASDAQ Market System, the Company shall deliver to the investor an Ordinary Share Purchase Warrant (the “Warrant”), providing the investor with a right to purchase such number of fully-paid and non-assessable restricted Ordinary Shares of the Company that is equal in value to twenty-five percent (25%) of the investor’s loan principal, at an exercise price that is equal to the price of the Company’s shares in the public offering (the “Warrant Shares”), or in the event that the investor converts the loan principal into Ordinary Shares of the Company, then the Company shall issue the Warrant to such investor concurrently with the issuance of the conversion shares, and the exercise price for the Warrant Shares shall be the closing price of the Company’s Ordinary Shares, as applicable, on the conversion date of the loan principal. The investor may exercise the Warrant at any time starting six (6) months following the grant of such Warrant and up to three (3) years thereafter. The table below details the carrying value of the loan as of December 31, 2018:

	As of December 31,	
	2018	2017
Short-term loan principal (see Note 10)	\$ 30,012	\$ -
Less: original issue discount	(3,000)	-
Less: Fair value of derivative instrument	(9,000)	-
	\$ 18,012	\$ -

NOTE 6 – LIABILITY FOR MINIMUM ROYALTIES

At inception of the Company, the Company entered into a license agreement with B.G. Negev Technologies and Applications Ltd. (a wholly owned subsidiary of Ben Gurion University – Israel) and Mor Research Applications Ltd. (a wholly owned subsidiary of Clalit Medical Services – Israel). According to the license agreement, the Company is committed to pay minimum royalties to the licensors some of which are payable without any connection to the Company’s sales (see also Note 10B).

NOTE 7 – OTHER CURRENT LIABILITIES

	As of December 31,	
	2018	2017
Accrued payroll and related taxes	\$ 111,076	\$ 16,424
Provision for vacation	12,807	5,392
Accrued expenses	87,540	87,975
	\$ 211,423	\$ 109,791

TODOS MEDICAL LTD.
NOTES TO FINANCIAL STATEMENTS (cont.)

NOTE 8 – SHORT-TERM LOANS FROM SHAREHOLDERS

During the years 2011-2014, the Company received loans from two separate shareholders. The loans mature on December 31, 2019 and bear no interest. The loans are denominated in New Israel Shekels (NIS) and are linked to the Israeli consumer price index as of January 1, 2015. The loans may be prepaid by the Company from time to time according to the Company's cash availability.

During 2016, the Company repaid one of the shareholders an aggregate amount of \$23,529 on account of the loan.

In November 2018, the company entered into agreement with one of the shareholders to assign his loan in the amount of US\$350,000 to S.B. Nihul Mekarkein Ltd. and Sorry Doll Ltd collectively (the beneficiary). According to the agreement, the Company and the beneficiary agreed to convert the loan into Ordinary Shares of the Company at a conversion price of US\$0.10 per share, (3,500,000 Shares). The conversion of the loan into Ordinary Shares will be completed within 3 business days of shareholder approval of the conversion transaction. In addition, the Company agreed to grant the beneficiary an option to purchase twice the amount of the conversion shares, (7,000,000 ordinary shares) at a price-per-share of US\$0.20 for a period of 5 years from the signing of the conversion agreement.

As the agreement is subject to the shareholder approval which has not yet been obtained, the loan as of the date of approval of these financial statements is presented according to the original terms and conditions, as a short-term loan.

NOTE 9 – DERIVATIVE WARRANTS LIABILITY

The Company allocated approximately \$19,655, \$244,000 and \$168,000, for the years ended December 31, 2018, 2016 and 2015, respectively, of proceeds from its units under the Private Placement Memorandum ("PPM") (See also Note 10F. and 2M.) to the fair value of 600,000, 4,518,406 and 3,106,000 warrants issued during 2018, 2016 and 2015, respectively, in connection with the PPM that are classified as a liability. The warrants are classified as a liability because of provisions in such warrants that allow for the net cash settlement of such warrants in the event of certain fundamental transactions, as defined in the warrant agreement (some of which are not considered solely within the control of the Company).

The remaining outstanding warrants and terms as of December 31, 2018 and 2017 is as follows:

<u>Issuance date</u>	<u>Outstanding as of December 31, 2017</u>	<u>Outstanding as of December 31, 2018</u>	<u>Exercise Price</u>	<u>Exercisable as of December 31, 2018</u>	<u>Exercisable Through</u>
Series (2015)	3,106,000	1,502,500	\$ 0.5	1,502,500	April 2021
Series (2016)	2,853,406	2,628,406	\$ 0.5	2,628,406	May 2019
Series (2018)	-	600,000	\$ 0.125	600,000	November 2021
	5,959,406	4,730,906			

Since certain conditions in the warrant agreements do not meet the specific conditions for equity classification, the Company is required to classify the fair value of these warrants as a liability, with changes in fair value to be recorded as income (loss) due to change in fair value of warrant liability. The estimated fair value of warrant liability at December 31, 2018 and December 31, 2017, was \$28,525 and \$1,063,745, respectively.

As quoted prices in active markets for identical or similar warrants are not available, the Company uses directly observable inputs in the valuation of its derivative warrant liabilities (level 3 measurement).

The Company uses the Black-Scholes valuation model to estimate fair value of these warrants. In using this model, the Company makes certain assumptions about risk-free interest rates, dividend yields, volatility, expected term of the warrants and other assumptions. Risk-free interest rates are derived from the yield on U.S. Treasury debt securities. Dividend yields are based on our historical dividend payments, which have been zero to date. The expected term of the warrants is based on the time to expiration of the warrants from the date of measurement.

TODOS MEDICAL LTD.
NOTES TO FINANCIAL STATEMENTS (cont.)

NOTE 9 – DERIVATIVE WARRANTS LIABILITY (cont.)

During April 2017, the Company offered to the holders of the warrants to lower the exercise price of the warrants from \$0.5 per share to \$0.4 per share for a limited period of time of 8 weeks.

As a result of such offer, during May 2017, certain holders exercised 1,665,000 warrants into the same number of Ordinary Shares for cash consideration of \$666,000.

The fair value of the inducement was measured in an amount of \$166,500. Such amount was recognized as an additional financing expense in the Company's Statement of Loss for the year ended December 31, 2017.

As of the date of exercise, the fair value of the warrants exercised which amounted to \$297,200 (after consideration of the effect of the inducement), was reclassified to equity rather than derivative warrant liabilities.

During May 2018, the Company offered to the holders of the warrants the option to convert 25% of the warrants into shares in exchange for extending the exercise the period of their warrants for an additional 3 years.

As a result of such offer, during May 2018, certain holders exercised 722,500 warrants into the same number of Ordinary Shares for cash consideration of \$361,250.

As of December 2018, a total of 1,106,000 warrants from series (2015) expired in a total amount of \$178,498.

The following table summarizes the observable inputs used in the valuation of the derivative warrant liabilities as of December 31, 2018 and December 31, 2017:

	As of December 31, 2018			As of December 31, 2017	
	Series (2015)	Series (2016)	Series (2018)	Series (2015)	Series (2016)
	\$	\$	\$	\$	\$
Share price (U.S. dollars)	0.094	0.094	0.094	0.59	0.59
Exercise price (U.S. dollars)	0.5	0.5	0.125	0.5	0.5
Expected volatility	63%	63%	63%	67%	67%
Risk-free interest rate	2.92%	2.92%	2.92%	1.0%	1.0%
Dividend yield	-	-	-	-	-
Expected term (years)	2.4	0.47	2.88	0.37	0.77
		Series (2015)	Series (2016)	Series (2018)	Total
Balances at December 31, 2016		\$ 76,768	\$ 182,948	-	\$ 259,716
Exercised		-	(297,200)	-	(297,200)
Changes in fair value		477,648	623,581	-	1,101,229
Balances at December 31, 2017		\$ 554,416	\$ 509,329	-	\$ 1,063,745
Amount classified to equity upon exercise expired		(88,803)	(40,162)	-	(128,965)
		(178,498)	-	-	(178,498)
Issued		-	-	19,655	19,655
Changes in fair value		(281,119)	(466,293)	-	(747,412)
Balances at December 31, 2018		<u>\$ 5,996</u>	<u>\$ 2,874</u>	<u>19,655</u>	<u>\$ 28,525</u>

In accordance with ASC-820-10-50-2(g), the Company has performed a sensitivity analysis of the derivative warrant liabilities of the Company which are classified as level 3 financial instruments. The Company recalculated the value of warrants by applying a +/- 5% changes to the input variables in the Black-Scholes model that vary overtime, namely, the volatility and the risk-free rate. A 5.0% decrease or increase in volatility would not have materially changed the value of the warrants. A 5.0% decrease or increase in the risk-free rate would not have materially changed the value of the warrants; the value of the warrants is not strongly correlated with small changes in interest rates. The Company estimates the share price of \$0.125 as share value representative of the last price the Company raised capital from private issuers in November 2018. As of December 31 2018 the Company recorded \$925,910 in the finance expenses with \$178k relating to warrants expiration.

TODOS MEDICAL LTD.
NOTES TO FINANCIAL STATEMENTS (cont.)

NOTE 10 – COMMITMENTS AND CONTINGENT LIABILITIES

- A. From 2012 through 2013, the Company received grants from the OCS (Office of the Chief Scientist) in the total amount of \$162,017, for its plans to develop a series of patient-friendly blood tests that enable the early detection of a variety of cancers (the “Development Plan”). Such contingent obligation has no expiration date. During 2016, the OCS approved further grants (under the same terms) up to a maximum amount of approximately \$185,000, of which the Company received \$110,220 during 2016. The receipt of such amounts is dependent on numerous conditions being met. No amounts were received during 2017 and 2018. The Company is required to pay royalties to the OCS at a rate of 3% in the first three years and 3.5% starting from the fourth year, of the proceeds from the sale of the Company’s products arising from the Development Plan up to an amount equal to \$272,237, plus annual interest equal to 12-month LIBOR applicable to dollar deposit.
- B. At inception of the Company, the Company entered into a license agreement with B.G. Negev Technologies and Applications Ltd (a wholly owned subsidiary of Ben Gurion University – Israel) and Mor Research Applications Ltd. (a wholly owned subsidiary of Clalit Medical Services – Israel) (the “Licensors”) in which the Company obtained an exclusive world-wide license to develop, research, commercialize, produce, market and sub-license, products based on the Licensors’ technology. The Company’s technology is built on this license which is therefore material to the Company. According to the license agreement, future royalties would be paid to the licensors based on the following royalty rates:

On net sales of:	<u>%</u>
• leukemia related products	3.0
• other products	2.5
• in certain limited circumstances, rates may be reduced to	2.0
On fixed sublicense income (with no sublicense income on sales by sub licensee):	<u>%</u>
• leukemia related products	20.0
• other products	15.0
On fixed sublicense income (with sublicense income on sales by sub licensee):	<u>%</u>
• leukemia related products	10.0
• other products	7.5

Without any connection to the Company’s sales, the Company is required to pay minimum royalties to the Licensors according to the following schedule (subject to the termination clause described below):

1. Year 2015 - \$10,000
2. Year 2016 - \$25,000
3. Year 2017 and on - \$50,000 per year.

In any specific year, the total royalties payable to the Licensors shall be the higher of:

- the regular royalties based on the royalty rates as described above and
- the minimum royalties.

The minimum royalties will be paid to the Licensors regardless of whether the Company succeeds in generating revenues from sales of the products arising from the usage of the Licensors’ technology.

The license agreement is for an unlimited term, unless terminated earlier by either of the parties. Each party is entitled to terminate the agreement as a result of a material breach or a failure to comply with a material term by the other party, as a result of liquidation or insolvency of the other party (“Termination for Cause”). In addition, the Company was entitled to terminate the agreement if at any time, during the period of 7 years following the effective date of the transaction, the Company, at its sole discretion, determined that commercialization of the leukemia licensed products is not commercially viable. After such period, the Company is not entitled to terminate this license agreement other than in accordance with the Termination for Cause provisions. As of December 31, 2018, the Company did not reach a determination regarding the viability of the commercialization of the leukemia licensed products.

TODOS MEDICAL LTD.
NOTES TO FINANCIAL STATEMENTS (cont.)

NOTE 10 – COMMITMENT AND CONTINGENT LIABILITIES (cont.)

B. (cont.)

However, since the 7-year period ended prior to December 31, 2018, the Company may not terminate the agreement other than Termination for Cause. The Company has accrued the amount of the non-cancellable minimum royalties and the future liability with respect to the commitment to pay minimum royalties to the Licensors for any future periods in a total amount of \$373,000 of which \$185,000 is considered a current liability and \$188,000 is considered non-current. This balance was measured based on the future cash payments discounted using an interest rate of 21% which represents, according to management estimate, the applicable rate of risk for the Company.

During 2017, the Company and the Licensors agreed on an amendment to the agreement in respect of the years 2015, 2016 and 2017 (in an aggregate amount of \$85,000), according to which the minimum royalties payable to the Licensors shall be paid on the earlier of (i) August 1, 2017; and (ii) within 3 days following the date on which the Company shall have received an equity investment with net proceeds of not less than \$10,000,000. As of December 31, 2018, the Company had not paid any of the minimum royalties to the Licensors with respect to any of the years 2015 through 2018. The Company and the Licensor are negotiating to further amend the agreement in respect of the amounts of the minimum royalties.

C. In January 2015, the Company signed a one-year lease agreement for the lease of 108 sq. m. of office space in Rehovot, Israel for a monthly consideration of NIS 6,780 (approximately \$1,830). The lease was renewed by the Company on February 1, 2018 for an additional term of one year at NIS 7,200 (approximately \$1,892) per month, with automatic renewal for a second one-year period at NIS 7,400 per month, unless one party provides the other with written notice of non-renewal. Lease payments are linked to the Israeli CPI based on the CPI published on February 15, 2015, which until December 31, 2018, has not changed significantly. The total expected future lease commitments from January 2019 and onwards (until December 2019) are approximately NIS 84,000 (\$22,000).

D. In October 2015, the Company signed an agreement with a non-Israeli company to procure governmental and quasi-governmental grants to support the research and development of the Company. The agreed upon fee for such service is totally dependent on the success of obtaining such grants, so that the Company will never incur a net cost in this regard. After paying approximately \$56,000, the Company will thereafter pay 10% of the grants received. During 2016, the Company received approximately \$56,000, which was paid out as per the above-mentioned agreement. As of December 31, 2018, the Company did not receive and does not expect to receive any amounts regarding this agreement.

E. Care G.B Plus Ltd

On December 20, 2018, the Company signed an exclusive reseller agreement with Care G.B. Plus Ltd (the Reseller) to market, distribute, and resell the Company's breast cancer screening products to customers located in and taking delivery in the State of Israel (the Territory). The agreement is subject to approval by the shareholders of the Company.

The Reseller's exclusive right to market and sell the Products in the Territory is subject to the Reseller achieving milestones set by both parties. As of December 31, 2018, the Company has not yet generated any sales.

F. Ostrovitsky loan conversion

In November 2018, the Company entered into agreement with one of its shareholders to assign his loan to S.B. Nihul Mekarkein Ltd. and Sorry Doll Ltd. (the beneficiary). According to the agreement, the Company and the beneficiary agreed to convert the loan into ordinary shares of the Company at price of US\$0.10 per share- (3,500,000 Shares). The conversion of the loan into ordinary shares shall be completed subject to the approval of the shareholders of the Company. In addition, the Company agreed to grant the beneficiary an option to purchase twice the amount of the converted stocks, (7,000,000 ordinary shares), to be available to purchase at a stock price of US\$0.20 per share, for a period of 5 years from the signing of this contract. (See Note 8).

G. On November 24, 2018, the Company entered into a binding letter of intent with Amarantus Bioscience Holdings, Inc. ("Amarantus"), a biotechnology holding company, for the establishment of a joint venture to develop LymPro Test®, an immune-based neurodiagnostic blood test originally developed at the University of Leipzig, as a diagnostic blood test for detection of Alzheimer's disease (the "Joint Venture Transaction"). Pursuant to the letter of intent, the Company undertook to issue to Amarantus 19.99% of the Company's outstanding ordinary shares, in exchange for 19.99% of Breakthrough Diagnostics, Inc., a wholly-owned subsidiary of Amarantus. As part of the joint venture transaction, all rights to the LymPro Test and certain other diagnostic assets will be assigned by Amarantus to Breakthrough Diagnostics. In addition, Amarantus undertook to grant the Company an exclusive option, in effect for sixty (60) days, to acquire the remaining 80.01% of Breakthrough Diagnostics in exchange for an additional 30.01% of the Company's outstanding shares. The exclusive option will be exercisable upon Amarantus entering into an amended and restated license agreement with the University of Leipzig. The closing of the joint venture transaction is subject to the Company raising \$1,000,000 in equity or debt financing.

TODOS MEDICAL LTD.
NOTES TO FINANCIAL STATEMENTS (cont.)

NOTE 10 – COMMITMENT AND CONTINGENT LIABILITIES (cont.)

H. On July 30, 2018, the Board of Directors of Todos Medical Ltd. resolved that Dr. Herman Weiss, will cease to serve as the Company's current Chairman of the Board of Directors, and appointed him as Chief Executive Officer of the Company effective immediately. Additionally, in conjunction with the appointment of Dr. Weiss as Chief Executive Officer, Rami Zigdon, the Company's then-current Chief Executive Officer, left his current position but was appointed as the Company's Chief Business Officer and will continue serving as a member of the Company's Board of Directors.

The Company's Compensation Committee and Board of Directors have approved the following compensation package for Dr. Weiss, to be retroactive to August 1, 2018, which will be presented to the shareholders of the Company for approval at the annual meeting of shareholders:

- *Salary:* NIS 47,840 per month
- *Bonus:* Annual performance bonus of up to 35% of annual salary + 1% additional options, linked to the achievement of performance goals to be established by the Board of Directors each year.
- *Equity:* The Company will grant the CEO options to purchase 5% of the Company's issued and outstanding shares as of March 25, 2019, at an exercise price equal to the fair market value of the Company's shares on the date of grant, in accordance with the following vesting schedule:
 - 25% will vest on grant
 - 25% will vest on the consummation of the Company's planned public offering (the "Public Offering Date")
 - 25% will vest quarterly in the first year following the Public Offering Date
 - 25% will vest quarterly in the second year following the Public Offering Date
- *Notice Period:* 3 months
- *Severance Payments:* 6 months' salary following effective date of termination
- *Change in Control Payment:* In the event the CEO is terminated due to a change of control, the Company will pay the CEO 12 months' salary (instead of the 6 months' salary) following the effective date of termination.
- *Change in Control Acceleration:* In the event of a change of control transaction following the Public Offering Date vesting will be accelerated, and all of the options will become fully vested.

The company made a provision in the financial statements of \$83,000 to reflect the compensation liability to Dr. Herman Weiss for services provided as the chief executive officer, as part of other current liabilities (see Note 7).

NOTE 11 – SHAREHOLDERS' DEFICIT

Convertible Preferred Shares:

According to the Company's prior Articles of Association, which were revised on August 9, 2015, each preferred share entitled its holder to the following rights, until such preferred share is converted into an ordinary share: (a) the right to receive notices and participate in general meetings, vote there at, receive dividends whenever they are paid on the ordinary shares and to receive liquidation dividends from the assets of the Company upon liquidation; (b) anti-dilution right that is not transferrable; and (c) the right to appoint one (1) director, provided that the holder holds 5% or more of the issued share capital of the Company. During the reported periods all the issued and outstanding preferred shares were held by Mr. Zigdon, the CEO of the Company.

On March 16, 2017, and following the effective date of the registration of the securities of the Company for quotation on OTCQB, the Company's shareholders at a General Meeting adopted Amended and Restated Articles of Association of the Company and approved the conversion of all preferred shares into the same number of ordinary shares (total of 3,333,471 shares). Accordingly, as of December 31, 2017, there are no preferred shares issued and outstanding and the Company is no longer required to issue any additional preferred shares to Mr. Zigdon. Following the registration of securities and the conversion of the preferred shares, the Company issued to Mr. Zigdon 18,379 ordinary shares related to ordinary shares issued during 2017 prior to the March 2017 conversion date.

TODOS MEDICAL LTD.
NOTES TO FINANCIAL STATEMENTS (cont.)

NOTE 11 – SHAREHOLDERS’ DEFICIT (cont.)

Ordinary Shares:

- A. Upon inception, the Company issued 3,000,000 Ordinary Shares of NIS 0.01 par value, which were held by the Company’s previous CEO. Such Ordinary Shares were converted to Convertible Preferred Shares.

On January 29, 2012 the Company issued to an investor 27,000,000 Ordinary Shares of NIS 0.01 par value, upon the conversion of a \$160,987 (NIS 600,000) loan.

As of that date, it was agreed between the investors who gained control over the Company and the then existing shareholder of the Company (“the former controlling shareholder”) that the respective shares of the former controlling shareholder would be converted into preferred shares. For the preferred share rights and privileges refer to the beginning of Note 10 above.

- B. Effective as of March 31, 2014, an investor was to be issued 123,900 ordinary shares in exchange for \$57,356 (200,000 NIS) received by the Company in February, 2014. Although these shares had not yet formally been issued by December 31, 2014, they have been included in the shareholders’ deficit (as receipt on account of shares) and loss per ordinary share relating to 2014. These shares were issued during 2015.

- C. On October 7, 2014, the Company signed a share purchase agreement with certain investors for \$350,593 in exchange for 9,000,000 ordinary shares of NIS 0.01 par value.

As the investment was to be executed in installments, the 9,000,000 shares were issued to a trustee that would hold the shares in trust until fully paid by the investors. The trustee released the shares to the investors following the completion of each significant transfer. As of December 31, 2014, the investor was entitled to 5,746,200 ordinary shares corresponding to an investment of \$223,840. During 2015 all these shares were released to the investors and the remaining purchase amount was paid to the Company.

- D. In March 2015, the general meeting of the shareholders resolved to increase the registered share capital and performed a share split so after the increase and share split, the registered share capital of the Company was increased from NIS 100,000 to NIS 10,000,000, divided into 990,000,000 ordinary shares par value NIS 0.01 each, and 10,000,000 preferred shares par value NIS 0.01 each of the Company. On this date the amended and restated articles of association were adopted. In March 2015, the board of directors approved the grant of 29 bonus shares for each 1 share of the Company held by the shareholders. Unless otherwise noted, all shares and per share amounts for all periods presented have been retroactively restated to reflect the split and the issuance of bonus shares.

- E. In March 2015, the Company approved a private placement memorandum for a funding round of up to \$ 2,000,000 and issuance of units for a price of \$ 0.20 for each unit consisting of: (A) 1 ordinary share par value NIS 0.01 and (B) 1 three-year warrant to purchase 1 ordinary share par value NIS 0.01 of the Company at a price of \$ 0.50.

During 2016 and 2015 the Company has raised the gross sum of \$903,681 and \$621,200, respectively, and issued 4,518,406 and 3,106,000, respectively, ordinary shares par value NIS 0.01 each and warrants to purchase an equal number of ordinary shares par value NIS 0.01 each. The proceeds of such units, net of related expenses (which amounted to \$155,321), and net amounts allocated to the warrants recorded as a liability (see Notes 2N. and 8), were reflected in the shareholders’ deficit, allocated between ordinary share capital and additional paid in capital, as applicable. The proportional amount of related expenses associated with the warrants’ portion of the units, has been recorded under finance expenses.

During April 2017, the Company offered to the holders of the warrants to lower the exercise price of the warrants from \$0.5 per share to \$0.4 per share for a limited period of time of 8 weeks.

As a result of such offer, during May 2017, certain holders exercised 1,665,000 warrants to the same number of Ordinary Shares for a cash consideration of \$666,000 (net amount of \$599,400)

The fair value of the inducement was measured in an amount of \$166,500. Such amount was recognized as an additional financing expense in the Company’s Statement of Comprehensive Loss.

As of the date of exercise, the fair value of the warrants exercised which amounted to \$297,200 (after consideration of the effect of the inducement), was reclassified to equity rather than derivative warrant liabilities.

TODOS MEDICAL LTD.
NOTES TO FINANCIAL STATEMENTS (cont.)

NOTE 11 – SHAREHOLDERS’ DEFICIT (cont.)

Ordinary Shares (cont.):

- F. In October 2017, the Company signed a share purchase agreement with certain investors for \$625,000 in exchange for 1,061,125 ordinary shares of NIS 0.01 par value. As of December 31, 2017, all of these ordinary shares were sold and the Company received net proceeds of \$562,553.
- G. In June 2015, the Company approved the issuance of 1,000,000 fully vested ordinary shares to Maxim Partners LLC (“Maxim”) pursuant to an agreement entered with Maxim in April 2015 engaging Maxim to provide financial advisory and investment banking services to the Company. The fair value (based on recent share issuances - see Note 11F. above) of the issued shares of \$200,000 was recorded as a stock-based expense, with a corresponding amount reflected in shareholders’ deficit, allocated between ordinary share capital and additional paid in capital, as applicable. Maxim is entitled to certain registration rights. Under the agreement, in addition to the issuance of shares as mentioned above, the Company undertook to pay Maxim for such services, a fee of \$10,000 per month, for the term of the agreement, accruing and payable only upon consummation of a financing transaction between the Company and a third party introduced by Maxim, in addition to a fee for a transaction consummated with such third party as detailed in the agreement and reimbursement of expenses in connection with such services provided. As of December 31, 2017, the Company has recorded a provision in the amount of \$30,000. In addition, Maxim shall have a right of first offer for acting as lead book runner in the event that the Company shall seek to raise additional capital by way of an offering – private or public. The agreement is terminable by either party by a 30 days prior written notice.
- In December 2018, the Company entered into a new engagement agreement with Maxim which superseded the April 2015 agreement. Pursuant to the new agreement, the Company appointed Maxim as its exclusive financial and sole management underwriter in connection with a proposed public offering to raise up to \$7 million. Maxim will be provided with an underwriting discount or spread of up to eight percent (8.0%) of the public offering price. Upon the Company’s receipt of bridge financing, the Company shall transfer to Maxim, an amount of \$15,000 as an advance to be applied towards such underwriting discount.
- H. On May 8, 2016, Company’s previous CEO exercised 103,428 options granted under the 2015 Israeli Option plan (see note 12 below) into 103,428 ordinary shares of the Company for total exercise price of \$273.
- I. On April 4, 2017, Company’s employee exercised 81,432 options granted under the 2015 Israeli Option plan (see note 12 below) into 81,432 ordinary shares of the Company for total exercise price of \$226. The remaining non-vested options of 228,858 were forfeited upon termination in accordance with the original terms of the options.
- J. On August 15, 2018, a certain consultant converted 620,521 options to 620,521 ordinary share at an exercise price of NIS0.01.
- K. On November 18, 2018, the Company signed a share purchase agreement with an investor for \$100,000 in exchange for 800,000 ordinary shares of NIS 0.01 par value and 600,000 warrants for 3 years in exercise price of the lowest of \$0.125 or the lowest price during the 5 trading days before the exercise notice.

Warrants and restricted stock:

- A. On October 18, 2016, the Company entered into a Consulting agreement with a consultant (the “Consultant”), pursuant to which the Consultant undertook to provide strategic cooperation and technology consulting for a period of two years from the date of the agreement. Unless terminated, the agreement will be automatically renewed for consecutive one-year periods. Based on the agreement, the Company issued the Consultant 620,521 warrants to purchase ordinary shares of the Company at an exercise price of NIS 0.01 (approximately \$0.0026) per share. The warrants expire 18 months following the commencement date. Out of the warrants, 232,696 warrants were immediately vested and the remaining are vested in 15 parts of 25,855 warrants starting October 31, 2016. The Company evaluated the fair value of the warrants using the Black-Scholes option pricing model assuming a 1% risk free interest rate, 0% dividend yield, and 67% volatility, and estimated the fair value of such warrants to be \$91,490. As a result, the Company recognized compensation expenses in 2017 and 2016 in the amount of \$41,360 and \$45,746, respectively included in research and development expenses.

TODOS MEDICAL LTD.
NOTES TO FINANCIAL STATEMENTS (cont.)

NOTE 11 – SHAREHOLDERS’ DEFICIT (cont.)

Warrants and restricted stock (cont.):

- B. On June 20, 2016, the Company entered into a Consulting Service Agreement with PCG Advisory Group (“PCG”), pursuant to which PCG undertook to provide the Company with markets advisory, investor relations and media strategies for a period of 7 months commencing the date of the agreement. As consideration for the above services the Company agreed to pay PCG a monthly cash compensation in the amount of \$2,500. In addition, the Company undertook to issue to PCG 50,000 ordinary shares for each calendar month. As of December 31, 2016, the Company recorded a related stock-based compensation expense of \$48,750 based on the fair value of the 325,000 shares (and a price per share of \$0.15). During 2017, the Company recorded related stock-based compensation expense of \$3,750 based on the fair value of the 25,000 shares (and a price per share of \$0.15).
- C. During May 2018, the Company offered to the holders of the warrants to exercise their warrants in exchange for extending their expiration date for an additional 3 years. As a result of such offer, during May 2018, certain holders exercised 722,500 warrants into the same number of Ordinary Shares for a cash consideration of \$361,250. (See Note 9). The total costs paid regarding this transaction were approximately \$36,000.

NOTE 12 – STOCK OPTIONS

On January 11, 2016, the Company’s Board of Directors approved and adopted the Todos Medical Ltd. 2015 Israeli Share Option Plan (the “2015 Plan”), pursuant to which the Board may award options to purchase its ordinary shares to designated participants. Subject to the terms and conditions of the 2015 Plan, the Board of Directors has full authority in its discretion, from time to time and at any time, to determine (i) the designate participants; (ii) the terms and provisions of the respective Option Agreements, including, but not limited to, the number of Options to be granted to each Optionee, the number of Shares to be covered by each Option, provisions concerning the time and the extent to which the Options may be exercised and the nature and duration of restrictions as to the transferability or restrictions constituting substantial risk of forfeiture and to cancel or suspend awards, as necessary; (iii) determine the Fair Market Value of the Shares covered by each Option; (iv) make an election as to the type of Approved 102 Option under Israeli IRS law; (v) designate the type of Options; (vi) take any measures, and to take actions, as deemed necessary or advisable for the administration and implementation of the 2015 Plan; (vii) interpret the provisions of the 2015 Plan and to amend from time to time the terms of the 2015 Plan.

The 2015 Plan permits the grant of up to 6,000,000 options to purchase ordinary shares subject to adjustments set in the 2015 Plan. As of December 31, 2018, there were 4,241,685 ordinary shares available for future issuance under the 2015 Plan.

The following table presents the Company’s stock option activity for employees and directors of the Company for the years ended December 31, 2018 and December 31, 2017:

	Number of Options	Weighted Average Exercise Price
Outstanding at December 31, 2017	1,758,315	0.0026
Granted	-	-
Exercised	-	-
Forfeited or expired	-	-
Outstanding at December 31, 2018	<u>1,758,315</u>	<u>0.0026</u>
Number of options exercisable at December 31, 2018	<u>1,137,731</u>	<u>0.0026</u>
	Number of Options	Weighted Average Exercise Price
Outstanding at December 31, 2016	2,068,605	0.0026
Granted	-	-
Exercised	(81,432)	0.0026
Forfeited or expired	(228,858)	-
Outstanding at December 31, 2017	<u>1,758,315</u>	<u>0.0026</u>
Number of options exercisable at December 31, 2017	<u>827,443</u>	<u>0.0026</u>

TODOS MEDICAL LTD.
NOTES TO FINANCIAL STATEMENTS (cont.)

NOTE 12 – STOCK OPTIONS (cont.)

The fair value of options granted was estimated at the dates of grant using the Black-Scholes option pricing model. The following are the data and assumptions used:

	Years ended December 31, 2016
Dividend yield	0
Expected volatility (%) (*)	100%
Risk-free interest rate (%)	1%
Expected term (years) (**)	2.5
Exercise price (US dollars)	0.0026
Stock price (US dollars) (***)	0.15

(*) Due to the low trading volume of the Company’s Common Stock, the expected volatility was based on the historical volatility of the share price of other public companies that operate in the same industry sector as the Company.

(**) Due to the fact that the Company does not have sufficient historical exercise data, the expected term was determined based on the “simplified method” in accordance with SEC Staff Accounting Bulletin No. 110.

(***) The Common Stock price, per share reflects the Company’s management’s estimation of the fair value per share of Common Stock. In reaching its estimation for 2016 grants, management considered, among other things, the valuation of the issuance of the shares under the private placement (see Note 11F above)

Costs incurred in respect of stock-based compensation for employees and directors, for the years ended December 31, 2018, 2017 and 2016 amounted to \$47,672, \$113,758 and 210,180, respectively.

The following table summarizes information about options to employees, officers and directors outstanding at December 31, 2018 under the plan:

Exercise Price	Options Outstanding		Options Exercisable	
	Number of Options	Weighted Average Remaining Contractual Life (Years)	Number of Options	Weighted Average Exercise Price
0.0026	1,758,315	2.03	1,137,731	0.0026

As of December 31, 2018, the aggregate intrinsic value for the options exercisable according to \$0.094 price per share was \$103,989 with a weighted average remaining contractual life of 2.03 years.

TODOS MEDICAL LTD.
NOTES TO FINANCIAL STATEMENTS (cont.)

NOTE 13 – RESEARCH AND DEVELOPMENT EXPENSES, NET

	Year ended December 31		
	2018	2017	2016
Salaries and related expenses	\$ 178,486	\$ 144,250	\$ 145,997
Stock-based compensation	12,077	22,883	48,056
Professional fees	22,271	18,888	37,426
Laboratory and materials	70,779	143,644	109,299
Patent expenses	82,367	65,654	24,956
Rent and maintenance	40,146	41,673	41,289
Liability for minimum royalty expenses (*)	--	238,000	50,000
Depreciation	25,650	24,083	20,695
Travel expenses	3,804	2,152	2,942
Insurance and other expenses	23,604	19,300	3,293
	<u>459,184</u>	<u>720,527</u>	<u>483,953</u>
Less: Grants from the OCS and others (**)	-	-	(166,046)
	<u>\$ 459,184</u>	<u>\$ 720,527</u>	<u>\$ 317,907</u>

(*) See Note 10B.

(**) See Note 10A and 10D.

NOTE 14 – GENERAL AND ADMINISTRATIVE EXPENSES

	Year ended December 31		
	2018	2017	2016
Salaries and related expenses	\$ 190,207	\$ 67,541	\$ 29,254
Stock-based compensation	35,595	90,875	162,124
Communication and investor relations	230,194	83,836	5,121
Professional fees (*)	269,980	224,407	150,341
Insurance and other expenses	193,718	150,428	64,142
	<u>\$ 919,694</u>	<u>\$ 617,087</u>	<u>\$ 410,982</u>

(*) includes listing expenses

NOTE 15 – FINANCING INCOME (EXPENSES), NET

	Year ended December 31		
	2018	2017	2016
	US Dollars		
Change in fair value of warrants liability and fair value of warrants expired (see Note 9)	\$ 925,910	\$ (1,101,229)	\$ 117,577
Inducement related to warrants exercised	-	(166,500)	-
Expenses related to issuing warrants	-	-	(34,272)
Exchange rate differences and other finance income (expenses)	45,427	(70,029)	(7,877)
Liability for minimum royalty expenses	(50,000)	--	--
Financing income (expenses), net	<u>\$ 921,337</u>	<u>\$ (1,337,758)</u>	<u>\$ 75,428</u>

TODOS MEDICAL LTD.
NOTES TO FINANCIAL STATEMENTS (cont.)

NOTE 16 – INCOME TAX

The Company files its income tax report in the state of Israel and is subject to taxation laws applicable in Israel.

- A. On January 4, 2016, the Israeli parliament passed the Law for Amendment of the Income Tax Ordinance No. 216, which, among other things reduced the standard Israeli corporate income tax rate from 26.5% to 25% effective as of January 2016.

In December 2016, the Israeli parliament passed the Economic Efficiency Law (Legislative Amendments to Achieve Budget Targets for the 2017 and 2018 Budget), which set a further reduction of corporate tax from 25% to 23%. The provisions of the law included a Temporary Order stipulate that the corporate tax rate in 2017 will be 24%. As a result, the corporate tax rate that will apply in 2017 will be 24% and the corporate tax rate that will take effect from 2018 onwards will be 23%

- B. The Company has final (considered final) tax assessments through the 2013 tax year.
- C. As of December 31, 2018, the Company has carried forward losses for Israeli income tax purposes of approximately \$3.7 million which can be offset against future taxable income for an indefinite period of time.
- D. The Company is still in its development stage and has not yet generated revenues, therefore, it is more likely than not that sufficient taxable income will not be available for the tax losses to be utilized in the future. Therefore, a valuation allowance was recorded to reduce the deferred tax assets to its recoverable amounts.

Composition of deferred tax assets:	As of December, 31	
	2018	2017
Net loss carry-forward	\$ 1,121,229	\$ 814,000
Valuation allowance	(1,121,229)	(814,000)
	-	-

- E. For the years ended December 31, 2018, 2017 and 2016, the following table reconciles the statutory income tax rate to the effective income tax rate:

	Year Ended December 31,		
	2018	2017	2016
Tax rate	23%	24%	25%
Tax expense (benefit) at statutory rate	\$ (105,234)	\$ (642,090)	\$ (163,365)
Tax rate differential	-	28,057	(55,376)
Decrease in taxes from permanent differences in stock-based compensation	10,964	27,301	52,545
Decrease in taxes from permanent difference in warrants liabilities	(212,959)	304,254	29,394
Loss carryforwards-change in valuation allowance	307,229	282,478	136,802
Income tax expense (benefit)	\$ -	\$ -	\$ -

TODOS MEDICAL LTD.
NOTES TO FINANCIAL STATEMENTS (cont.)

NOTE 17 – LOSS PER ORDINARY SHARE

The loss and the weighted average number of ordinary shares used in computing basic and diluted loss per ordinary share for the years ended December 31, 2018, 2017 and 2016, are as follows:

	Year ended December 31		
	2018	2017	2016
Loss for the year	\$ (457,541)	\$ (2,675,372)	\$ (653,461)
Less: Loss attributed to preferred shares	-	31,950	32,483
Loss for the year attributable to ordinary shareholders	\$ (457,541)	\$ (2,643,422)	\$ (620,978)
Weighted average number of ordinary shares outstanding attributable to ordinary shareholders	70,869,924	68,587,261	62,467,556

During the years ended December 31, 2018, 2016 and 2015, 600,00, 4,518,406 and 3,106,000, three-year warrants, respectively, were issued - as described in Note 9. These warrants were not taken into account in calculating either the basic or diluted loss per ordinary share, as their effect was anti-dilutive. During the years ended December 31, 2018 and 2017 and 2016 there were no other potentially dilutive instruments (except for the convertible preferred shares).

During the years ended December 31, 2018, and 2017 and 2016 the total weighted average number of ordinary shares related to outstanding options and warrants excluded from the calculation of the diluted loss per share was 6,489,221 and 7,717,721 and 1,182,066 respectively.

NOTE 18 – RELATED PARTIES

- A. Effective as of May 1, 2015, the Company entered into an employment agreement with Mr. Rami Zigdon, the previous chief executive officer of the Company, who owned all the Company's preferred shares. From the Company's inception to the effective date of the agreement, Mr. Zigdon provided the Company with management services as an independent contractor. As of the effective date of the agreement, Mr. Zigdon was employed as chief executive officer on a full-time basis. The agreement may be terminated by either party by ninety days written notice or by the Company under exceptional circumstances as detailed in the agreement. Pursuant to the agreement, Mr. Zigdon is entitled to a gross monthly salary of NIS 15,000 (approximately \$3,900) linked to the Israeli CPI known at the effective date of the agreement as well as reimbursement of vehicle expenses up to an annual amount of NIS 16,000 (approximately \$4,200). The gross monthly salary shall be increased to NIS 25,000 (approximately \$6,600) from the date on which the Company shall have cash in its bank account of least NIS 3,500,000 (approximately \$920,000) (the "Triggering Date") that is sourced from capital injections/non-repayable amounts only, as confirmed by the Company's CFO. In the event that during the term of the agreement, on a certain date the Company shall have at least NIS 4,000,000 (approximately \$1,050,000) cash in its bank account that is sourced from capital injection/non-repayable amounts only, as confirmed by the Company's CFO, Mr. Zigdon shall be entitled to a payment in the sum of NIS 12,333 (approximately \$ 3,200) multiplied by the number of calendar months that had passed from the effective date of the agreement and until the month ending prior to the Triggering Date. In addition, Mr. Zigdon is entitled to participate in the Company's incentive program that will be adopted by the Company. Furthermore, Mr. Zigdon will be entitled to options to purchase Company shares all subject to an option plan to be adopted by the appropriate organs of the Company. The number of options, vesting and such other terms of grant of the options are detailed in Note 18B. below. Mr. Zigdon is entitled to customary fringe benefits under Israeli laws. If the agreement is terminated by the Company, other than for "cause" as defined in the agreement, Mr. Zigdon shall be entitled to an adjustment bonus equal to 3 times the last gross monthly salary or in the event that the Company will have more than \$3 Million cash in hand, the adjustment bonus shall be equal to 6 times his last gross monthly salary. The agreement contains provisions regarding non-competition, confidentiality of information and assignment of inventions.

On July 30, 2018, the Board of Directors of the Company resolved that Dr. Herman Weiss will cease to serve as the Company's current Chairman of the Board of Directors, and appointed him as Chief Executive Officer of the Company, effective immediately. Additionally, in conjunction with the appointment of Dr. Weiss as Chief Executive Officer, Rami Zigdon, the Company's previous Chief Executive Officer, left his position but was appointed as the Company's Chief Business Officer and will continue serving as a member of the Company's Board of Directors.

The Company intends to enter into an employment agreement with Dr. Weiss at a later date. (see Note 10)

TODOS MEDICAL LTD.
NOTES TO FINANCIAL STATEMENTS (cont.)

NOTE 18 – RELATED PARTIES (cont.)

- B. As part of the 2015 Plan described in Note 12 above, in November 2015, the Board of Directors of the Company approved the issuance of share options to three employees, including our previous CEO and CTO, at an exercise price of NIS 0.01 per share. Mr. Zigdon received 1,241,163 options of which, half vest over a period of twenty-four months, subject only to a service condition, and half of the options vest upon the achievement of 8 milestones which includes, among others, closing of equity financing of at least \$2,000,000, obtaining FDA approval for the performance of clinical trials and other clinical measurements. Milestones which are not met within 48 months from the date of the grant (November 2019) shall expire. The fair value of the stock options granted to Mr. Zigdon was estimated at \$183,049 (see Note 11 above). On May 8, 2016, Mr. Zigdon exercised 103,428 vested options into ordinary shares for total exercise price of \$273. All of the options not exercised of exercisable shall expire on January 11, 2021. Compensation expenses recognized for the awards subject to performance conditions commence when the Company determines that achievement of the performance conditions is probable.
- C. Moshe Schlisser (a director as of February 27, 2016) and Ephraim Schlisser (Moshe's father) hold managerial positions with a company named A.S. Ivor Israel Ltd. ("Ivor"). Ivor was assigned its rights and obligations from Iberica Investments LLC ("Iberica"), which was a party to a 2015 consulting agreement pursuant to which Iberica agreed to provide assistance with the Company's fundraising. During the years ended December 31, 2018 and 2017, the Company paid Ivor and Iberica approximately \$36,150 and \$128,000, respectively, pursuant to this consulting agreement. The Company terminated the Iberica consulting agreement, effective December 28, 2018.
- D. Crow Technologies 1977 Ltd., a company engaged in the manufacturing of plastics and electronic components, has an exclusive right to manufacture products for the Company (and any component of the products) for a price that is higher by 50% to that of the market prices of manufacturing such products or components in Israel. As of the date hereof, Crow Technologies has not exercised its exclusive right. The products of the Company do not have any electronic parts. While the Company's products developed through the current date, do have plastic parts, the cost of these parts approximate \$0.10 per unit. The Company believes that the exclusive right held by Crow Technologies is immaterial to the ultimate price for which the Company will sell its products or even the overall estimated cost of production of its products.

NOTE 19 – SUBSEQUENT EVENTS

Convertible bridge loan transaction

On February 27, 2019, we entered into a convertible bridge loan agreement, and issued notes and warrants relating thereto, to obtain an aggregate loan of \$1,350,500 from several private lenders, including DPH Investment Ltd., a holder of 11.5% of our shares (as of such date), to finance the Company's activities through the consummation of a proposed public offering and our planned up listing to the NASDAQ Capital Market. The convertible bridge loan agreement signed on February 27, 2019 superseded and replaced the convertible bridge loan agreement for \$30,000, signed on December 30, 2018, that is described in Note 5 above. The loan, which has an original issue discount of ten percent (10%), bears interest at a flat rate of ten percent (10%) and has a maturity date six months after receipt of the loan funds. The loan is convertible into ordinary shares of the Company after the maturity date at a conversion price equal to 70% of the average closing bid price of the Company's Ordinary Shares in the five days prior to the conversion. In the event the Company's defaults under the loan agreement, the conversion price will be reduced to 60% of the average closing bid price of the Company's Ordinary Shares in the 15 days prior to the conversion. In addition, the lenders received 25% warrant coverage, with the warrant exercise price to be equal to the offering price in the proposed public offering, or, in the event the loan is converted into shares, the warrant exercise price will be equal to the applicable closing bid price of the Company's shares at the time of the conversion of the loan.

On March 10, 2019, we entered into an amendment to the bridge loan agreement. The amendment provides for a 10% penalty if we repay the loan prior to the maturity date. In addition, we agreed to grant the lenders an additional 25% warrant coverage, under the same terms as the original warrant, but with a warrant exercise price equal to 150% of the closing bid price of our shares on the day prior to the closing of the bridge loan transaction.

TODOS MEDICAL LTD.
NOTES TO FINANCIAL STATEMENTS (cont.)

NOTE 19 – SUBSEQUENT EVENTS (cont.)

Amarantus Transaction

On February 27, 2019, the Company entered into a joint venture agreement with Amarantus Bioscience Holdings, Inc, pursuant to which the Company issued Ordinary Share representing 19.99% of the Company to Amarantus, in exchange for Amarantus transferring to the Company 19.99% of Breakthrough Diagnostics, Inc. (“Breakthrough”), a wholly-owned subsidiary of Amarantus, and for Amarantus assigning its amended and restated license agreement with the University of Leipzig for an exclusive license to develop and commercialize the LymPro Test®, an immune-based neurodiagnostic blood test for the detection of Alzheimer’s disease (the “License”), to Breakthrough. In addition, as part of the transaction, the Company provided Amarantus with an interest-free loan in the amount of \$45,000 to be used to pay certain financial obligations of Amarantus owed to the University of Leipzig prior to the assignment of the License to Breakthrough, in connection with the license agreement and a related sponsored research agreement. The maturity date of the loan is May 1, 2019. In addition, the Company provided Breakthrough with an interest-free loan in the amount of \$135,000 to be used to pay certain financial obligations of Breakthrough owed to the University of Leipzig after the assignment of the License to Breakthrough, in connection with the license agreement and the related sponsored research agreement. The maturity date of this loan is September 30, 2019. The Company expects to loan up to an additional \$180,000 to cover additional fees that will be owed by Breakthrough to the University of Leipzig in connection with the license agreement and the sponsored research agreement.

As part of the joint venture with Amarantus, the Company was granted an option, in effect for sixty (60) days, to acquire the remaining 80.01% of Breakthrough held by Amarantus in exchange for the issuance to Amarantus of Ordinary Shares of the Company representing an additional thirty percent (30%) of the Company, such that upon consummation of the transaction the Company will own 100% of Breakthrough and Amarantus will own 49.99% of the Company.

Assignment of Loan Agreement
(the "Agreement")

Held and signed on 28th of November 2018

Between

Adeline Holding Limited
Company ID: HE 217415
located at 5th strati Mirivilli,
CY-2046 Strovolos, Nicosia,
Cyprus.

And Mr. Itzhak Austrubitzky, ID 839549
located at 119 Jabotinsky st.
Tel-Aviv, apt 2.
(Hereinafter known as "the Assigners")
as Party A;

& Between

Sorry Doll LTD, company Number 515561769
located at: 102nd Hayarkon st. Tel-Aviv
(Hereinafter known as "the Beneficiary 1")

S.B Nihul Mekarkein LTD, company Number 511604100
located at: 33rd Dubnov st. Tel-Aviv
(Hereinafter known as "the Beneficiary 2")
(Together known as "the Beneficiary")
as Party B;

& Between

Todos Medical LTD, ID 514437128
located at: 1st Hamada st. Rehovot.
(Hereinafter known as "the Company")
as Party C;

Whereas, the Company owes **the Assigners** the sum of 1,221,710 NIS (one million two hundred twelve thousand seven hundred ten new Israeli Shekels, equal to about US\$350,000) as stated in **the Company's** accounting records and books as a shareholder's loan (Hereinafter known as "**the Loan**") (the Records are attached as **Appendix A** of this Agreement); and

Whereas, the Assigners wish to grant all their rights in **the Loan** to **the Beneficiary** or a 3rd party on its behalf or whomever **the Beneficiary** shall appoint; and

Whereas, the Company wishes to convert **the Loan** to stock capital, and **the Beneficiary** hereby agree that after the signing of this Agreement, subject to shareholder approval, **the Company** shall convert **the Loan** to stock capital to be registered in favor of **the Beneficiary** or anyone on its behalf, or anyone it shall appoint (50% to Beneficiary 1, and 50% to Beneficiary 2); and

Whereas, the Company is negotiating with an investments bank that is interested in investing in the Company a sum of approximately 5,000,000 USD (Hereinafter known as "**the Bank**") – this representation is fundamental to this Agreement;

Now, it is therefore agreed upon, declared and determined between the Parties:

1. The preamble to this Agreement and the attached appendix are an integral part of this Agreement.
2. **The Assigners** hereby transfer, at the signing of this Agreement, all their rights in **the Loan**, as stated above, to **the Beneficiary** or anyone on its behalf, or anyone it shall appoint.
3. **The Company**, by signing this Agreement, hereby approves the transfer of **the Loan** rights to **the Beneficiary** or anyone on its behalf, or anyone it shall appoint, and shall modify its accounting records and books so that they show that the Loan is registered in the name of **the Beneficiary** or anyone on its behalf, or anyone it shall appoint in the Company accounting records.
4. Subject to shareholder approval, **The Company** and **the Beneficiary** hereby agree that **the Loan** shall be converted into 3,500,000 Ordinary Shares of the **Company** (the "**Conversion Shares**"), at a conversion price of ten cents (US\$0.10) per share (the "**Conversion**"). The conversion of **the Loan** into stock capital shall be completed within three (3) business days of approval of this Agreement by the Company's shareholders. Upon conversion of the Loan, the Company shall be forever released from all its obligations and liabilities with respect to the Loan (including all accrued interest), which shall be deemed to have been paid in full.
5. Subject to shareholder approval, **the Company** shall also grant **the Beneficiary**, or anyone on its behalf, or anyone it shall appoint, an option (the "**Option**") to purchase twice the amount of the converted stock, namely, 7,000,000 restricted Ordinary Shares of the Company (the "**Option Shares**", and together with the Conversion Shares, the "**Investment Shares**"), at an exercise price of twenty cents (US\$0.20) per share, which Option shall be in effect for a period of five (5) years from the signing of this Agreement. (Hereinafter known as "**the Option Period**"). Total potential shares to be owned by the Beneficiary will be 10,500,000 shares, after the initial acquisition of 3,500,000 Conversion Shares and the Option to acquire 7,000,000 Options Shares.
6. **The Company** shall be accountable, that once the Option is exercised, the Company shall commit all lawfully necessary procedures as to name **the Beneficiary**, anyone on its behalf, or anyone it shall appoint, as the shareholder of the Option Shares.
7. It is hereby clarified, that should **the Beneficiary**, or anyone on its behalf, or anyone it shall appoint, choose to exercise the Option partially, as it is defined above, such partial exercise shall not cause a shortening of **the Option Period**, and/or in any way damage **the Beneficiary's** rights to exercise the remainder of the granted Option till the end of the Option Period.

8. Adjustment of Exercise Price. If the Company at any time or from time to time effects a subdivision of its outstanding Ordinary Shares, the number of Option Shares issuable upon exercise of the Option immediately before the subdivision shall be proportionately increased and the exercise price shall proportionately decrease, and conversely, if the Company at any time or from time to time combines its outstanding Ordinary Shares, the number of Option Shares issuable upon exercise of the Option immediately before the combination shall be proportionately decreased and the exercise price shall proportionately increase. Any adjustment under this Section 8 shall become effective at the close of business on the date the subdivision or combination becomes effective.

9. Information on the Company. Each Beneficiary has been furnished with or has had access at the EDGAR Website of the SEC to the Company's Form 20-F filed on May 15, 2018 for the fiscal year ended December 31, 2017 and the financial statements included therein for the year ended December 31, 2017, together with all subsequent filings made with the SEC available at the EDGAR website ("Reports"). In addition, each Beneficiary may have received in writing from the Company such other information concerning its operations, financial condition and other matters as such Beneficiary has requested in writing, and has considered all factors such Beneficiary deems material in deciding on the advisability of investing in the Ordinary Shares of the Company.

10. Representations, Warranties, and Acknowledgments of the Beneficiary

Each Beneficiary hereby represents, warrants, and acknowledges the following:

10.1 No Registration. The Beneficiary understands and acknowledges that the Investment Shares to be issued pursuant to this Agreement have not been registered under the securities laws of any jurisdiction and therefore the Beneficiary may be required to hold the Investment Shares for an indeterminate period.

10.2 Investment Intent. The Beneficiary is acquiring the Investment Shares for the Beneficiary's own account as principal, not as a nominee or agent, for investment purposes only, and not with a view to, or for, resale or distribution, in whole or in part. The Beneficiary agrees that a legend to the foregoing effect may be placed upon any and all certificates issued representing the Investment Shares. Further, the Beneficiary does not have any contract, undertaking, agreement or arrangement with any person to sell, transfer or grant participation to such person or to any third person, with respect to the Investment Shares.

10.3 Financial Ability and Risk. The Beneficiary is aware that investment in the Company involves a high degree of risk, may result in a lack liquidity, and places substantial restrictions on transferability of interest. The Beneficiary has sufficient financial resources available to support the loss of all or a portion of Beneficiary's investment in the Company, has no need for liquidity in the investment in the Company, and is able to bear the economic risk of the investment. The Beneficiary is sophisticated and experienced in investment matters, and, as a result, is in a position to evaluate an investment in the Company.

10.4 Regulation S Exemption. The Beneficiary is not a U.S. Person. The Beneficiary understands that that the Investment Shares are being offered and sold to him in reliance on an exemption from the registration requirements of United States federal and the state securities laws under Regulation S promulgated under the Securities Act, and that the Company is relying upon the truth and accuracy of the representations, warranties, agreements, acknowledgments, and understandings of the Beneficiary to determine the applicability of such exemptions and the suitability of the Beneficiary to acquire the Investment Shares.

11. This Agreement fully express and summarizes the **Parties'** consent with regards to the matters and subjects debated in it, and it replaces and cancels any display, agreement, negotiation, costume, memorandum, and any other document held among the parties, with regards to said matters and subjects.

12. It shall not be concluded by the behavior of the parties, explicit or otherwise, that there have been any changes to, or cancelations to this Agreement. a concession of one of the parties to a fulfillment of an order, condition or right, derived from this Agreement, in one instance, explicit or otherwise, shall not be considered a concession in other instances.

13. The court adjudicated in Tel-Aviv shall have complete and exclusive legal oversight with regard to this Agreement.

signed today between:

The Assigners:

Adeline Holding Limited

Itzhak Austrubitzky

Name:
Title:

Itzhak Austrubitzky

The Beneficiary:

S.B Nihul Mekarkein

Sorry Doll Ltd.

Name:
Title:

Name:
Title:

The Company:

Todos Medical Ltd.

Name: Herman Weiss
Title: CEO

MARKETING AND RESELLER AGREEMENT
(the "Agreement")

THIS AGREEMENT is made and entered into this 20th day of December 2018 (the "Effective Date"), by and between **Todos Medical Ltd.**, a corporation organized and existing under the laws of the State of Israel, with an address at 1 Hamada St., Rehovot, Israel ("Todos") and **Care G. B. Plus Ltd.**, a corporation organized and existing under the laws of the State of Israel, with an address at Rechov HaYasmin 50, Carmei Yosef, Israel (the "Reseller").

WHEREAS, Todos has developed and owns a proprietary blood screening test for the early detection of certain forms of cancer which consists of a Physician Kit (for collecting blood samples) and a Lab Kit (for separating plasma and mononuclear cells in the blood samples) which consists of an Isolation Kit and an Analysis Kit, all as more fully described on Exhibit A attached hereto (the "Products"), as well as a proprietary algorithm for the analysis of the blood samples data; and

WHEREAS, the Reseller is interested in marketing, distributing, and reselling the Products to customers located in and taking delivery in the State of Israel, including the territory of the Palestinian Authority, (the "Territory" and the "Customers"), all in accordance with the terms set forth herein;

NOW THEREFORE in consideration of the agreements, covenants, and conditions hereinafter set forth, the parties agree as follows:

1. Grant of Rights

1.1 Subject to the terms and conditions of this Agreement, Todos hereby grants the Reseller a non-sublicensable, non-transferable, exclusive right to distribute and sell the Products to Customers in the Territory; provided, however, that Reseller may sub-license or transfer its distribution rights to a subsidiary or affiliate of the Reseller. The Reseller shall have a right of first refusal to include within this Agreement any additional products developed, manufactured, or sold by the Company following the Effective Date that are not currently included in Exhibit A, and upon the exercise of such right, the term "Products" shall be expanded to mean such additional products as well. For purposes of clarity, the parties agree that upon Todos's development of a blood screening test for colon cancer, such product shall be added to this Agreement and included within the definition of "Products", subject to the Reseller and Todos agreeing on the commercial terms for such product, including the price.

1.2 The Reseller shall not market, distribute, or sell the Products, whether directly or indirectly, to customers outside of the Territory. This Section 1.2 is a fundamental provision of this Agreement.

1.3 Subject to Section 1.4 below, Todos shall not market, distribute, or sell the Products, whether directly or indirectly, to customers inside of the Territory in any manner other than through the Reseller.

1.4 Notwithstanding the grant of exclusivity to the Reseller, nothing herein shall derogate from Todos's right to distribute the Products in the Territory for non-revenue producing purposes such as research, testing, evaluation, proof of concept, and clinical trials.

2. Exclusivity

2.1 The Reseller's exclusive right to market and sell the Products in the Territory is subject to the Reseller achieving the following milestones by the end of each year this Agreement is in effect (the "Annual Milestones"):

<i>Year</i>	<i>Annual Milestone(s)</i>
Year 1	Not Applicable
Each Year Thereafter	The parties will agree at the beginning of the year on the Annual Milestone for such year

2.2 If the Reseller sells less than 50% of any year's Annual Milestone, Todos, in its sole discretion, may either (a) cancel the Reseller's exclusivity, and market, distribute, and sell the Products in the Territory directly or indirectly through other distributors and resellers, while leaving the Reseller with a non-exclusive right to distribute and sell the Products for the remainder of the term, or (b) terminate the Agreement upon one hundred eighty (180) days prior written notice, provided that the Reseller does not cure its failure to achieve 50% of the applicable year's Annual Milestone within the 180-day notice period.

3. Duties of Todos

3.1 Todos shall provide technical assistance and advice to support the Reseller's preparation of marketing materials, including technical sales literature, catalogs and the like, to be used in the Territory.

3.2 Todos shall provide the Reseller, at no charge, with initial training relating to the efficient use and operation of the Products as well as instruction regarding use of all associated equipment required to effectively carry out the TM-B1 and TM-B2 cancer screening tests. Additionally, Todos will provide the Reseller with training relating to the handling of all blood samples throughout the screening process, and any and all other training, guidance and support reasonably required to sell the Products in the Territory.

3.3 Todos shall provide the Reseller, at no charge, with technical support relating to the use of the Products.

3.4 Todos shall support the Reseller, at no charge, in providing Customers with scientific data supporting the efficacy of the Products.

3.5 Todos is responsible for obtaining AMAR approval from the Israeli Ministry of Health.

3.6 Todos shall comply with all relevant standards of quality assurance and shall ensure that the Products conform to all Israeli standards and certifications.

3.7 Todos shall appoint a relationship manager, who shall serve as the primary point of contact with Reseller regarding all matters arising from the business relationship contemplated in this Agreement.

3.8 Todos shall be available for periodic meetings with the Reseller to discuss any issues arising in connection with this Agreement.

3.9 Todos shall fulfill with reasonable dispatch all orders received from the Reseller and accepted by Todos.

3.10 Todos shall refer to the Reseller all Product inquiries and sales opportunities in the Territory that come to the attention of Todos.

4. Duties of the Reseller

4.1 The Reseller shall use all commercially reasonable efforts to market, promote, distribute, and sell the Products to Customers in the Territory, and shall, on its own account, provide a trained and competent sales and marketing team for the efficient promotion and sale of the Products. The Reseller shall achieve the commercialization milestones by the dates set forth in the Commercialization Timetable attached hereto as Exhibit C.

4.2 The Reseller shall be responsible for preparing marketing materials, including technical sales literature, catalogs and the like, to be used in the Territory. All marketing materials shall be subject to the prior written approval of Todos.

4.3 Except for AMAR approval which is the responsibility of Todos, the Reseller shall be responsible for obtaining all necessary governmental, regulatory, and other permits and licenses required to distribute and sell the Products in Israel. Todos shall provide the Reseller with all required assistance in this matter in order to obtain the necessary licenses and permits.

4.4 The Reseller shall be responsible for setting up at least one laboratory in the Territory to support the assay protocol (the "Laboratory"), including the provision of a FTIR that is approved by Todos, as further described in Exhibit B. The Reseller shall obtain the prior approval of Todos for all lab equipment. The Reseller will contract with existing certified laboratories in Israel to obtain the blood samples data, subject to the approval by Todos of each such laboratory.

4.5 The Reseller shall be responsible for providing post-sale support services to Customers, and shall, on its own account, provide a trained and competent support team for the efficient support of the Products. The Reseller shall retain a medical doctor to assist with the provision of support services.

4.6 The Reseller shall run a fifty (50) patient pilot trial to evaluate the performance of the Laboratory and the Reseller's support team.

4.7 The Reseller shall follow Todos's protocols in dealing with or handling the Products, including the shipment of blood samples to the laboratory.

4.8 The Reseller shall, in marketing, selling, and distributing the Products, not make any promises, representations, statements, warranties or guarantees on behalf of Todos or concerning the Products, except as are expressly authorized in writing by Todos.

4.9 The Reseller shall comply at all times with all applicable laws, rules, regulations, and industry standards relating to the storage, packaging, marketing, distribution, laboratory work, and sale of the Products in the Territory.

4.10 The Reseller shall appoint a relationship manager, who shall serve as the primary point of contact with Todos regarding all matters arising from the business relationship contemplated in this Agreement. Todos's relationship manager shall meet with Todo no less frequently than quarterly and provide a status report on the Reseller's commercialization efforts. In addition, the Reseller will promptly bring to the notice of Todos any information which it has or which it may receive in future which is likely to be of interest, benefit, or use to Todos in relation to both the marketing of the Products in the Territory and the future market requirements of Customers.

4.11 The Reseller shall provide Todos with feedback for at least one percent (1%) of the consumed tests, including providing the actual screening result (by a yearly base) of each test.

4.12 The Reseller shall not market, distribute, or sell any product that competes with Products, nor provide services to any direct competitor of Todos.

4.13 The Parties hereby declare and confirm their awareness to the fact that to the date of the signing of this Agreement, Todos has yet to sell a single Product and lacks any and all sales experience and/or knowledge of the matter. The Reseller shall act as a pioneer in the sales department and shall share with Todos all the sales experience and information it shall gather in order to help Todos' with its worldwide sales.

4.14 The Reseller shall be entitled to enter into agreements with its subsidiaries and affiliates to act as sub-distributors and/or selling agents of the Products in the Territory.

4.15 The Reseller hereby declares its awareness that Todos has not yet acquired the required AMAR approval for distribution of the Products in the Territory nor FDA approval.

5. Ordering, Pricing, and Payment Procedures

5.1 Non-Binding Forecasts. On the first day of each calendar quarter, the Reseller will provide Todos with a non-binding rolling weekly forecast of the Reseller's estimated Product purchase requirements over the upcoming six months (the "Forecasts").

5.2 Orders. From time to time as needed, the Reseller shall provide Todos with firm purchase orders for the Products. Each purchase order shall include the name and address of the Customer. All orders are subject to written acceptance by Todos, which acceptance shall be provided unless the order contains terms that differ from the terms set forth in this Agreement.

5.3 Product Price. The Reseller shall be entitled to purchase the Products from Todos for resale to Customers at a price between US\$[] and US\$[], with the actual price to be agreed upon by the Parties (the "Product Price"). At the end of each year this Agreement is in effect, the Parties will discuss each party's costs and whether to revise the Product Price. Todos shall provide the Reseller with Products for clinical trials at no charge.

5.4 Lead Time. The lead time for each Lab Kit is three (3) months, and the lead time for each Physician Kit is one month, provided that Reseller's order for the Products does not deviate from the applicable Forecast by more than ten percent (10%).

5.5 Delivery. Todos shall ship ordered Products to the Reseller within ninety (90) days of Todos's acceptance of the applicable purchase order DAP Reseller's warehouse (Incoterms 2010), provided that Reseller's order for the Products does not deviate from the applicable Forecast by more than ten percent (10%).

5.6 Todos shall provide the Reseller with the screening results and analysis of each customer blood sample data sent to Todos within one business day of receiving the blood sample data.

5.7 Payment for Products. Todos shall invoice the Reseller for all sums due for Products ordered upon shipment of the ordered Products to the Reseller, and the Reseller shall pay such sums by no later than thirty (30) days from the date of shipment. All payments made to Todos shall be in New Israeli Shekels.

5.8 Taxes. Reseller shall be responsible for paying all sales, use, excise, and value-added taxes imposed on the sale or use of the Products.

6. Reporting and Audit Rights

6.1 Books and Records. During the term and for a period of three (3) years following the termination or expiration of this Agreement, the Reseller shall maintain complete books of accounts and records consistent with sound business and accounting principles and practices consistently applied.

6.2 Quarterly Reports. Within fifteen (15) days of the end of each quarter, the Reseller shall provide Todos with a written report of (a) the quantities of Products distributed, sold, or otherwise transferred; the prices at which the Products were sold; and payments received therefore; and (b) the identity and location of all Customers to whom Products were sold, during the preceding quarter (each a "Quarterly Report").

6.3 Audits. Todos shall have the right to have an inspection and audit of all the relevant accounting and sales books and records of Reseller conducted by an independent auditor reasonably acceptable to both parties. Any such audit shall be upon five (5) days prior written notice and shall be conducted during normal business hours. If any such audit should disclose any material error in the Quarterly Reports or any resale of the Products by Reseller in contravention of the terms of this Agreement, in addition to any other remedies to which Todos shall be entitled, Reseller shall promptly reimburse Todos for the reasonable cost of the audit.

6.4 On-Site Inspections. Todos shall have the right to conduct periodic on-site inspections to ensure the quality control of the cancer screening processes and the Reseller's compliance with Todos's protocols.

6.5 Medical Device Reporting. The Reseller shall provide Todos with reports of any adverse events and product problems in accordance with the Mandatory Medical Device Reporting regulations of 21 CFR 803.

7. Warranties

7.1 Performance Warranty. Todos warrants that for a period of one (1) year from the date of delivery of each Product to the Reseller, the Product, except for those components that have a shorter expiration date as set forth on Exhibit A, shall perform substantially in accordance with the Product's documentation and specifications, and shall be free from all defects in materials, manufacture, and workmanship. Todos shall correct or repair any reported non-conformity or defect, or replace the non-conforming Product with a Product that conforms to this warranty.

7.2 Non-Infringement. Todos represents and warrants to the Reseller that Todos has full right to produce and sell the Products as contemplated by this Agreement, and that the Reseller's exercise of the resale rights granted herein will not violate any copyright, patent, or other proprietary right of any third party.

7.3 EXCEPT FOR THE EXPRESS WARRANTIES STATED IN THIS SECTION 7, TODOS DISCLAIMS ANY AND ALL WARRANTIES, INCLUDING ANY IMPLIED WARRANTY OR CONDITION OF MERCHANTABILITY, DURABILITY OR FITNESS FOR A PARTICULAR PURPOSE. NO REPRESENTATION OR OTHER AFFIRMATION OF FACT, INCLUDING BUT NOT LIMITED TO STATEMENTS REGARDING PERFORMANCE OF THE PRODUCTS, WHICH IS NOT CONTAINED IN THIS AGREEMENT, SHALL BE DEEMED TO BE A WARRANTY BY TODOS.

8. Insurance.

Each party shall carry appropriate and commercially reasonable amounts of insurance adequate for the activities detailed in this Agreement, as well as sufficient levels of all legally mandated insurance, if any.

9. Intellectual Property

9.1 Reseller acknowledges and agrees that any and all proprietary rights, trade secrets, trademarks, trade names, copyrights, patents, know-how, and other intellectual property rights used or embodied in, related to, or associated with the Products, including all developments, modifications, enhancements, improvements, and derivative works thereof, and all documentation with respect thereto, are and shall remain the sole and exclusive property of Todos or its licensors.

9.2 Subject to the terms and conditions of this Agreement, Todos hereby grants Reseller a limited license to use the Todos name and Todos's trademarks, trade names, service marks, logos and related symbols (the "Todos Marks") in the performance of its activities hereunder and in the marketing of the Products in the Territory. The Reseller's use of the Todos Marks shall be subject to Todos's prior approval. The Reseller will use Todos's designated trademarks, trade names, and intellectual property related notices on or in all marketing materials and packaging, and the Reseller shall market and sell the Products under the Todos brand name. The Reseller will not register or take other action with respect to any Todos Mark used anywhere in the world by Todos, except to the extent authorized in writing by Todos in advance.

9.3 Reseller shall immediately bring to the attention of Todos any improper or wrongful use of Todos's trademarks or other intellectual or commercial property rights which come to the notice of Reseller, and will, in the performance of its duties hereunder, use every effort to safeguard the property rights and interests of Todos, and will, at the request and cost of Todos, take all steps required by Todos to defend such rights.

9.4 Reseller acknowledges that it does not have and that it will not obtain any proprietary interest in the Todos Marks and agrees not to use the same in any other manner and to discontinue all use thereof immediately upon termination of the Agreement.

10. Confidentiality

10.1 Any technical, scientific, design, or commercial information transferred by one Party to the other under this Agreement which is identified as confidential or which may reasonably be deemed to be confidential, shall be considered confidential and shall be maintained in confidence by the receiving party. In addition, each party shall comply with all applicable health care privacy rules and regulations and maintain the confidentiality of all health care and patient information.

10.2 The receiving party shall maintain in confidence and protect the secrecy of all confidential information of the other Party, and agrees that it shall not disclose, transfer, use in an unauthorized manner, copy, or allow access to any such confidential information to any employees, agents, or third parties, except for those who have a need to know such confidential information to fulfill the purposes of this Agreement, and who are bound by contractual obligations of confidentiality and limitation of use sufficient to give effect to this Section 10. In no event shall the receiving party disclose any of the other Party's confidential information to any competitor of the disclosing party.

10.3 The receiving party shall use the same degree of care to avoid publication, unauthorized disclosure, and unauthorized use of such confidential information as it applies with respect to its own confidential information (but no less than reasonable care), and shall take all reasonable care to ensure that such confidential information is not disclosed to third parties, except insofar as: (a) such confidential information is made public by the disclosing party; (b) such confidential information is in the public domain otherwise than as a consequence of a breach of the obligations herein undertaken; or (c) such confidential information was previously and demonstrably known to the receiving party, or was subsequently independently developed.

10.4 The terms of this Agreement shall be deemed to be confidential information. Each party undertakes that it will not make any announcement or issue any circular or other publicity relating to the existence or subject matter of this Agreement, the terms of this Agreement, or the transactions contemplated hereby, without the prior written approval of the other party as to such announcement's/circular's/publicity's content, form, and manner of publication.

10.5 Each party acknowledges that the unauthorized use, commercialization or disclosure of the other party's confidential information would cause irreparable harm to such other party. The parties acknowledge that remedies at law may be inadequate to redress the actual or threatened unauthorized use, commercialization, or disclosure of such confidential information and that the foregoing restrictions may be enforced by temporary and permanent injunctive relief without necessity of posting bond. In addition, any award of injunctive relief shall include recovery of associated costs and expenses (including reasonable attorneys' fees).

10.6 The provisions of this Section 10 shall survive the expiration or termination of this Agreement.

11. Term and Termination

11.1 This Agreement shall be effective as of the Effective Date and shall continue in effect for a period of five (5) years from the Reseller's first purchase order for Product issued to Todos (the "Initial Term"), unless terminated earlier by one of the parties in accordance with the terms of this Section 11. Upon completion of the Initial Term, provided that the Reseller has achieved the Annual Milestones, the term of the Agreement shall be automatically renewed for an additional five (5) years. Thereafter, at the end of each renewal term, the Agreement shall renew for an additional two (2) years unless one party provides the other party with prior written notice of non-renewal at least sixty (60) days prior to the expiration of the then-current term.

11.2 Notwithstanding anything to the contrary, a party may terminate this Agreement upon the occurrence of any of the following events, and such party shall not be liable to the other party for the proper exercise of such right:

(a) The other party materially breaches this Agreement and continues in such breach for thirty (30) days after the non-breaching party has given written notice thereof to the other party; or

(b) For a period of ninety (90) consecutive days, the other party is declared to be insolvent or is the subject of bankruptcy or liquidation proceedings, whether compulsory or voluntary, or has a receiver, judicial administrator or similar officer appointed over all or any material part of its assets, or any security holder or encumbrance lawfully takes possession of any property of or in possession of the other party, or if the other party ceases to carry on its business.

12. Limitation of Liability

12.1 IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR ANY INCIDENTAL, CONSEQUENTIAL, INDIRECT, SPECIAL, OR PUNITIVE DAMAGES (INCLUDING, BUT NOT LIMITED TO, LOST PROFITS, BUSINESS INTERRUPTION, LOSS OF BUSINESS INFORMATION OR OTHER PECUNIARY LOSS) REGARDLESS OF WHETHER SUCH LIABILITY IS BASED ON BREACH OF CONTRACT, TORT (INCLUDING NEGLIGENCE), STRICT LIABILITY, BREACH OF WARRANTIES, FAILURE OF ESSENTIAL PURPOSE OR OTHERWISE AND EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

12.2 Except with regard to a breach of confidentiality, a party's indemnification obligations hereunder, or infringement of intellectual property rights, either party's total liability to the other party under this Agreement shall be limited to the amounts paid or payable by the Reseller to Todos during the twelve-month period preceding the interposition of the claim.

13. Indemnification

13.1 Todos's Duty to Indemnify. Todos shall defend against any claim or lawsuit by a third party (a "Claim") against Reseller to the extent such Claim alleges that the Products infringe any patent, copyright, or trademark or misappropriate a trade secret of a third party, and will indemnify Reseller against all costs, damages, losses, liabilities and expenses (including reasonable attorneys' fees and costs) ("Damages") awarded against Reseller by a court of competent jurisdiction, or agreed to in a written settlement agreement signed by Todos, arising out of such Claim. Todos shall have no indemnification obligation or other liability for any Claim of infringement arising from (a) use of the Products other than in accordance with this Agreement; (b) modification of the Products or the combination of the Products with any other products, services, or materials if the Products would not be infringing without such modification or combination; or (c) any third party products, services, or materials. If Reseller's use of the Products under the terms of this Agreement is enjoined or Todos determines that such use may be enjoined, then Todos may, at its sole option and expense, either (i) procure for Reseller a license to continue using the Products in accordance with the terms of this Agreement; (ii) replace or modify the allegedly infringing Products to avoid the infringement; or (iii) terminate this Agreement.

13.2 Reseller's Duty to Indemnify. Reseller agrees to defend any Claim against Todos (i) that the Reseller's actions infringe any third party patent, or copyright, or any other proprietary right; or (ii) arising out of any act or omission by Reseller relating to the Products. Reseller will indemnify Todos (and its directors, employees and agents) against all Damages awarded against Todos or agreed to in a written settlement agreement signed by Reseller arising out of such Claim.

13.3 General Indemnity. Each party shall defend and indemnify the other party and its employees, officers, directors and agents against all Damages for Claims for bodily injury, death, or damage to real property or tangible physical equipment, proximately caused by the indemnifying Party in the course of performing this Agreement.

13.4 Conditions to Indemnification. The obligations set forth in this Section 13 shall apply only if (i) the indemnified Party promptly notifies the indemnifying Party in writing of a claim upon learning of or receiving the same; (ii) the indemnified Party provides the indemnifying Party with reasonable assistance requested by the indemnifying Party, at the indemnifying Party's expense, for the defense and settlement, if applicable, of any claim; and (iii) the indemnified Party provides the indemnifying Party with the exclusive right to control and the authority to settle any claim.

13.5 Sole and Exclusive Remedies. THE RIGHTS AND OBLIGATIONS IN THIS SECTION 13 ARE THE INDEMNIFYING PARTY'S SOLE AND EXCLUSIVE OBLIGATIONS, AND THE INDEMNIFIED PARTY'S SOLE AND EXCLUSIVE REMEDIES, WITH RESPECT TO ANY SUCH CLAIMS.

14. Relationship of the Parties

The parties to this Agreement are independent contractors. No relationship of principal to agent, master to servant, employer to employee, or franchisor to franchisee is established hereby between the parties. Neither party has the authority to bind the other or incur any obligation on the other's behalf. Any agreement for the sale of Products negotiated or executed between the Reseller and a Customer shall be binding upon the Reseller alone. The Reseller is not authorized to, and shall not, enter into any contracts nor make any other commitments on behalf of or in the name of Todos, unless expressly authorized in writing to do so by Todos. Reseller shall not incur any liabilities, obligations, or commitments on behalf of Todos.

15. Miscellaneous

15.1 Entire Agreement. This Agreement, including its exhibits, constitutes the entire agreement between the parties concerning the subject matter hereof, and supersedes all prior or contemporaneous statements, representations, discussions, negotiations, and agreements, both oral and written.

15.2 Amendments or Waiver. This Agreement may not be amended or modified except in a writing signed by authorized officers of both parties. No order, invoice, or similar document will modify the terms of this Agreement even if accepted by the receiving party.

15.3 Severability. In the event that any one or more of the provisions of this Agreement shall be found to be illegal or unenforceable, this Agreement shall nevertheless remain in full force and effect, and such term or provision shall be deemed severed unless such severance defeats the purpose of this Agreement or results in substantial injustice to one of the parties.

15.4 No Waiver. Neither of the party's rights to enforce provisions of this Agreement shall be affected by any prior course of dealing, waiver, delay, omission, or forbearance.

15.5 Assignment. This Agreement and the rights granted hereunder shall not be assigned, encumbered by security interest or otherwise transferred by the Reseller without the prior written consent of Todos, except for the assignment or transfer of rights to a subsidiary company or an affiliated company.

15.6 Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of Israel, and the courts of Tel-Aviv, Israel

15.7 Arbitration. Any dispute, controversy, or claim relating to, connected with, or arising out of this Agreement, including any question regarding its existence, validity, or termination, shall be referred to and finally resolved by arbitration in accordance with the Arbitration Law, before a single arbitrator to agreed upon by both parties and in lack of such agreement as to the identity of the arbitrator, each side shall be eligible, within 7 days of any notice given by any party to the other, to request that the head of the Tel-Aviv Bar Association appoint said arbitrator.

[Remainder of Page Left Blank]

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their duly authorized representatives.

Todos Medical Ltd.

/s/ Herman Weiss

Name: Herman Weiss

Title: CEO

Date: 20/12/2018

Care G. B. Plus Ltd.

/s/ Assaf Gold

Name: Assaf Gold

Title: Manager

Date: 20/12/2018

Lists of Exhibits:

Exhibit A: The Products

Exhibit B: The Laboratory

Exhibit C: Commercialization Timetable

EXHIBIT A

THE PRODUCTS

Each unit of Product consists of one Physician Kit and one Laboratory Kit.

TM-B1 breast cancer screening test and TB-B2 breast cancer diagnostic test

General Information:

Physician Kit:

Laboratory Kit: The Laboratory Kit consists of the Isolation Kit and the Analysis Kit.

Isolation Kit:

Item 7 (page 8) in the “Isolation Kit” are items that are not provided with the kit and the Reseller is responsible to purchase these items.

Analysis Kit:

Item 7 (page 8) in the “Analysis Kit” are the items that are not provided with the kit and the Reseller is responsible to purchase these items.

Components with an expiration date:

[please insert]

EXHIBIT B

THE LABORATORY

[please insert description of the laboratory and its components]

EXHIBIT C

COMMERCIALIZATION TIMETABLE

Milestone	Target Date
Todos to obtain AMAR approval	Q3 2019
Reseller to set-up a diagnostic Laboratory (internal or external) that complies with the requirements in the TM-B2 Isolation Kit Instruction for Use.	Q3 2019
Reseller to commence 30-50 Women Pilot Trial.	
Isolation at Reseller's lab, and FTIR analysis at Todos's facility.	Q3 2019
Reseller to commence commercial sales.	Q4 2019
Todos to provide kits and computer analysis of files.	Q4 2019

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO
EXCHANGE ACT RULE 13A-14(A)/15D-14(A)
AS ADOPTED PURSUANT TO SECTION 302
OF THE SARBANES-OXLEY ACT OF 2002**

I, Herman Weiss, certify that:

1. I have reviewed this Annual Report on Form 20-F of Todos 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 registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer 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 registrant 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 registrant, 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 registrant'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 registrant'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 registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant'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 registrant'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 registrant's internal control over financial reporting.

/s/ Herman Weiss

Herman Weiss
Chief Executive Officer

Date: March 27, 2019

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO
EXCHANGE ACT RULE 13A-14(A)/15D-14(A)
AS ADOPTED PURSUANT TO SECTION 302
OF THE SARBANES-OXLEY ACT OF 2002**

I, David Ben Naim, certify that:

1. I have reviewed this Annual Report on Form 20-F of Todos 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 registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer 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 registrant 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 registrant, 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 registrant'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 registrant'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 registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant'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 registrant'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 registrant's internal control over financial reporting.

/s/ David Ben Naim

David Ben Naim
Chief Financial Officer

Date: March 27, 2019

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL
OFFICER 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 of Todos Medical Ltd. (the "Company") on Form 20-F for the fiscal year ended December 31, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of Herman Weiss and David Ben Naim does certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Herman Weiss

Herman Weiss
Chief Executive Officer

Date: March 27, 2019

/s/ David Ben Naim

David Ben Naim
Chief Financial Officer

Date: March 27, 2019