

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549**

FORM 20-F/A

(Amendment No. 1)

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

OR

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

For the fiscal year ended December 31, 2019

OR

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

Date of event requiring this shell company report _____

For the transition period from _____ to _____

Commission File No.: 000-56026

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)

Gerald Commissiong

Chief Executive Officer

(650) 862-5391

Gerald@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: **None**.

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.

103,573,795 Ordinary Shares, par value NIS 0.01 per share as of December 31, 2019.

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 every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

Yes No

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 whether the registrant has filed a report on and attestation to its management’s assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. []

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

U.S. GAAP [X]

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 [X]

EXPLANATORY NOTE

Todos Medical Ltd. (the “**Company**”) is filing this Amendment No. 1 on Form 20-F/A (this “**Amendment**”) to its Annual Report on Form 20-F for the fiscal year ended December 31, 2019 (the “**Original Report**”), which was originally filed with the Securities and Exchange Commission (the “**SEC**”) on June 15, 2020. The purpose of this Form 20-F/A is to add to the Form 20-F, the audited financial statements of the Company for the year ended December 31, 2017 (the “2017 Financial Statements”) which were inadvertently omitted from the Original Report. In addition, disclosure related to the 2017 Financial Statements has been added to the Operating and Financial Review and Prospects section of this Amendment.

In addition, as required by Rule 12b-15 under the Exchange Act, new certifications by the Company's principal executive officer and principal financial officer are filed herewith as exhibits to this Amendment, under Item 19 hereof, pursuant to Rule 13a-14(a) or 15d-14(a) of the Exchange Act. The Company is also including the certifications required under Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350) (Section 906 of the Sarbanes-Oxley Act of 2002).

Except as described in this Explanatory Note, this Amendment does not amend any other information set forth in the Original Report, and the Company has not updated disclosures to reflect any events that occurred subsequent to June 15, 2020.

The following information is required by the SEC order issued on March 25, 2020 (Release No. 34-88465) (the “SEC Order”), which provides conditional relief to public companies that are unable to timely comply with their filing obligations as a result of the novel Coronavirus outbreak.

On April 7, 2020, we filed a Report on Form 6-K with the SEC stating that we are relying on the SEC Order to extend the filing date of our Annual Report on Form 20-F because we were unable to file our Annual Report on Form 20-F by the original deadline of April 30, 2020, due to circumstances related to COVID-19. Specifically, as set forth in the 6-K, COVID-19 caused severe disruptions in travel and transportation and limited access to the our facilities resulting in limited support from our staff which in turn delayed our ability to complete our review and prepare our Annual Report on Form 20-F in a timely manner. Our Form 6-K indicated that we estimated that we will be able to file the Form 20-F on or about June 14, 2020, which is within the additional 45-day period from the original due date provided for in the SEC Order.

TODOS MEDICAL LTD.

FORM 20-F

ANNUAL REPORT FOR THE FISCAL YEAR ENDED DECEMBER 31, 2019

TABLE OF CONTENTS

	<u>Page</u>
<u>PART I</u>	
ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS	1
ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE	1
ITEM 3. KEY INFORMATION	1
ITEM 4. INFORMATION ON THE COMPANY	35
ITEM 4A. UNRESOLVED STAFF COMMENTS	60
ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS	60
ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES	71
ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS	94
ITEM 8. FINANCIAL INFORMATION	97
ITEM 9. THE OFFER AND LISTING	99
ITEM 10. ADDITIONAL INFORMATION	99
ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK	115
ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES	115
<u>PART II</u>	
ITEM 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES	116
ITEM 14. MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS AND USE OF PROCEEDS	116
ITEM 15. CONTROLS AND PROCEDURES	116
ITEM 16A. AUDIT COMMITTEE FINANCIAL EXPERT	117
ITEM 16B. CODE OF ETHICS	117
ITEM 16C. PRINCIPAL ACCOUNTANT FEES AND SERVICES	118
ITEM 16D. EXEMPTIONS FROM THE LISTING STANDARDS FOR AUDIT COMMITTEES	118
ITEM 16E. PURCHASE OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS	118
ITEM 16F. CHANGE IN REGISTRANT'S CERTIFYING ACCOUNTANT	118
ITEM 16G. CORPORATE GOVERNANCE	118
ITEM 16H. MINE SAFETY DISCLOSURE	118
<u>PART III</u>	
ITEM 17. FINANCIAL STATEMENTS	119
ITEM 18. FINANCIAL STATEMENTS	119
ITEM 19. EXHIBITS.	119

INTRODUCTION

Todos Medical Ltd. (“Todos Medical,” the “Company,” “we,” “our,” “us”), is a medical diagnostics company engaged in the development and commercialization of blood tests for the detection of immune-related diseases, beginning with cancer. Our core proprietary technology centers on testing blood cells using a Fourier-transform infrared (FTIR) spectrometer to turn biological information into data, and then using our patented Total Biochemical Infrared Analysis (TBIA) deep learning data analytics platform to mine the data in order to develop algorithms that are indicative of the presence of cancer, and the tissue of origin in the body where the cancer is located. The TBIA detection method is based on cancer’s influence on the immune system that triggers biochemical changes in peripheral blood. The primary advantages of the TBIA platform are the high accuracy (sensitivity and specificity) and low costs of goods sold (COGS) due to the biological information being captured using spectroscopy versus biological antibody capture methods that require the manufacture of multiple antibodies to capture a biological signature. TBIA is based upon technology originally invented by the researchers at Ben Gurion University (BGU) and Soroka Medical Center of Israel (Soroka), whose intellectual property has been licensed to us. We have received a CE Mark in the European Union authorizing the commercial use of the TBIA platform in the diagnosis of breast cancer and colon cancer. We have been issued patents in the United States, Europe and other international jurisdictions covering the use of TBIA to detect solid tumors. We have also entered into distribution agreements with development partners in preparation for the commercial launch of TBIA for breast cancer in Israel, Romania and Austria during the second half of 2020. Our academic partners at BGU have also published research suggesting FTIR has the potential to be used to identify the presence of viral and bacterial infections, and the Company is currently evaluating how best to pursue its technology in these areas in light of increased commercial interest for viral detection methods in light of the recent outbreak of novel Coronavirus (SARS-CoV-2, or COVID-19) worldwide.

Because of the novelty and highly disruptive nature of TBIA analysis using FTIR to diagnose disease, we believe the best path forward to bring Todos’ core technology to market in the United States is to demonstrate comparability with blood tests that are built on technology platforms that are in widespread use. Due to the relative scarcity of commercial blood tests in areas such as cancer and Alzheimer’s disease, we entered into agreements whereby we have agreed to acquire companies that have developed proprietary blood tests in those therapeutic indications in order to gain a foothold in the marketplace and fine tune our FTIR platform while fully commercializing these more advanced tests in the United States. We chose to expand into Alzheimer’s disease because we view Alzheimer’s as cancer of neuronal cells that are incapable of completing cell division due to their post-mitotic nature.

On March 30, 2020, our Board of Directors determined to exercise our option to acquire all of the shares of Provista, and on April 2, 2020 it gave notice of such determination to Provista. At an extraordinary general meeting on May 11, 2020, our shareholders approved the consideration to be issued to SIH as consideration for the acquisition. The Provista acquisition will enable us to gain exclusive worldwide rights to the commercial-stage breast cancer test Videssa™. However, the acquisition cannot be consummated unless and until our Ordinary Shares are listed for trading on NASDAQ.

At our 2019 annual meeting of shareholders, our shareholders approved a resolution authorizing us to exercise our option to acquire the remaining 80.01% of Breakthrough from Amaranthus in exchange for an additional 30% of our then issued and outstanding Ordinary Shares. While the Breakthrough option has not yet been exercised, the option has been extended by both parties and remains in effect. Breakthrough is a joint venture we formed with Amaranthus to gain ownership of exclusive worldwide rights to the Alzheimer's blood test called the Lymphocyte Proliferation Test (LymPro Test™). Taken together with our core TBIA FTIR-based platform, we believe Todos is positioned to become the worldwide leader in the field of immune-based diagnostics. The Company formed the subsidiary Todos Medical Singapore Ltd. for the purpose of advancing clinical trials of the Company's core technology for breast cancer in Southeast Asia.

Additionally, in view of our status as a leader in the field of immune-based diagnostics, we made the strategic corporate decision to enter the field of COVID-19 testing. Similarly to our strategy in cancer and Alzheimer's where we felt more traditional, advanced technologies would serve as the basis for market entry before bringing our proprietary FTIR-based TBIA platform forward, we decided to enter the COVID-19 space by gaining rights to existing technologies developed by other companies. As such, we entered into distribution agreements with multiple companies to gain rights to rapid IgM/IgG COVID-19 antibody test kits, RNA extraction machines, RNA extraction reagents, qPCR reagents and digital PCR reagents so as to be able to offer a comprehensive suite of solutions to laboratories worldwide. Additionally, the Company has entered into a joint venture with NLC Pharma to bring to market a unique development-stage viral protease based saliva point of care cell phone enabled diagnostic device that allows for the rapid detection of the presence of SARS-CoV-2 full length RNA in saliva which has the unique benefit of also indicating when viral replication has slowed or ceased. This technology will potentially have a significant impact for the development of virus targeting therapeutic development strategies, as well as clearance for return to life activities post-infection. As a complementary strategy to COVID-19 testing, we have entered into distribution agreements for certain personal protective equipment ("PPE") and medical devices, including ventilators, that are have complementary sales channels to our COVID-19 testing products and services. We believe this strategy has the potential to help accelerate our commercial distribution channels as we begin to commercialize our core technology, and the technologies we are currently acquiring via the Provista and Breakthrough acquisitions.

More specifically as it relates to our emerging COVID-19 diagnostic testing business, in the first half of 2020 we have been able to focus the Company's human capital on securing rights and validating newly sourced diagnostic testing platforms and establishing sales distribution channels for our suite of COVID-19 products and services. To that end, we are focused on the following tasks:

1. Todos Medical Ltd. (Israel): Identification of innovation in diagnostic testing products, services and related PPE, including medical devices such as ventilators, as well as import/export of our suite of products from our manufacturers' country of origin and country of destination, primarily focusing our marketing efforts in Europe and Africa. The Company is able to utilize its broad network of international contacts who originate from Israel to identify opportunity.

2. Todos Medical USA (United States of America): US Food & Drug Administration (FDA) authorized medical importer and distributor focused on the distribution the Company's testing products and services and PPE to customers in the North America and Latin America. Todos Medical USA has formed the subsidiary Corona Diagnostics, LLC, for the purpose of marketing COVID-19 related products in the United States and contracting with Provista Diagnostics, Inc. to validate potential products the Company is contemplating distributing and creating marketing materials for the testing products based upon those validations.

3. Todos Medical Singapore, Pte. Ltd.: Health Sciences Authority (HSA), which is the equivalent of the FDA in Singapore, authorized medical importer and distributor focused on distributing test kits for the Company's core technologies in Southeast Asia.

The Company believes that by identifying key areas of inefficiency in the COVID-19 testing space, and addressing those bottlenecks, whether they be scientific, technical or logistical, we can capture market share in a new and rapidly growing medical testing industry that, according to Research and Markets, is expected to reach approximately \$44.5 billion for 2020.

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 OTCQB tier of the OTC Markets under the symbol "TOMDF."

Unless otherwise indicated, all references to the "Company," "we," "our," "Todos" and "Todos Medical" refer to Todos Medical Ltd. and its subsidiaries, Todos Medical USA, a Nevada corporation, and 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, 2019 are translated using the rate of NIS 3.456 to \$1.00, the exchange rate reported by the Bank of Israel on December 31, 2019; 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.

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 ultimate impact of the current COVID-19 pandemic, or any other health epidemic, on our business, our clinical trials, our research programs, healthcare systems or the global economy as a whole;
- 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, 2015 through December 31, 2019. We have derived the following selected statements of operations data for the years ended December 31, 2019, 2018 and 2017 the selected balance sheet data as of December 31, 2019 and 2018 from our audited 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, 2017, 2016 and 2015, and the selected consolidated balance sheet data as of December 31, 2017, 2016, and 2015 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 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 financial statements.

U.S. dollars in thousands, except share data Consolidated Statements of Operations Data	Year Ended December 31,				
	2019	2018	2017	2016	2015
Research and development expenses	\$ (756)	(459)	(721)	(318)	(374)
Marketing expenses	(667)	-	-	-	-
General and administrative expenses	(2,093)	(920)	(617)	(411)	(457)
Operating loss	(3,515)	(1,379)	(1,338)	(729)	(831)
Financing income (expenses), net	(5,334)	921	(1,337)	75	12
Share in losses of affiliated company accounted for under equity method	(2,966)	-	-	-	-
Net loss	(11,815)	(458)	(2,675)	(653)	(819)
Basic and diluted net loss per share	\$ (0.13)	(0.01)	(0.04)	(0.01)	(0.02)
Basic and diluted weighted average number of ordinary shares outstanding	92,024,188	70,869,924	68,587,261	62,467,556	45,190,017

Consolidated Balance Sheet Data

U.S. dollars in thousands, except share data	Year Ended December 31,				
	2019	2018	2017	2016	2015
Cash and cash equivalents	\$ 12	\$ 64	\$ 683	\$ 439	\$ 156
Working capital (deficit)	\$ (1,524)	\$ (1,093)	\$ 468	\$ 325	\$ 107
Total assets	\$ 91	\$ 199	\$ 816	\$ 584	\$ 292
Total current liabilities	\$ 1,662	\$ 1,199	\$ 245	\$ 135	\$ 79
Total non-current liabilities	\$ 4,678	\$ 217	\$ 1,911	\$ 853	\$ 742
Shareholders' deficit	\$ (6,249)	\$ (1,216)	\$ (1,340)	\$ (404)	\$ (528)
Number of Ordinary Shares outstanding	103,573,795	72,399,932	70,256,911	63,747,504	59,125,670
Number of Preferred Shares Outstanding	-	-	-	3,333,471	3,096,195

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 \$11,814,515, and \$457,541 in the fiscal years ended December 31, 2019, and 2018, respectively. As of December 31, 2019, our accumulated deficit was \$17,507,868. 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 December 31, 2019, we had cash and cash equivalents \$12,155, and as of June 15, 2020, our unaudited cash and cash equivalents were approximately \$300,000. In 2019, 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 months after the date of this annual report on Form 20-F. 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, 2019, 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 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 products, commercializing our products 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 products;
- 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 believe our existing protocols and measurement instruments are sufficient to support the initial commercial launch in Israel, Romania and Austria. However, 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 once we have successfully commercialized and have begun research activities on this second-generation protocols and measurement instruments. The changes we plan to implement in the second-generation 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 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 were previously approved to sell our products in Israel, and we have restarted the regulatory approval process in Israel and expect the regulatory approval process in Israel to take approximately an additional six months from the date of this annual report on Form 20-F, although there may be delays due to the Coronavirus pandemic.

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 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 below in the section titled “***Risks Related to Our Operations in Israel***”), 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, we do not maintain insurance for fires, floods and other natural disasters nor do we have insurance covering 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.

From time to time, we may become involved in various lawsuits and legal proceedings, including securities class action litigation. In the past, biotechnology and pharmaceutical companies have experienced significant stock price volatility, particularly when associated with binary events such as clinical trials and product approvals. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business and results in a decline in the market price of our common stock.

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

On December 19, 2019, we entered into an exclusive option agreement (the "Option Agreement") with Strategic Investment Holdings LLC ("SIH"), Ascenda Biosciences LLC ("Ascenda"), and Provista pursuant to which Ascenda granted us the exclusive option to acquire all of the outstanding shares of Provista in consideration for an aggregate of \$10 million of our Ordinary Shares (calculated as described in the Option Agreement), of which \$2 million of Ordinary Shares (or 30,100,072 Ordinary Shares) have been issued to SIH to date. To the extent that the value of the assets transferred to us in the transaction are not comparable to the value of our Ordinary Shares issued or to be issued to SIH pursuant to the Option Agreement, we may face a tax exposure in both Israel and the United States.

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

On February 27, 2019, we entered into a joint venture agreement with Amaranthus Bioscience Holdings, Inc. ("Amaranthus") pursuant to which we issued Ordinary Share representing 19.99% of the then-issued and outstanding Ordinary Shares of our Company to Amaranthus, in exchange for Amaranthus transferring to us 19.99% of Breakthrough, which was then 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 the extent that the value of the assets transferred to us in the transaction is not comparable to the value of the shares of our Ordinary Shares issued to Amaranthus in this transaction, we may face a tax exposure in both Israel and the United States.

Our U.S. Holders may suffer adverse tax consequences if we were to be characterized as a passive foreign investment company, or PFIC.

Generally, if for any taxable year 75% or more of our gross income is passive income, or at least 50% of our assets are held for the production of, or produce, passive income, we would be characterized as a passive foreign investment company, or PFIC, for U.S. federal income tax purposes. There can be no assurance that we will not be classified as a PFIC in any year. If we were to be characterized as a PFIC for U.S. federal income tax purposes in any taxable year during which a U.S. Holder, as defined in “Taxation — U.S. Tax Considerations”, owns Ordinary Shares, such U.S. Holder could face adverse U.S. federal income tax consequences, including having gains realized on the sale of our Ordinary Shares classified as ordinary income, rather than as capital gains, a loss of the preferential rate applicable to dividends received on our Ordinary Shares by individuals who are U.S. Holders and having interest charges apply to distributions by us and the proceeds of share sales. Certain elections exist that may alleviate some of the adverse consequences of PFIC status and would result in an alternative treatment (such as mark-to-market treatment) of our Ordinary Shares; however, we do not intend to provide the information necessary for U.S. Holders to make “qualified electing fund elections”, or QEF elections, if we are classified as a PFIC, and, accordingly, such elections would not be available to U.S. Holders. See “Taxation — U.S. Tax Considerations”.

Our business may be adversely affected by the ongoing Coronavirus pandemic.

The outbreak of the novel Coronavirus (COVID-19) has evolved into a global pandemic. The Coronavirus has spread to many regions of the world. The extent to which the Coronavirus impacts our business and operating results will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning the Coronavirus and the actions to contain the Coronavirus or treat its impact, among others.

As a result of the continuing spread of the Coronavirus, certain aspects of our business operations may be delayed. Specifically, as a result of the shelter-in-place orders and other mandated local travel restrictions, among other things, the research and development activities of certain of our partners may be affected, resulting in delays to our clinical trials, and we can provide no assurance as to when such trials will resume at this time.

Furthermore, site initiation, participant recruitment and enrollment, participant dosing, distribution of clinical trial materials, study monitoring and data analysis may be paused or delayed due to changes in hospital or university policies, federal, state or local regulations, prioritization of hospital resources toward pandemic efforts, or other reasons related to the pandemic. If the Coronavirus continues to spread, some participants and clinical investigators may not be able to comply with clinical trial protocols. For example, quarantines or other travel limitations (whether voluntary or required) may impede participant movement, affect sponsor access to study sites, or interrupt healthcare services, and we may be unable to conduct our clinical trials. Further, if the spread of the Coronavirus pandemic continues and our operations are adversely impacted, we risk a delay, default and/or nonperformance under existing agreements which may increase our costs. These cost increases may not be fully recoverable or adequately covered by insurance.

Infections and deaths related to the pandemic may disrupt the United States' healthcare and healthcare regulatory systems. Such disruptions could divert healthcare resources away from, or materially delay FDA or foreign regulatory agency review and/or approval with respect to, our clinical trials. It is unknown how long these disruptions could continue, were they to occur. Any elongation or de-prioritization of our clinical trials or delay in regulatory review resulting from such disruptions could materially affect the development and study of our product candidates.

We currently utilize third parties to, among other things, manufacture raw materials. If any third-party party in the supply chain for materials used in the production of our product candidates are adversely impacted by restrictions resulting from the Coronavirus outbreak, our supply chain may be disrupted, limiting our ability to manufacture our product candidates for our clinical trials and research and development operations.

The spread of the Coronavirus, which has caused a broad impact globally, including restrictions on travel and quarantine policies put into place by businesses and governments, may have a material economic effect on our business. While the potential economic impact brought by and the duration of the pandemic may be difficult to assess or predict, it has already caused, and is likely to result in further, significant disruption of global financial markets, which may reduce our ability to access capital either at all or on favorable terms. In addition, a recession, depression or other sustained adverse market event resulting from the spread of the Coronavirus could materially and adversely affect our business and the value of our common stock.

The ultimate impact of the current pandemic, or any other health epidemic, is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, our research programs, healthcare systems or the global economy as a whole. However, these effects could have a material impact on our operations, and we will continue to monitor the situation closely.

Risks Related to our COVID-19 Antibody Test

In connection with the marketing and sale of our COVID-19 antibody test, we are relying on FDA policies and guidance provisions that have recently changed and may continue to change. If we misinterpret this guidance or the guidance changes unexpectedly and/or materially, potential sales of our COVID-19 antibody test could be impacted.

The FDA issued non-binding guidance for manufacturers relating to the pathway to enable FDA notification following confirmed validation for devices related to testing for COVID-19 under the Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency. Following the issuance of the guidance published on March 16, 2020, revised guidance specific to COVID-19 'antibody tests' was issued. Newer guidance was published on May 4, 2020 further describing the requirements for serology tests to continue to be marketed under an Emergency Use Authorization. If our interpretation of the newly revised guidance is incorrect or specifics around the guidance change, sales of our COVID-19 antibody test could be materially impacted.

There can be no assurance of market acceptance for our COVID-19 antibody test.

The commercial success of our COVID-19 antibody test will depend upon its acceptance as medically useful and cost-effective by physicians and other members of the medical community, patients and third-party payers. Broad market acceptance can be achieved only with substantial education about the benefits and limitations of such tests, as well as resolution of concerns about their appropriate use. Our reputation and the public image of our COVID-19 antibody test kits may be impaired if they fail to perform as expected or are perceived as difficult to use. Despite quality control testing, defects or errors could occur with the tests. Thus, there can be no assurance our COVID-19 antibody test will gain market acceptance on a timely basis, if at all, and purchasers of such tests could choose to purchase competitors' tests instead. Failure to achieve market acceptance and/or the impact of strong competition will have a material adverse effect on our business, financial condition and results of operations.

We rely on a third party to manufacture the COVID-19 antibody tests for us, and if such third party refuses or is unable to supply us with the COVID-19 test kits, our business will be materially harmed.

We rely on a third party to manufacture the COVID-19 antibody tests. If any issues arise with respect to the manufacturer's ability to manufacture and deliver to us the COVID-19 tests, our business could be materially harmed. In addition, the manufacturer may be unable to provide us with an adequate supply of COVID-19 antibody tests for various reasons, including, among others, if it becomes insolvent, if a United States regulatory authority or other governments block the import or sale of the COVID-19 tests or if it fails to maintain its rights to manufacture the COVID-19 test. If we are unable to keep up with demand for the COVID-19 antibody test kits, our revenue growth could be impaired, market acceptance for the test could be adversely affected, and our customers might instead purchase our competitors' diagnostic tests.

We have relied and expect to continue to rely on third parties to conduct studies of the COVID-19 diagnostic tests that will be required by the FDA or other regulatory authorities, and those third parties may not perform satisfactorily.

Although we are selling our COVID-19 antibody test kits by virtue of recent FDA guidance allowing for reduced product clinical and analytical studies, we have relied on third parties, such as independent testing laboratories and hospitals, to conduct such studies. Our reliance on these third parties will reduce our control over these activities. These third-party contractors may not complete activities on schedule or conduct studies in accordance with regulatory requirements or our study design. We cannot control whether they devote sufficient time, skill and resources to our studies. Our reliance on third parties that we do not control will not relieve us of any applicable requirement to prepare, and ensure compliance with, various procedures required under good clinical practices. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties need to be replaced or if the quality or accuracy of the data they obtain is compromised due to their failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our studies may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for additional diagnostic tests.

A pandemic, epidemic or outbreak of an infectious disease, such as COVID-19, may materially and adversely affect our business and operations.

The recent outbreak of COVID-19 originated in Wuhan, China, in December 2019 and has since spread to multiple countries, including the United States and several European countries. On March 11, 2020, the World Health Organization declared the outbreak a pandemic. The COVID-19 pandemic is affecting the United States and global economies and may affect our operations and those of third parties on which we rely, including by causing disruptions in the supply of our product candidates and the conduct of future clinical trials. In addition, the COVID-19 pandemic may affect the operations of the FDA and other health authorities, which could result in delays of reviews and approvals, including with respect to our product candidates. Additionally, while the potential economic impact brought by, and the duration of the COVID-19 pandemic is difficult to assess or predict, the impact of the COVID-19 pandemic on the global financial markets may reduce our ability to access capital, which could negatively impact our short-term and long-term liquidity. The ultimate impact of the COVID-19 pandemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, financing or clinical trial activities or on healthcare systems or the global economy as a whole. However, these effects could have a material impact on our liquidity, capital resources, operations and business and those of the third parties on which we rely.

Risks Related to Our Intellectual Property

We may not successfully maintain our existing license agreement with BGU and Soroka 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. Our failure to maintain our existing license 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 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 In Vitro Diagnostics (“IVD”) have recently been revised and major changes need to be made in order to keep our CE Mark. These changes will need to be made by 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 “Rabin”), and Kaplan Medical Center (“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 organizations, 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.

United States Federal and state privacy laws, and equivalent laws of other 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. In addition, we expect to incur operating expenses denominated in various currencies, and therefore, our operating results will also be 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. Inflation in Israel and changes to the dollar-NIS exchange rate did not have a material adverse effect on the results of our operations in 2019 or 2018.

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, most 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 controlled the Gaza strip since 2007) and the Hezbollah (an Iranian-backed 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.

Although Israel has entered into various agreements with Egypt, Jordan, and the Palestinian Authority, there has been an increase in unrest and terrorist activity, which began in October 2000 and has continued with varying levels of severity. The establishment in 2006 of a government in the Gaza Strip by representatives of the Hamas militant group has created additional unrest and uncertainty in the region. In 2006, a conflict between Israel and the Hezbollah in Lebanon resulted in thousands of rockets being fired from Lebanon up to 50 miles into Israel. Starting in December 2008, for approximately three weeks, Israel engaged in an armed conflict with Hamas in the Gaza Strip, which involved missile strikes against civilian targets in various parts of Israel and negatively affected business conditions in Israel. In November 2012, for approximately one week, Israel experienced a similar armed conflict, resulting in hundreds of rockets being fired from the Gaza Strip and disrupting most day-to-day civilian activity in southern Israel. Most recently, in July 2014, Israel yet again experienced rocket strikes against civilian targets in various parts of Israel, as part of an armed conflict commenced between Israel and Hamas. If continued or resumed, these hostilities may negatively affect business conditions in Israel in general and our business in particular. Our insurance policies do not cover us for the damages incurred in connection with these conflicts or for any resulting disruption in our operations. The Israeli government, as a matter of law, provides coverage for the reinstatement value of direct damages that are caused by terrorist attacks or acts of war; however, the government may cease providing such coverage or the coverage might not be enough to cover potential damages. 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 products, our operations may be materially adversely affected.

In addition, since the end of 2010, numerous acts of protest and civil unrest have taken place in several countries in the Middle East and North Africa, many of which involved significant violence. The civil unrest in Egypt, which borders Israel, resulted in the resignation of its president Hosni Mubarak, and to significant changes to the country's government. In Syria, also bordering Israel, a civil war is continuing to take place. The ultimate effect of these developments on the political and security situation in the Middle East and on Israel's position within the region is not clear at this time.

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.

In addition, Iran has threatened to attack Israel and is widely believed to be developing nuclear weapons. Iran is also believed to have a strong influence among extremist groups in the region, such as Hamas in Gaza, Hezbollah in Lebanon, and various rebel militia groups in Syria. Additionally, a violent jihadist group named Islamic State of Iraq and Levant, or ISIL, is involved in hostilities in Iraq and Syria. Although ISIL's activities have not directly affected the political and economic conditions in Israel, ISIL's stated purpose is to take control of the Middle East, including Israel. These situations may potentially escalate in the future to more violent events, which may affect Israel and us. Any armed conflicts, terrorist activities, or political instability in the region could adversely affect business conditions and could harm our results of operations and could make it more difficult for us to raise capital. Parties with whom we do business may 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.

The legislative power of the State resides in the Knesset, a unicameral parliament that consists of 120 members elected by nationwide voting under a system of proportional representation. Israel's most recent general elections were held on April 9, 2019, September 17, 2019 and March 2, 2020. Although a government was recently formed for the first time since December 2018, the uncertainty surrounding the results of the recent elections may continue. Actual or perceived political instability in Israel or any negative changes in the political environment, may individually or in the aggregate adversely affect the Israeli economy and, in turn, our business, financial condition, results of operations and prospects.

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.

Our operations may be disrupted by the obligations of personnel to perform military service.

As of June 12, 2020, we had four employees, two of whom were based in Israel. Some of our employees may be called upon to perform up to 36 days (and in some cases more) of annual military reserve duty until they reach the age of 40 (and in some cases, up to 45 or older) and, in emergency circumstances, could be called to immediate and unlimited active duty. In the event of severe unrest or other conflict, individuals could be required to serve in the military for extended periods of time. Since September 2000, in response to increased tension and hostilities, there have been occasional call-ups of military reservists, including in connection with the 2006 conflict in Lebanon, and the December 2008, November 2012 and July 2014 conflicts with Hamas, and it is possible that there will be additional call-ups in the future. Our operations could be disrupted by the absence of a significant number of our employees related to military service or the absence for extended periods of one or more of our key employees for military service. Such disruption could materially adversely affect our business and results of operations. Additionally, the absence of a significant number of the employees of our Israeli suppliers and contractors related to military service or the absence for extended periods of one or more of their key employees for military service may disrupt their operations.

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. We are a "foreign private issuer" under the Exchange Act, and intend to follow certain home country corporate governance practices, and our shareholders may not have the same protections afforded to shareholders of companies that are subject to all corporate governance requirements under the listing rules of the Nasdaq Stock Market LLC, or the Nasdaq Listing Rules.

The rights and responsibilities of the holders of our Ordinary Shares are governed by our articles of association, as amended (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. For instance, we follow home country practice in Israel with regard to the quorum requirement for shareholder meetings. As permitted under the Companies Law, our Amended Articles provide that the quorum for any meeting of shareholders shall be the presence of at least two shareholders present in person, by proxy, or by a voting instrument, who hold at least 25% of the voting power of our shares. Moreover, 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, or against our officers and directors in Israel, or to assert U.S. securities laws claims in Israel or to serve process on our officers and directors in Israel.

We were incorporated in Israel. A majority of our executive officers and directors reside outside of the United States, and all of our assets and most of the assets of these persons are located outside the United States. 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.

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, 2019, we have been awarded an aggregate of \$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 (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, 2019, we had not paid any royalties to the IIA. In 2019, 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, including an increased royalty rate.

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, 2019 and 2018, we did not apply for or receive any grants from the IIA.

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. Although we are in the process of applying to have our Ordinary Shares listed on The Nasdaq Capital Market, an active trading market for our shares may never develop or be. If an active market for our Ordinary Shares does not develop, it may be difficult for our shareholders to their securities without depressing the market price for their Ordinary Shares, or at all.

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 amount of convertible debt and a number of stock options and stock warrants outstanding, and while such convertible debt, options and warrants are outstanding, it may be more difficult to raise additional equity capital.

As of December 31, 2019, and December 31, 2018, we had outstanding stock options to purchase 2,267,571 and 1,758,316 Ordinary Shares, respectively. As of December 31, 2019, and December 31, 2018, we had outstanding stock warrants to purchase 28,294,679 and 4,730,906 Ordinary Shares, respectively. In addition, during the years ended December 31, 2019 and December 31, 2018, we issued convertible notes in an aggregate net principal amount of \$1,442,250 and \$27,000, respectively. During the period of January 1, 2020 through June 12, 2020, loan principal and interest of \$553,973 has been converted into 36,668,926 Ordinary shares. We may find it more difficult to raise additional equity capital while such debt instruments, 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 our outstanding options and warrants or conversion of our outstanding debt 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; however, due to the COVID-19 pandemic, the SEC has granted a 45-day extension for issuers whose annual reports, including annual reports on Form 20-F, were otherwise due on or prior to July 1, 2020, and we have taken advantage of that extension. Foreign private issuers are also exempt from the Regulation Fair Disclosure, aimed at preventing issuers from making selective disclosures of material information.

In order to maintain our current status as a foreign private issuer, more than 50% of our outstanding voting securities must not be directly or indirectly owned by residents of the U.S., and we must not have any of the following: (i) a majority of our executive officers or directors being U.S. citizens or residents, (ii) more than 50% of our assets being located in the U.S., or (iii) our business being principally administered in the U.S. Although we have elected to comply with certain U.S. regulatory provisions, our loss of foreign private issuer status would make such provisions mandatory. The regulatory and compliance costs to us under U.S. securities laws as a U.S. domestic reporting company may be significantly higher. If we are not a foreign private issuer, we will be required to file periodic reports and registration statements on U.S. domestic reporting company forms with the SEC, which are more detailed and extensive than the forms available to a foreign private issuer. We may also be required to modify certain of our policies to comply with accepted governance practices associated with U.S. domestic reporting companies. Such conversion and modifications will involve additional costs. In addition, we may lose our ability to rely upon exemptions from certain corporate governance requirements on U.S. stock exchanges that are available to foreign private issuers.

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. Moreover, some of our outstanding debt instruments restrict our ability to pay cash dividends while they are outstanding. 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.

Our Ordinary Shares are subject to the “penny stock” rules of the SEC and the trading market in the securities is limited, which makes transactions in the stock cumbersome and may reduce the value of an investment in the stock.

Rule 15g-9 under the Exchange Act establishes the definition of a “penny stock,” for the purposes relevant to us, as any equity security that has a market price of less than \$5.00 per share or with an exercise price of less than \$5.00 per share, subject to certain exceptions. For any transaction involving a penny stock, unless exempt, the rules require: (a) that a broker or dealer approve a person’s account for transactions in penny stocks; and (b) the broker or dealer receive from the investor a written agreement to the transaction, setting forth the identity and quantity of the penny stock to be purchased.

In order to approve a person’s account for transactions in penny stocks, the broker or dealer must: (a) obtain financial information and investment experience objectives of the person and (b) make a reasonable determination that the transactions in penny stocks are suitable for that person and the person has sufficient knowledge and experience in financial matters to be capable of evaluating the risks of transactions in penny stocks.

The broker or dealer must also deliver, prior to any transaction in a penny stock, a disclosure schedule prescribed by the SEC relating to the penny stock market, which, in highlight form: (a) sets forth the basis on which the broker or dealer made the suitability determination; and (b) confirms that the broker or dealer received a signed, written agreement from the investor prior to the transaction. Generally, brokers may be less willing to execute transactions in securities subject to the “penny stock” rules. This may make it more difficult for investors to dispose of our common stock and cause a decline in the market value of our common stock.

Disclosure also has to be made about the risks of investing in penny stocks in both public offerings and in secondary trading and about the commissions payable to both the broker or dealer and the registered representative, current quotations for the securities and the rights and remedies available to an investor in cases of fraud in penny stock transactions. Finally, monthly statements have to be sent disclosing recent price information for the penny stock held in the account and information on the limited market in penny stocks.

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.

You may experience dilution of your ownership interest due to the issuance of additional ordinary shares upon the conversion of our convertible debt, especially since our convertible debt has fluctuating conversion rates that are set at a discount to market prices of our ordinary shares during the period immediately preceding conversion.

During the year ended December 31, 2018, the Company raised a net amount of \$27,000, as part of convertible bridge loan transactions. During the year ended December 31, 2019, the Company raised a net amount of \$1,374,470 as part of convertible bridge loan transactions. In the event we do not repay our convertible debt prior to the maturity date for these loans, the lenders may choose to convert their loans, which in most cases are convertible into our Ordinary Shares after the maturity date at a conversion price equal to 70% of the average closing bid price of our Ordinary Shares in the five days prior to the conversion. In the event we default under the loan agreement, the conversion price will be reduced to 60% of the average closing bid price of our Ordinary Shares during the 15 days prior to the conversion. This could result in material dilution to our existing shareholders. Because the conversion price is based upon the trading prices of our Ordinary Shares at the time of conversion, the number of Ordinary Shares into which the convertible debt may be converted may increase without an upper bound. If the trading prices of our Ordinary Shares are low when the conversion price of the convertible debt is determined, we would be required to issue a greater number of Ordinary Shares to the converting debtholder, which could cause substantial dilution to our shareholders. In addition, if any or all of the holders of our convertible debt convert and then sell our Ordinary Shares, this could result in an imbalance of supply and demand for our Ordinary Shares and reduce our stock price. The further our stock price declines, the further the adjustment of the conversion price will fall and the greater the number of Ordinary Shares we will have to issue upon conversion, resulting in further dilution to our shareholders.

The trading price of our ordinary shares may be reduced as a result of our grant of registration rights.

We have granted the lenders who participated in our convertible bridge loan financing with piggyback registration rights. This means that they will have the right to require us to register their shares for resale under the Securities Act in the event we file a registration statement with the SEC following the filing of our Registration Statement on Form F-1. Registration of those shares for resale under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act immediately upon the effectiveness of such registration. Any sales of the registered securities by these shareholders could adversely affect the trading 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. Our principal executive office is located at 1 Hamada Street, Rehovot, 7670301 Israel and our telephone number in Israel is +972-52-642-0126.

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. The SEC also maintains an Internet site that contains reports, proxy and information statements 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 <https://www.sec.gov>. Puglisi & Associates is our agent in the United States, and its address is 850 Library Avenue, Suite 204, Newark, Delaware 19711.

Breakthrough Diagnostics Acquisition

On February 27, 2019, we entered into a joint venture agreement with Amarantus, pursuant to which we issued Ordinary Share representing 19.99% of our then outstanding Ordinary Shares to Amarantus, in exchange for Amarantus transferring to us 19.99% of Breakthrough, a wholly-owned subsidiary of Amarantus, and for Amarantus assigning the License to Breakthrough. As part of the transaction, we agreed to provide working capital to Breakthrough to support Breakthrough's operations. As part of the Breakthrough joint venture, we were granted an exclusive option, which was limited to an exercise period of 60 days from its date, to acquire the remaining 80.01% of Breakthrough from Amarantus. At our 2019 annual meeting of shareholders, our shareholders approved a resolution authorizing us to exercise our option to acquire the remaining 80.01% of Breakthrough from Amarantus in exchange for an additional 30% of our then issued and outstanding Ordinary Shares. While the Breakthrough option has not yet been exercised, the option has been extended by both parties and remains in effect. Our Chief Executive Officer, Gerald Commissiong, is also the Chief Executive Officer of Amarantus.

Breakthrough is developing the LymPro Test as a blood-based diagnostic test for Alzheimer's disease. LymPro was originally invented at the University of Leipzig in Germany (Leipzig) by Dr. Thomas Arendt based on the theory that the immune system is perturbed in Alzheimer's. LymPro works by evaluating the cell surface marker CD69 on peripheral blood lymphocytes following a mitogenic stimulation. The underlying scientific basis for LymPro is that Alzheimer's patients have a dysfunctional immune system that perturbs the cellular division process, and inappropriately allows mature neurons in the brain to enter the mitotic process (cell division/cell cycle), leading to an attempt at cell proliferation. When this happens, the neurons start the cell division process, but cannot complete the process and therefore end up with two cellular infrastructures in a single cell, resulting in 'ploidy' which is a condition where more than one strand of DNA is present in a cell. Ploidy leads to the upregulation of signaling pathways that produce proteins in quantities that are too large for the cell to properly fold. Misfolded beta amyloid is a well-known misfolded protein marker for Alzheimer's disease that deposits in increasing concentrations in certain areas of the brain as the disease progresses. This inappropriate cell division activation process is also present in the lymphocytes of Alzheimer's patients, and its measurement allows for the diagnosis of Alzheimer's using peripheral. In 2019, Breakthrough funded a clinical trial at Leipzig that demonstrated data generated using LymPro was predictive of data measuring beta amyloid ($r = 0.849$, $p = 00000216$) in Alzheimer's patients. The 2019 data generated at Leipzig demonstrated that LymPro scores were closely correlated with standard scores for beta amyloid brain deposit concentrations. We believe that the LymPro Test can be used to identify the body's immune system response to Alzheimer's, allowing physicians and biopharmaceutical companies to diagnose early and monitor the progression of Alzheimer's disease, which has the potential to be an extremely valuable tool for the development of novel treatments for Alzheimer's.

Provista Diagnostics Acquisition

On December 19, 2019, we entered into the Option Agreement with SIH, the sole owner of Ascenda, Ascenda, the sole owner of Provista, and Provista. Pursuant to the Option Agreement, Ascenda granted us an exclusive option until March 31, 2020, subject to extension, to acquire all of the shares of Provista. In consideration for the option, we issued SIH 17,091,096 Ordinary Shares, or the equivalent of \$1 million of our Ordinary Shares on the date of issuance. Subsequently, on April 2, 2020, we issued SIH an additional 13,008,976 Ordinary Shares, which was the equivalent of an additional \$1 million (collectively, the "Option Shares") in exchange for an extension of the exclusive option to June 30, 2020.

On March 30, 2020, our Board of Directors determined to exercise the option to acquire all of the shares of Provista, and on April 2, 2020 it gave notice of such determination to Provista. At an extraordinary general meeting on May 11, 2020, our shareholders approved the consideration to be issued to SIH as consideration for the acquisition. We believe that the acquisition of Provista, a development stage cancer diagnostic company, is in our best interests because Provista's blood test for breast cancer called Videssa® is in a more advanced stage than our blood test for breast cancer in terms of commercialization in the United States. Videssa was previously commercialized by Provista in a product launch in 2016 at a time when reimbursement in the United States was undergoing significant change due to the implementation of the Affordable Care Act (the "ACA"). Under rules prior to the implementation of the ACA, new diagnostic tests were primarily reimbursed using a strategy called 'Code Stacking' which involved taking pre-existing Current Procedural Terminology ("CPT") codes for medical procedures and diagnostic biomarkers, adding the value of each allowable component of the new diagnostic test together, and charging the end user the combined allowable amount as determined by the Centers for Medicare & Medicaid Services ("CMS"). As part of the implementation of the ACA, Code Stacking was replaced with Evidence-based Valuation ("EBV") where a new diagnostic test had to undergo clinical utility testing to determine reimbursement pricing. Clinical utility testing involves conducting a clinical trial with a new diagnostic test as if it were the standard of care, and identifying the full value of the changes to the healthcare system based upon the results of that trial, and establishing a new unique CPT code for the new diagnostic test based upon the value identified in the clinical utility study. In Provista's initial commercial launch, its reimbursement requests were rejected by CMS due to lack of EBV, and therefore the product was pulled from the market in 2018. In the intervening period between 2018 and 2020, Provista gathered additional scientific and clinical information regarding Videssa and has completed the drafting of a protocol to conduct a prospective clinical utility study to establish EBV. We intend to acquire Provista and fund the EBV study to satisfy CMS and establish a unique CPT code for Videssa. It is possible that CMS may grant limited CPT code based upon the preliminary data that Provista will present in discussions with CMS so that a present number of Videssa tests may be reimbursed to offset the financial burden of running the clinical utility study, and our team is working closely with Provista's team to engage with CMS in those discussions, although there are no assurances that any such limited reimbursement will occur. As part of the clinical utility study, we intend to piggyback data gathering for our breast cancer tests based upon specimens gathered for the Videssa clinical utility study, which would have the effect of dramatically increasing the quantity of data available for the our breast cancer tests. Therefore, upon our acquisition of Provista, we may be able to accelerate the timeline pursuant to which we may be able to bring our blood tests to the market as a result of working closely with the Videssa tests in United States which management believes is in our best interests and that of our shareholders. The Provista acquisition is conditioned upon our Ordinary Shares being listed on Nasdaq.

Our capital expenditures for the years 2019 and 2018 amounted to \$1,073 and \$15,370, 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 derived mainly from fundraising.

We are an “emerging growth company,” as defined in Section 2(a) of the Securities Act of 1933, as amended (“Securities Act”), as implemented under the Jumpstart Our Business Startups Act of 2012 (“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 of 2002, as amended (Sarbanes-Oxley Act). We will remain an emerging growth company until the earlier of (i) the last day of the fiscal year in which we have total annual gross revenues of \$1.07 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of our initial public offering; (iii) the date on which we have issued more than \$1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the Securities and Exchange Commission (“SEC”).

We are a foreign private issuer as defined by the rules under the Securities Act and the Securities Exchange Act of 1934 (“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.

B. Business Overview

Todos Medical Ltd. (“Todos Medical,” the “Company,” “we,” “our,” “us”), is a medical diagnostics company engaged in the development and commercialization of blood tests for the detection of immune-related diseases, beginning with cancer. Our core proprietary technology centers on testing blood cells using an FTIR spectrometer to turn biological information into data, and then using our patented TBIA deep learning data analytics platform to mine the data in order to develop algorithms that are indicative of the presence of cancer, and the tissue of origin in the body where the cancer is located. The TBIA detection method is based on cancer’s influence on the immune system that triggers biochemical changes in peripheral blood. The primary advantages of the TBIA platform are the high accuracy (sensitivity and specificity) and low COGS due to the biological information being captured using spectroscopy versus biological antibody capture methods that require the manufacture of multiple antibodies to capture a biological signature. TBIA is based upon technology originally invented by the researchers at BGU and Soroka, whose intellectual property has been licensed to us. We have received a CE Mark in the European Union authorizing the commercial use of the TBIA platform in the diagnosis of breast cancer and colon cancer. We have been issued patents in the United States, Europe and other international jurisdictions covering the use of TBIA to detect solid tumors. We have also entered into distribution agreements with development partners in preparation for the commercial launch of TBIA for breast cancer in Israel, Romania and Austria during the second half of 2020. Our academic partners at BGU have also published research suggesting FTIR has the potential to be used to identify the presence of viral and bacterial infections, and the Company is currently evaluating how best to pursue its technology in these areas in light of increased commercial interest for viral detection methods in light of the recent outbreak of novel Coronavirus (SARS-CoV-2, or COVID-19) worldwide.

Because of the novelty and highly disruptive nature of TBIA analysis using FTIR to diagnose disease, we believe the best path forward to bring Todos’ core technology to market in the United States is to demonstrate comparability with blood tests that are built on technology platforms that are in widespread use. Due to the relative scarcity of commercial blood tests in areas such as cancer and Alzheimer’s disease, we entered into agreements whereby we have agreed to acquire companies that have developed proprietary blood tests in those therapeutic indications in order to gain a foothold in the marketplace and fine tune our FTIR platform while fully commercializing these more advanced tests in the United States. We chose to expand into Alzheimer’s disease because we view Alzheimer’s as cancer of neuronal cells that are incapable of completing cell division due to their post-mitotic nature.

On March 30, 2020, our Board of Directors determined to exercise our option to acquire all of the shares of Provista, and on April 2, 2020 it gave notice of such determination to Provista. At an extraordinary general meeting on May 11, 2020, our shareholders approved the consideration to be issued to SIH as consideration for the acquisition. The Provista acquisition will enable us to gain exclusive worldwide rights to the commercial-stage breast cancer test Videssa™. However, the acquisition cannot be consummated unless and until our Ordinary Shares are listed for trading on NASDAQ.

At our 2019 annual meeting of shareholders, our shareholders approved a resolution authorizing us to exercise our option to acquire the remaining 80.01% of Breakthrough from Amaranthus in exchange for an additional 30% of our then issued and outstanding Ordinary Shares. While the Breakthrough option has not yet been exercised, the option has been extended by both parties and remains in effect. Breakthrough is a joint venture we formed with Amaranthus to gain ownership of exclusive worldwide rights to the Alzheimer's blood test called the Lymphocyte Proliferation Test (LymPro Test™). Taken together with our core TBIA FTIR-based platform, we believe Todos is positioned to become the worldwide leader in the field of immune-based diagnostics. The Company formed the subsidiary Todos Medical Singapore Ltd. for the purpose of advancing clinical trials of the Company's core technology for breast cancer in Southeast Asia.

Additionally, in view of our status as a leader in the field of immune-based diagnostics, we made the strategic corporate decision to enter the field of COVID-19 testing. Similarly to our strategy in cancer and Alzheimer's where we felt more traditional, advanced technologies would serve as the basis for market entry before bringing our proprietary FTIR-based TBIA platform forward, we decided to enter the COVID-19 space by gaining rights to existing technologies developed by other companies. As such, we entered into distribution agreements with multiple companies to gain rights to rapid IgM/IgG COVID-19 antibody test kits, RNA extraction machines, RNA extraction reagents, qPCR reagents and digital PCR reagents so as to be able to offer a comprehensive suite of solutions to laboratories worldwide. Additionally, the Company has entered into a joint venture with NLC Pharma to bring to market a unique development-stage viral protease based saliva point of care cell phone enabled diagnostic device that allows for the rapid detection of the presence of SARS-CoV-2 full length RNA in saliva which has the unique benefit of also indicating when viral replication has slowed or ceased. This technology will potentially have a significant impact for the development of virus targeting therapeutic development strategies, as well as clearance for return to life activities post-infection. As a complementary strategy to COVID-19 testing, we have entered into distribution agreements for certain PPE and medical devices, including ventilators, that are have complementary sales channels to our COVID-19 testing products and services. We believe this strategy has the potential to help accelerate our commercial distribution channels as we begin to commercialize our core technology, and the technologies we are currently acquiring via the Provista and Breakthrough acquisitions.

More specifically as it relates to our emerging COVID-19 diagnostic testing business, in the first half of 2019 we have been able to focus the Company's human capital on securing rights and validating newly sourced diagnostic testing platforms and establishing sales distribution channels for our suite of COVID-19 products and services. To that end, we are focused on the following tasks:

1. Todos Medical Ltd. (Israel): Identification of innovation in diagnostic testing products, services and related PPE, including medical devices such as ventilators, as well as import/export of our suite of products from our manufacturers' country of origin and country of destination, primarily focusing our marketing efforts in Europe and Africa. The Company is able to utilize its broad network of international contacts who originate from Israel to identify opportunity;

2. Todos Medical USA (United States of America): FDA authorized medical importer and distributor focused on the distribution the Company's testing products and services and PPE to customers in the North America and Latin America. Todos Medical USA has formed the subsidiary Corona Diagnostics, LLC, for the purpose of marketing COVID-19 related products in the United States and contracting with Provista Diagnostics, Inc. to validate potential products the Company is contemplating distributing and creating marketing materials for the testing products based upon those validations;

3. Todos Medical Singapore, Pte. Ltd.: HSA which is the Singapore equivalent of the FDA, authorized medical importer and distributor focused on distributing test kits for the Company's core technologies in Southeast Asia.

The Company believes that by identifying key areas of inefficiency in the COVID-19 testing space, and addressing those bottlenecks, whether they be scientific, technical or logistical, we can capture market share in a new and rapidly growing medical testing industry that, according to Research and Markets, is expected to reach approximately \$44.5 billion for 2020. We are a medical diagnostics company engaged in the development and commercialization of blood tests for the detection of immune-related diseases, beginning with cancer. Our core technology centers on testing blood cells using a FTIR spectrometer to turn biological information into data, and then using our proprietary TBIA data analytics platform to prospectively mine the data to develop algorithms that are indicative of the presence of cancer, and the tissue of origin in the body where the cancer is located. The TBIA detection method is based on cancer's influence on the immune system that triggers biochemical changes in peripheral blood. The primary advantages of the TBIA platform are the high accuracy (sensitivity and specificity) and very low COGS due to the biological information being captured using spectroscopy versus biological markers. TBIA is based upon technology originally invented by the researchers at BGU and Soroka, whose intellectual property has been licensed to us. We have received a CE Mark in the European Union authorizing the commercial use of the TBIA platform in the diagnosis of breast cancer and colon cancer. We have been issued patents in the United States, Europe and other international jurisdictions covering the use of TBIA to detect solid tumors. We have also entered into a distribution agreement with a development partner in preparation for the commercial launch of TBIA for breast cancer in Romania and Austria during the second half of 2020. Through our Breakthrough joint venture, we have also entered the field of early detection of Alzheimer's disease. We believe that Alzheimer's and cancer share certain immune-related characteristics that make their joint development advantageous.

Our two most advanced blood tests for cancer are for the screening and diagnosis of breast cancer. TM-B1 is our breast cancer test for the screening and diagnosis of breast cancer in all women, and TM-B2 is our breast cancer test for the screening and diagnosis of breast cancer in women who have ‘dense breasts.’ Dense breasts, medically categorized as BI-RADS 3 and BI-RADS 4, make mammograms largely ineffective because the biophysical structure of the breast does not allow high enough resolution on the mammogram X-ray to determine whether or not a tumor is present, leading to potentially unnecessary additional imaging tests and breast biopsies in women who have dense breasts. Our TMC blood test is for the screening and diagnosis of colon cancer. In April 2019, we entered into a commercial distribution agreement with Orot+, a division of Lucas-Orot, for the pre-commercial and commercial launch of the TM-B1 and TM-B2 breast cancer tests in Romania and Austria. We have been working together with Orot to complete a pre-commercial clinical study in Romania (the “Romania Study”) as the first proof of principle that TM-B1 and TM-B2 can be deployed in the commercial breast cancer diagnostics marketplace. We expect to commercially launch TM-B1 and TM-B2 with Orot in Romania in 2020 upon completion of the Romania Study, and thereafter will launch in Austria; however, some of our tests have been delayed due to the impact of the Coronavirus pandemic.

Recent Developments

SARS-nCoV-2 related business

On March 17, 2020, Todos USA entered into a non-exclusive distribution agreement with 3D Biomedicine Science & Technology Co., Ltd. (3D Med) to market 3D Med’s novel Coronavirus (SARS-nCoV-2) and SARS-nCoV-19 + Influenza A/Influenza B polymerase chain reaction (PCR) test kits, and extraction solution (automated RNA extraction system and optimized extraction reagents) in the United States and Israel. 3D Med has applied for Emergency Use Authorization (EUA) with the FDA.

On March 19, 2020, Todos USA entered into an exclusive sub-distribution agreement with Gibraltar Brothers & Associates LLC (Gibraltar) to market Shanghai Liangrun Biomedicine Technology Co., Ltd’s (Liangrun) immunochromatography-based colloidal gold SARS-nCoV-2 fingerprick IgM/IgG rapid antibody test (Shanghai Colloidal Gold) in the United States and Israel. Gibraltar was granted exclusive territorial distribution rights to market Shanghai Colloidal Gold by Liangrun. Liangrun has applied for EUA with the US FDA.

On March 23, 2020, Todos USA expanded its agreement with Gibraltar to add products and territories. The products added to the agreement were Shanghai PCR test kits, and the territories added included Singapore, Malaysia, Indonesia, Thailand, Myanmar, Vietnam, the Philippines, Cambodia/Laos, Hong Kong, Japan, South Korea, Taiwan, India, United Kingdom, Sweden, Italy, the Gulf States, Dubai and the United Arab Emirates.

On March 23, 2020 Todos Medical USA (“Todos USA”) entered into a Joint Venture Agreement (the “Emerald Agreement”) with Emerald Organic Products, Inc., a Nevada corporation (“Emerald”), for the formation of Corona Diagnostics, LLC (the “Joint Venture”) in order to manage, operate and distribute viral testing currently controlled by Todos USA. It was agreed that (1) Todos USA will contribute diagnostic testing under its control that will be useful in detecting COVID-19 (“Viral Testing”), and will contribute the expertise and know-how to the Joint Venture necessary to validate the products for distribution; (2) Emerald will contribute capital for validation as per the budget as described in the Emerald Agreement and is responsible for developing and implementing the necessary financial structures for the distribution of the Viral Testing; (3) interest in the Joint Venture was 51% owned by Emerald and 49% owned by Todos USA; (4) Emerald was entitled to receive priority distributions from the Joint Venture up to the amount of any cash capital contributions made by Emerald; (5) the Board of Managers had three board members: two appointed by Emerald and one by Todos USA; and (6) the Joint Venture was for 25 years unless earlier dissolved by mutual agreement of Todos Medical USA and Emerald.

On April 24, 2020, Todos Medical USA entered into the Amended and Restated Collaboration Agreement with Emerald, pursuant to which Todos became the owner of 100% of the equity of the Joint Venture, and agreed to integrate its COVID-19 tests with Emerald’s telemedicine (Carie Health, Inc.) and independent pharmacy (Bonsa Health, Inc.) businesses to create a full solution to help facilitate the screening and diagnosis of individuals having indications of the COVID-19 Polymerase Chain Reaction (PCR) and/or antibody testing status, which may facilitate return to work programs in the United States.

On April 18, 2020, Todos USA entered into an Original Equipment Manufacturing (OEM) agreement with Zhengzhou Fortune Bioscience Co. Ltd. (Zhengzhou) for the manufacture of immunochromatography-based colloidal gold SARS-nCoV-2 fingerprick IgM/IgG and IgA/IgM/IgG – IgD/IgE rapid antibody test (Zhengzhou Colloidal Gold). Zhengzhou has applied for EUA with the US FDA.

On April 28, 2020, the Company announced positive data from a clinical study it completed evaluating the diagnostic concordance of Shanghai Colloidal Gold to PCR testing, as done by Quest Diagnostics, in hospitalized patients confirmed COVID-19 positive or negative (the disease caused by SARS-nCoV-2).

On May 7, 2020, Todos USA entered into an exclusive distribution agreement with Gnomegen, LLC for the distribution of SARS-nCoV-2 PCR test kits in the United States, Canada, Mexico, Israel, Singapore, Malaysia, Indonesia, Thailand, Myanmar, Vietnam, the Philippines, Cambodia/Laos, Hong Kong, Japan, South Korea, Taiwan, India, the United Kingdom, Sweden, Italy, France, Germany, Switzerland, Spain, India, Australia, Gulf States, Dubai, United Arab Emirates, Argentina, Aruba, Bahamas, Barbados, Belize, Bolivia (Plurinational State of), Brazil, Chile, Colombia, Costa, Rica, Dominican Republic, Ecuador, El Salvador, Martinique, Grenada, Guatemala, Guyana, Haiti, Honduras, Jamaica, Nicaragua, Panama, Paraguay, Peru, Saint Kitts, and Nevis, Suriname, Trinidad and Tobago, Uruguay and Venezuela. Zhengzhou has received EUA from the US FDA.

On May 12, 2020, Todos USA entered into a non-exclusive distribution agreement with Zhengzhou for the distribution of its suite of immunochromatography-based colloidal gold SARS-nCoV-2 fingerprick rapid antibody test kits. Zhengzhou has applied for EUA with the US FDA.

On May 18, 2020, we announced our first commercial sale of COVID-19 tests. The sale was made via a sub-distribution agreement with a U.S.-based medical distribution company with clients in state and local governments throughout the Southeastern United States who are seeking comprehensive testing solutions for return-to-work programs.

We market our COVID-19 test kits through our distributors, who include Dynamic Distributors, LLC, L1 Systems Ltd., Pangea Ltd., Parallax Diagnostics, Inc., Moshe Rothman and Test Diagnostics, Inc.

Fundraising

On February 10, 2020, the Company entered into a Business Development Agreement (the “BDA”) with Orion Capital Advisors, LLC (“BDC”) whereby BDC will provide business development service to the Company which include inter alia (a) review and advice concerning the technical design of existing and planned products or services; (b) business development assistance including terms of possible transactions and suggestions during negotiations; (c) sales assistance through the development of business models and sales strategy; (d) advice regarding financing, review of proposed term sheets, capitalization planning and, where appropriate, participation in negotiations; (e) strategic consulting regarding product planning, market development, marketing and public relations; (f) consulting on corporate structure, employee stock option structure, warrant arrangements and intellectual property planning; (g) introductions to potential strategic partners and other alliance candidates; (h) introductions to prospective customers for the Company’s products or services.

Upon signing the BDA, the Company issued 2,500,000 restricted ordinary shares to BDC.

The term of this Agreement is through August 10, 2020

On April 6, 2020 (the “Effective Date”), the Company entered into an engagement agreement (“Engagement Agreement”) with Dawson James Securities (“Dawson”) to act as lead or managing placement agent on a best efforts basis in connection with any public or private offering or other financing or capital-raising transaction of any kind (“Tail Financing”) to the extent that such financing or capital is provided to the Company by investors whom Dawson had introduced to the Company during a period of 60 days commencing the Effective Date (the “Engagement Period”) if such Tail Financing is consummated at any time during the Engagement Period or within the 12-month period following the expiration or termination of Agreement or the completion of the offering (the “Tail Period”). If the offering is completed, for a period of 12 months from the offering date, the Company grants Dawson the right of first refusal to act as lead managing underwriter or book runner, or as lead placement agent, for any and all future equity, equity-linked or debt (excluding commercial bank debt) offerings during such period, of the Company, or any successor to or any subsidiary of the Company.

In consideration for the services to be rendered by Dawson, the Company will pay to Dawson a placement agent fee of 8% of the gross proceeds received in the Tail Financing; provided that such fee will be reduced to 7% for investors introduced to Dawson by the Company. As additional compensation for Dawson’s services, the Company shall issue to Dawson or its designees at the closing of the Tail Financing (“Closing”) warrants (the “Placement Agent’s Warrants”) to purchase that number of Securities equal to 5% of the aggregate number of securities sold in the offering. The Placement Agent’s Warrants will be exercisable at any time and from time to time, in whole or in part, during the five-year period commencing six months from the closing of the Tail Financing, at a price per share equal to 125% of the price per Security issued in the Tail Financing. The Placement Agent’s Warrant will provide for a cashless exercise provision, registration rights (including a one-time demand registration right and unlimited piggyback rights) and customary anti-dilution provisions (for stock dividends and splits and recapitalizations).

On June 15, 2020 (the “Issuance Date”), the Company issued a convertible note in the original principal amount of \$375,000 (the “Rotbard Note”) to Mr. Shmuel Rotbard (the “Holder”), a resident of Israel, in a transaction that is exempt from registration under Regulation S under the Securities Act. We received \$315,000 under the Rotbard Note, which reflected an original issue discount equal to \$60,000. The Rotbard Note bears interest at a rate of 2% per annum. Both principal and interest are payable in one installment on June 15, 2021.

During the first 40 days after the Issuance Date, the Company has the right to redeem the Rotbard Note at a price equal to 125% of the Note’s face amount.

The Holder is entitled, at its option, at any time, to convert all or any amount of the principal face amount of the Rotbard Note and the accumulated interest then outstanding into the Company’s ordinary shares at a price equal to 80% of the lower of (i) the lowest closing bid price on the trading day prior to the Issuance Date or (ii) the lowest trading price of the ordinary shares as reported by the trading market on which the Company’s shares are traded, for the 20 prior trading days including the day upon which a conversion notice is received (the “Conversion Price”).

Upon the occurrence of a Sale Event as defined in the Rotbard Note, the Company shall, upon request of the Holder, redeem the Rotbard Note in cash for in an amount equal to 150% of the principal amount, plus accrued but unpaid interest through the date of redemption, or at the election of the Holder, the Holder may convert the unpaid principal amount of the Rotbard Note and the unpaid interest into ordinary shares of the Company at the Conversion Price immediately prior to such Sale Event.

Upon the occurrence of an Event of Default (as defined in the Rotbard Note), the Rotbard Note shall accrue interest at the lower of (i) 24% per annum or (ii) the highest rate of interest permitted by law. In addition, the Company will be subject to the penalty fee as described in paragraph 8 of the Rotbard Note.

The Rotbard Note is attached to this annual report on Form 20-F as Exhibit 4.12.

Industry Overview

According to the World Health Organization, cancer was the second leading cause of death globally in 2018, accounting for an estimated 9.6 million deaths, or one in six deaths. The World Health Organization further states that early detection can greatly reduce the current mortality rates. According to the European Cancer Journal, the total cost of cancer was €199 billion in Europe in 2018. Meanwhile, according to the American Cancer Society, the cost of cancer in the United States for the year 2015 was approximately \$80.2 billion. Furthermore, according to the National Cancer Institute, the cost of lost productivity alone in the United States due to cancer will be \$147.6 billion for 2020. Based on the amounts that people have been found willing to pay for another year of life, the National Cancer Institute estimates that the cost of cancer mortality was \$960.7 billion in 2000 and was predicted to be \$1,472.5 billion in 2020. The costs of cancer in terms of lives and suffering as well as financial, are staggering on a global basis. Both the United States and the European Union have set annual targets for early cancer detection.

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 products 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 Peripheral Blood Mononuclear Cells (“PBMCs”) (peripheral blood cells having a round nucleus, such as lymphocytes (T cells, B cells, NK cells) and monocytes) 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:

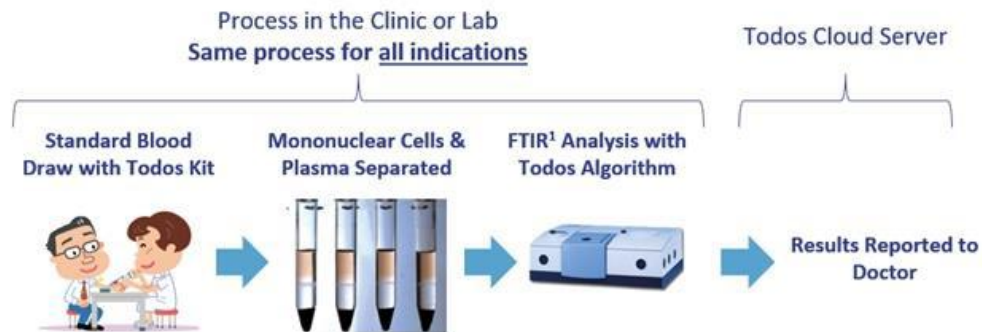
TM-B1 is a test designed specifically for breast cancer screening. It is indicated for women who meet the following criteria: female subjects aged 25 years and older without a diagnosis of inflammatory or autoimmune disease. TM-B1 is to be used as a diagnostic method to indicate whether a malignancy 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.

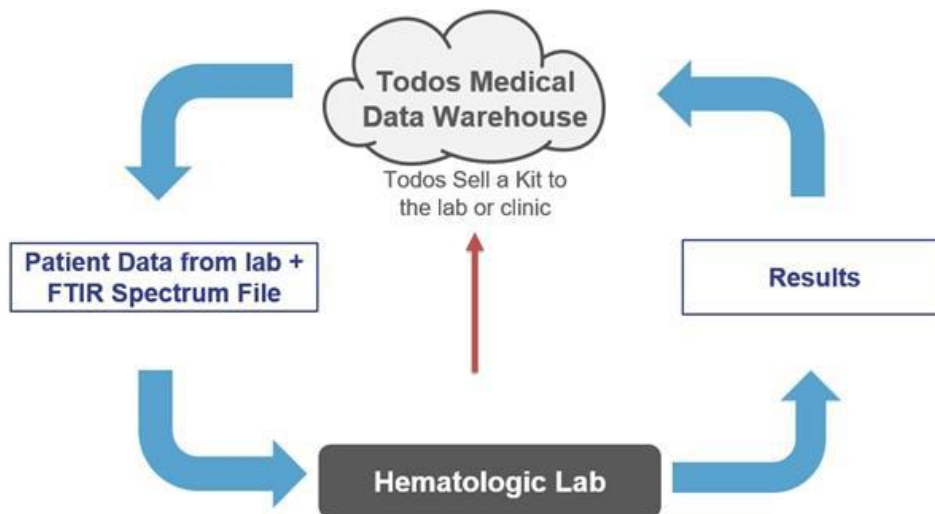
Work Flow

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 intend to sell the test kit to the lab or clinic which will then 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, and 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 June 15, 2020, our cash holdings amounted to approximately \$300,000. We believe that we will be able to use currently available capital resources for up to three months from the date of this annual report on Form 20-F. We will 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 product candidates; 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 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 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, and all subjects, healthy and leukemic, were diagnosed correctly resulting in 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, which we refer to 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 resulting in 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, which we refer to 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 resulting in 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 resulting in 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.).

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 us pursuant our license agreement with BG Negev and Mor Research Applications Ltd. (a wholly-owned subsidiary of Clalit Medical Services - Israel) referenced below. Nevertheless, our products are based on intellectual property licensed from BG Negev and Mor. There are no patents or patent applications which are licensed to us from any other entity. The intellectual property licensed to us under these agreements are related to know-how for the product.

To our management's knowledge, 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 us. The patents are entirely owned by us.

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, on May 20, 2020, we and the Licensor agreed to amend the agreement with respect to royalties due in years 2015 through 2020 (or an aggregate amount of \$235,000), according to which the minimum royalties payable to the Licensor shall be \$250,000 to be paid on December 31, 2020.

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.

Scientific Advisors

We consult with a Jorge Leon, a leading scientist in the evaluation of our technology and the development of our pipeline, and we seek advice from him on various scientific matters.

Jorge Leon, PhD - Advisor

Dr. Jorge Leon is internationally recognized for his pioneering work in molecular diagnostics. Dr. Leon holds a Ph.D. in cellular and molecular biology from New York University, and completed his postdoctoral studies at the German Cancer Research Center in Heidelberg and Columbia University in NYC. Dr. Leon's subsequent academic research at Columbia University focused on developing monoclonal antibody-based tumor marker assays and radio-immuno imaging devices, which are currently in wide use. In the early 1990s, Dr. Jorge Leon played an integral role in establishing and leading the molecular diagnostics laboratories at Quest Diagnostics. As Director of Molecular Diagnostics, Senior Director of Biotechnology Development, and Vice President of Applied Genomics, Dr. Leon spent twelve years developing Quest's molecular diagnostics strategy, which is now the world's largest molecular diagnostics service laboratory. In 2003, Dr. Leon founded Leomics Associates, Inc. a consulting firm committed to helping prestigious, successful companies and academic institutions develop molecular diagnostics and personalized medicine in the United States and globally. Dr. Jorge Leon and his experienced team specializes in identifying breakthrough opportunities and industry trends, and helps start-up businesses, academic centers and established companies successfully build and commercialize innovative business strategies, product pipelines, and test menus.

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 below, 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.

<u>Company</u>	<u>Symbol</u>	<u>Company Description</u>
Exact Sciences	EXAS	Marketing Cologuard stool-based detection test for the detection of colorectal cancer
Grail	Private	Developing blood-based diagnostics for all cancers based on liquid biopsy
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.

We primarily face competition in the COVID-19 testing market with testing products and systems developed by public and private companies such as GenMark Diagnostics, Inc., PerkinElmer, Quest Diagnostics Infectious Disease, Laboratory Corporation of America, Hologic, Thermo Fisher, Roche Diagnostics, and Abbott Molecular Diagnostics. Our diagnostic tests also face competition from laboratory developed tests (LDTs) developed by national and regional reference laboratories and hospitals. We believe that our testing systems compete largely on the basis of accuracy, reliability, enhanced laboratory workflow, multiplex capability, ease-of-use, turnaround time, customer service and support, patient safety, and return on investment for customers.

Many of our competitors have substantially greater financial, technical, research, and other resources and larger, more established marketing, sales, and distribution channels than we do. Many of our competitors also offer broader product lines and have greater brand recognition than we do. Moreover, our existing and new competitors may make rapid technological developments that may result in our technologies and products becoming obsolete before we recover the expenses incurred to develop them or before they generate significant revenue.

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 by 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 2020, 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 expected to complete the process and obtain MoH approval within 6 months; however, the process has been subject to bureaucratic delays. We expect the approval to take approximately an additional six months from the date of this annual report on Form 20-F, although there may be delays due to the Coronavirus pandemic

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, 2019 and 2018, we incurred \$755,699 and \$459,184, respectively, of research and development expense.

Our research and development efforts are financed in part through grants received from the IIA. Through December 31, 2019, 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

<u>SUPPLIER</u>	<u>MATERIAL</u>
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 two wholly-owned subsidiaries: Todos Medical USA, which is incorporated in Nevada, and 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, 7670301 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, 2020. 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

Todos Medical Ltd., is a medical diagnostics company engaged in the development and commercialization of blood tests for the detection of immune-related diseases, beginning with cancer. Our core proprietary technology centers on testing blood cells using an FTIR spectrometer to turn biological information into data, and then using our patented TBIA deep learning data analytics platform to mine the data in order to develop algorithms that are indicative of the presence of cancer, and the tissue of origin in the body where the cancer is located. The TBIA detection method is based on cancer's influence on the immune system that triggers biochemical changes in peripheral blood. The primary advantages of the TBIA platform are the high accuracy (sensitivity and specificity) and low COGS due to the biological information being captured using spectroscopy versus biological antibody capture methods that require the manufacture of multiple antibodies to capture a biological signature. TBIA is based upon technology originally invented by the researchers at BGU and Soroka, whose intellectual property has been licensed to us. We have received a CE Mark in the European Union authorizing the commercial use of the TBIA platform in the diagnosis of breast cancer and colon cancer. We have been issued patents in the United States, Europe and other international jurisdictions covering the use of TBIA to detect solid tumors. We have also entered into distribution agreements with development partners in preparation for the commercial launch of TBIA for breast cancer in Israel, Romania and Austria during the second half of 2020. Our academic partners at BGU have also published research suggesting FTIR has the potential to be used to identify the presence of viral and bacterial infections, and the Company is currently evaluating how best to pursue its technology in these areas in light of increased commercial interest for viral detection methods in light of the recent outbreak of novel Coronavirus (SARS-CoV-2, or COVID-19) worldwide.

Because of the novelty and highly disruptive nature of TBIA analysis using FTIR to diagnose disease, we believe the best path forward to bring Todos' core technology to market in the United States is to demonstrate comparability with blood tests that are built on technology platforms that are in widespread use. Due to the relative scarcity of commercial blood tests in areas such as cancer and Alzheimer's disease, we entered into agreements whereby we have agreed to acquire companies that have developed proprietary blood tests in those therapeutic indications in order to gain a foothold in the marketplace and fine tune our FTIR platform while fully commercializing these more advanced tests in the United States. We chose to expand into Alzheimer's disease because we view Alzheimer's as cancer of neuronal cells that are incapable of completing cell division due to their post-mitotic nature.

On March 30, 2020, our Board of Directors determined to exercise our option to acquire all of the shares of Provista, and on April 2, 2020 it gave notice of such determination to Provista. At an extraordinary general meeting on May 11, 2020, our shareholders approved the consideration to be issued to SIH as consideration for the acquisition. The Provista acquisition will enable us to gain exclusive worldwide rights to the commercial-stage breast cancer test Videssa™. However, the acquisition cannot be consummated unless and until our Ordinary Shares are listed for trading on NASDAQ.

At our 2019 annual meeting of shareholders, our shareholders approved a resolution authorizing us to exercise our option to acquire the remaining 80.01% of Breakthrough from Amarantus in exchange for an additional 30% of our then issued and outstanding Ordinary Shares. While the Breakthrough option has not yet been exercised, the option has been extended by both parties and remains in effect. Breakthrough is a joint venture we formed with Amarantus to gain ownership of exclusive worldwide rights to the Alzheimer's blood test called the Lymphocyte Proliferation Test (LymPro Test™). Taken together with our core TBIA FTIR-based platform, we believe Todos is positioned to become the worldwide leader in the field of immune-based diagnostics. The Company formed the subsidiary Todos Medical Singapore Ltd. for the purpose of advancing clinical trials of the Company's core technology for breast cancer in Southeast Asia.

Additionally, in view of our status as a leader in the field of immune-based diagnostics, we made the strategic corporate decision to enter the field of COVID-19 testing. Similarly to our strategy in cancer and Alzheimer's where we felt more traditional, advanced technologies would serve as the basis for market entry before bringing our proprietary FTIR-based TBIA platform forward, we decided to enter the COVID-19 space by gaining rights to existing technologies developed by other companies. As such, we entered into distribution agreements with multiple companies to gain rights to rapid IgM/IgG COVID-19 antibody test kits, RNA extraction machines, RNA extraction reagents, qPCR reagents and digital PCR reagents so as to be able to offer a comprehensive suite of solutions to laboratories worldwide. Additionally, the Company has entered into a joint venture with NLC Pharma to bring to market a unique development-stage viral protease based saliva point of care cell phone enabled diagnostic device that allows for the rapid detection of the presence of SARS-CoV-2 full length RNA in saliva which has the unique benefit of also indicating when viral replication has slowed or ceased. This technology will potentially have a significant impact for the development of virus targeting therapeutic development strategies, as well as clearance for return to life activities post-infection. As a complementary strategy to COVID-19 testing, we have entered into distribution agreements for certain PPE and medical devices, including ventilators, that are have complementary sales channels to our COVID-19 testing products and services. We believe this strategy has the potential to help accelerate our commercial distribution channels as we begin to commercialize our core technology, and the technologies we are currently acquiring via the Provista and Breakthrough acquisitions.

More specifically as it relates to our emerging COVID-19 diagnostic testing business, in the first half of 2019 we have been able to focus the Company's human capital on securing rights and validating newly sourced diagnostic testing platforms and establishing sales distribution channels for our suite of COVID-19 products and services. To that end, we are focused on the following tasks:

1. Todos Medical Ltd. (Israel): Identification of innovation in diagnostic testing products, services and related PPE, including medical devices such as ventilators, as well as import/export of our suite of products from our manufacturers' country of origin and country of destination, primarily focusing our marketing efforts in Europe and Africa. The Company is able to utilize its broad network of international contacts who originate from Israel to identify opportunity.

2. Todos Medical USA (United States of America): FDA authorized medical importer and distributor focused on the distribution the Company's testing products and services and PPE to customers in the North America and Latin America Todos Medical USA has formed the subsidiary Corona Diagnostics, LLC, for the purpose of marketing COVID-19 related products in the United States and contracting with Provista Diagnostics, Inc. to validate potential products the Company is contemplating distributing and creating marketing materials for the testing products based upon those validations.

3. Todos Medical Singapore, Pte. Ltd.: HSA, which is the Singapore equivalent of the FDA, authorized medical importer and distributor focused on distributing test kits in Southeast Asia.

The Company believes that by identifying key areas of inefficiency in the COVID-19 testing space, and addressing those bottlenecks, whether they be scientific, technical or logistical, we can capture market share in a new and rapidly growing medical testing industry that, according to Research and Markets, is expected to reach approximately \$44.5 billion for 2020.

Operating Results

A. Operating Expenses

Our current operating expenses consist of two components - research and development expenses, and general and administrative expenses. We also incur marketing expenses; however, the majority of our marketing expenses in 2019 were stock-based compensation.

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		
	2019	2018	2017
Salaries and related expenses	\$ 291,606	\$ 178,486	\$ 144,250
Stock-based compensation	230,908	12,077	22,883
Professional fees	65,506	22,271	18,888
Laboratory and materials	35,472	70,779	143,644
Patent expenses	51,491	82,367	65,654
Rent and maintenance	32,895	40,146	58,381
Depreciation	29,643	25,650	24,083
Insurance and other expenses	18,178	27,408	2,592
Total	\$ 755,699	\$ 459,184	\$ 480,375

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.

Marketing expenses

Marketing expenses consist primarily of salaries and share-based compensation expense.

The following table discloses the breakdown of marketing expenses:

	Year ended December 31		
	2019	2018	2017
Stock Based Compensation	\$ 420,000	\$ -	\$ -
Professional Fees	\$ 246,872	-	-

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		
	2019	2018	2017
Salaries and related expenses	\$ 325,879	\$ 190,207	\$ 67,541
Stock-based compensation	602,541	35,595	90,875
Communication and investor relations	106,886	230,194	83,836
Professional fees	943,175	269,980	224,407
Insurance and other expenses	114,164	193,718	150,428
General and administrative expenses	\$ 2,092,645	\$ 919,694	617,087

Comparison of the year ended December 31, 2019 to the year ended December 31, 2018

Results of Operations

Research and Development Expenses. Our research and development expenses for the year ended December 31, 2019 were \$755,699, compared to \$459,184 for the year ended December 31, 2018, representing a net increase of \$296,515, or 64.6%. The increase is primarily due to an increase in salaries and related expenses and stock-based compensation used for continued development of our products.

Marketing Expenses. Our marketing expenses increased from \$0 in 2018 to \$666,872 in 2019, providing an increase of \$666,872 or 100%. This increase was principally due to marketing efforts related to our anticipated uplisting.

General and Administrative Expenses. Our general and administrative expenses for the year ended December 31, 2019 were \$2,092,645, compared to \$919,694 for the year ended December 31, 2018, providing an increase of \$1,172,951 or 127.5%. The increase is primarily due to the increase in salaries and related expenses, stock-based compensation and professional services which consists mainly of legal and other fees relating our anticipated uplisting.

Finance (Income) Expenses, Net. Our net finance expenses for the year ended December 31, 2019 was \$5,333,875 compared to net finance income of \$921,337 for the year ended December 31, 2018, providing an increase of \$6,255,212 or 678.9%. The increase is primarily due to change in fair value of warrants liability, loss from extinguishment of loans from shareholders and amortization of discounts and accrued interest on convertible bridge loans.

Share in losses of affiliated company is accounted for under equity method. Our share in losses of affiliated company accounted for under equity method increased from \$0 in 2018 to \$2,965,801 in 2019, providing an increase of \$2,965,801 or 100%. This increase was principally due to impairment of investment in affiliated company and expiration of right to obtain control over affiliated company.

Net Loss. Our net loss for the year ended December 31, 2019 was \$11,814,515, compared to \$457,541 for the year ended December 31, 2018, providing an increase of \$11,356,974 or 2,482.2%. The increase is primarily due to the changes as mentioned above.

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 \$509,184, compared to \$720,527 for the year ended December 31, 2017, representing a net decrease of \$211,343, or 29.3%. 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 (\$971,337), compared to expenses of \$1,337,758 for the year ended December 31, 2017, providing a decrease of \$2,309,095. 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.

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, 2019, 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 US 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 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. From January 1, 2020 through June 15, 2020, we have raised a net amount of approximately \$900,000 pursuant to the convertible bridge loan transactions described in the Recent Developments section of this Form 20-F. As of June 15, 2020, our unaudited cash holdings were approximately \$300,000. 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 convertible bridge loans, grants from the IIA, and issuing Ordinary Shares and stock warrants (including warrants’ exercise).

The table below presents our cash flows:

STATEMENTS OF CASH FLOWS

U.S. dollars in thousands

	Year ended December 31		
	2019	2018	2017
Cash flows from operating activities:			
Net loss	\$ (11,815)	\$ (458)	\$ (2,675)
Adjustments required to reconcile net loss to net cash used in operating activities:			
Depreciation	30	26	24
Liability for minimum royalties	50	50	238
Stock-based compensation	1,253	48	114
Impairment of investment in affiliated company	1,345	-	-
Share in losses of affiliated company	448	-	-
Expiration of right to achieve control in affiliated company	1,173	-	-
Modification of terms relating to loans from shareholders	1,423	-	-
Exchange differences relating to loans from shareholders	49	(48)	67
Change in fair value of convertible bridge loans	2,322	-	-
Amortization of discounts and accrued interest on convertible bridge loans	959	-	-
Direct and incremental issuance costs related to convertible bridge loans transactions paid with Warrants	11	-	-
Change in fair value of derivative warrants liability and fair value of warrants expired	500	(926)	1,101
Inducement related to warrants exercised (Note 8)	-	-	167
Decrease (increase) in other current assets	24	(13)	1
Increase in accounts payables	363	163	(22)
Increase in other current liabilities	588	102	81
Net cash used in operating activities	<u>(1,276)</u>	<u>(1,056)</u>	<u>(904)</u>
Cash flows from investing activities:			
Loans granted to affiliated company	(448)	-	-
Purchase of property and equipment	(1)	(15)	(4)
Net cash used in investing activities	<u>(449)</u>	<u>(15)</u>	<u>(4)</u>
Cash flows from financing activities:			
Proceeds from issuance of units consist of convertible bridge loans and stock warrants, net	1,374	27	-
Proceeds from issuance of units consist of ordinary shares and stock warrants	295	100	226
Proceeds from exercise of stock warrants into ordinary shares, net	-	324	599
Net cash provided by financing activities	<u>1,669</u>	<u>451</u>	<u>1,162</u>
Change in cash, cash equivalents and restricted cash	(55)	(620)	224
Cash, cash equivalents and restricted cash at beginning of year	73	693	439
Cash, cash equivalents and restricted cash at end of year	<u>\$ 17</u>	<u>\$ 73</u>	<u>\$ 69</u>

Operating Activities

Net cash used in operating activities for the year ended December 31, 2019 was \$1,276,239 compared to \$1,056,296 in the year ended December 31, 2018, and \$904,410 in the year ended December 31, 2017. The increase in the cash flow used in operating activities in 2019 compared to 2018 is primarily due to increase from operating loss less stock-based compensation, impairment of investment in affiliated company, expiration of right to achieve control in affiliated company, modification of terms relating to loans from shareholders, change in fair value of convertible bridge loans, amortization of discounts and accrued interest on convertible bridge loans and change in fair value of derivative warrants liability and fair value of warrants expired.

Investing Activities

Net cash used in investing activities for the for the year ended December 31, 2019 was \$448,694, compared to net cash used in the year ended December 31, 2018 of \$15,370, and \$43,596 in the year ended December 31, 2017. The primary reason for the increase in investing activities was due to the loans granted by us to our joint venture, Breakthrough Diagnostics, Inc., for operating its ongoing activities.

Financing Activities

Net cash provided by financing activities for the year ended December 31, 2019 was \$1,669,470, compared to net cash provided by financing activities for the year ended December 31, 2018 of \$451,258, and \$1,162,230. This increase is primarily due to a cash received from the issuance of units consisting of convertible bridge loans and stock warrants, net.

Current Outlook

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 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.

We are currently distributing COVID-19 testing kits as a means of funding our operations.

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, 2019:

	<u>Payments due by period (US\$) Total</u>	<u>Less than 1 year</u>	<u>1-3 years</u>	<u>3-5 years</u>	<u>More than 5 years</u>
Shareholders' loans (1)	310,477	310,477	-	-	-
Convertible bridge loans, net	1,669,776	1,669,776			
Royalties to BGU (2)	423,000	235,000			188,000
Total (3)	2,403,253	2,215,253	-	-	188,000

(1) Between the years 2011 and 2014, we received loans from two shareholders. The loans were denominated in NIS, matured on December 31, 2019 and bore no interest. The loans were linked to the Israeli CPI as of January 1, 2015. In May 2020, we repaid the loans by issuing 8,750,000 of our ordinary shares having a market value of \$350,000 at issuance.

(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 June 12, 2020:

Name	Age	Position(s)
Gerald Commissiong	38	Chief Executive Officer and Director
Dr. Herman Weiss	49	Chairman of the Board of Directors
Daniel Hirsch	51	Chief Financial Officer and Director
Dr. Lauren Chung	47	External Director
Moshe Schlisser	31	External Director
Moshe Abramovitz	38	Director
Alon Ostrovitzky	35	Director

Executive Officers, Directors, and Key Employees

Gerald Commissiong, Chief Executive Officer and Director

Gerald Commissiong has served as our Chief Executive Officer and director since January 5, 2020. In addition, Mr. Commissiong serves as Chief Executive Officer, President and a member of the Board of Directors of Amarantus Bioscience Holdings, Inc. (“Amarantus”), of which he is a co-founder. Prior to becoming Chief Executive Officer of Amarantus in October 2011, Mr. Commissiong was the Chief Operating Officer of Amarantus. Mr. Commissiong graduated from Stanford University in Management Science and Engineering with a focus on Financial Decisions.

Dr. Herman Weiss, Chairman of the Board of Directors

Dr. Herman Weiss has served as a director of the Company since June 22, 2017 and Chairman of the Board of Directors since January 5, 2020. Dr. Weiss served as Chief Executive Officer of the Company from July 30, 2018 to January 5, 2020. In addition, 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 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.

Daniel Hirsch, Chief Financial Officer and Director

Daniel Hirsch has served as our Chief Financial Officer and director since January 5, 2020. Mr. Hirsch has been managing Partner of First Line Capital, LLC since 2002. Prior to 2002, Mr. Hirsch served as Senior Consultant at Integrated Healthcare based in Greenwich, Connecticut providing turn around services for large medical practices. From 1992 to 1998, Mr. Hirsch was Director of Primary Care for Hackensack University Medical Center in Hackensack, New Jersey.

Lauren Chung, Director

Dr. Lauren Chung has served as director of the Company since April, 2020. In 2012, Dr. Chung founded, and since then, she has served as Chief Executive Officer of MINLEIGH LLC, identifying, evaluating and partnering with companies for investments and strategic, operational, and commercial opportunities. Dr. Chung has over 20 years of healthcare investment management, investment banking, and advisory experience. Dr. Chung was a managing director in Healthcare Research at WestPark Capital. Previously, Dr. Chung was a co-founder of Tokum Capital Management, a global healthcare fund, which merged with Perella Weinberg Partners. Prior to that, Dr. Chung managed healthcare investment portfolios at RBR Capital, Kingdon Capital, and Pequot Capital. Earlier in her career, Dr. Chung was a recognized research scientist conducting cutting edge research in neurodegenerative and genetic disorders at Massachusetts General Hospital/Harvard Medical School and Boston Children's Hospital. Dr. Chung has published many leading peer-reviewed scientific journals. As a current and former director of public and private companies, Dr. Chung brings a valuable perspective for the Company's strategy and operations as well as extensive scientific insights. Dr. Chung holds a Ph.D. in Neuropathology from Columbia University-College of Physicians & Surgeons, and a BA with honors in Biochemistry and Economics from Wellesley College.

Moshe Schlisser, Director

Mr. Moshe Schlisser has served as a director of the Company since February 27, 2016. Mr. Schlisser currently also serves as a director at SmartGreen Ltd, Tantel Group Ltd and III Pte Ltd. Since 2018, Mr. Schlisser has been serving as General Partner at Shefa Capital Ltd, a Growth Venture Fund with a focus on mid to later stage deep technology investments. Mr. Schlisser has 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 a hot prepared dinner every night to over 50 homeless and underprivileged individuals and delivers weekend food packages to over 250 underprivileged families.

Moshe Abramovitz, Director

Mr. Moshe Abramovitz has served as a director of the Company 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. Abramowitz received training and a certificate to serve as a mediator from Bar Ilan University.

Alon Ostrovitzky, Director

Mr. Alon Ostrovitzky has been a director of the Company 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 photo-voltaic 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.

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, 2019. 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, 2019. Amounts paid in NIS are translated into U.S. dollars at the rate of NIS 3.456 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, 2019.

	Salary and Related Benefits, including Pension, Retirement and Other Similar Benefits	Share Based Compensation
All directors and executive officers as a group, consisting of six persons	\$ 476,000	\$ 30,000

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, 2019.

Annual Compensation - in thousands of USD - convenience translation

(1)	Salary and Related Benefits, including Pension, Retirement and Other Similar Benefits	Share Based Compensation	Total
Executive Officers			
Herman Weiss, M.D., CEO (1)	\$ 256	\$ 268	\$ 524
Rami Zigdon, CBO	\$ 94	\$ -	\$ 94
Udi Zelig, CTO	\$ 81	\$ -	\$ 81
David Ben Naim, CFO (2)	\$ 50	\$ -	\$ 50
	\$ 481	\$ 268	\$ 749

Resigned as Chief Executive Officer on January 5, 2020.

(2) Resigned as Chief Financial Officer on December 30, 2019.

Employment Agreements with Executive Officers

We have entered into written employment agreements with each of our executive officers, except for our CEO.

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, 2019, options to purchase 2,267,571 of our Ordinary Shares are outstanding under the Option Plan and 3,732,429 Ordinary Shares were available for future option grants under the Option Plan. During the year ended December 31, 2019, 620,581 options to acquire our Ordinary Shares under the Option Plan expired. 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 three and not more than seven directors, in addition to the two external directors. Currently, our Board of Directors consists of four directors plus two external 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.

Our directors do not have written service contracts and are not required to have them under the Israel Companies Law.

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. Lauren Chung and Mr. Moshe Schlisser.

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.

Under the Companies Law, the term “controlling shareholder” means a shareholder with the ability to direct the activities of the company, other than by virtue of serving as an office holder. A shareholder is presumed to be a controlling shareholder if the shareholder holds 50% or more of the voting rights in a company or has the right to appoint more than half of the directors of the company or its general manager. For the purpose of approving transactions with controlling shareholders, 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. For purposes of determining the holding percentage stated above, two or more shareholders who have a personal interest in a transaction that is brought for the company’s approval are deemed as joint holders.

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. Lauren Chung 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 has adopted an audit committee charter that is filed as Exhibit 1.2 to this annual report on Form 20-F. The audit committee charter sets 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 Mr. Moshe Schlisser, who serves as the chairperson, Ms. Lauren Chung 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. Lauren Chung, who serves as the chairperson, Mr. Moshe Schlisser and Mr. Moshe Abramovitz.

Compensation Committee Role

Our Board of Directors has adopted a compensation committee charter that is filed as Exhibit 1.3 to this annual report on Form 20-F. Responsibilities of the compensation committee are consistent with the requirements for compensation committees under the Companies Law which include 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. Our compensation policy was approved at our 2018 annual 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.

As of the date hereof, we have no internal auditor.

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. 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 Amended 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 (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, 2019, we had four full-time employees, two of whom are located in Israel, one in the United States and one in Singapore. Our President and Chief Executive Officer, Gerald Commissiong is located in the United States. Our Chief Financial Officer, Daniel Hirsch, and our Chief Business Officer, Rami Zigdon, are located in Israel. Joseph Wee is the Chief Executive Officer of our Singaporean subsidiary and is located in Singapore.

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.

E. Share Ownership.

The following table sets forth information regarding beneficial ownership of our Ordinary Shares as of June 3, 2020 by:

- 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 June 3, 2020 to be outstanding and to be beneficially owned by the person holding the options or warrants 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 196,624,681 ordinary shares outstanding as of June 3, 2020.

Unless otherwise noted below, the address of each shareholder, director and executive officer is c/o Todos Medical Ltd., 1 HaMada St., Rehovot, 7670301 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
Directors and executive officers:		
Dr. Herman Weiss	300,000	*
Gerald Commissiong(1)	17,986,999	9.15%
Rami Zigdon(2)	3,423,850	1.74%
Lauren Chung	0	*
Moshe Abramovitz	0	*
Alon Ostrovitzky	0	*
Moshe Schlisser	0	*
Daniel Hirsch	54,000	*
All directors and executive officers as a group (8 persons)	21,764,849	11.07%

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

(1) Represents 17,986,999 shares of common stock owned by Amarantus. Gerald Commissiong is the Chief Executive Officer of Amarantus and in such capacity holds voting and dispositive power over the securities held by such entity.

(2) Includes 1,000 shares underlying a warrant which is currently exercisable and 1,241,163 employee option shares that have been granted to Mr. Zigdon in January 2016, 103,428 out of which were vested and exercised by Mr. Zigdon and are currently held by ESOP Management & Trust Services Ltd. for the benefit of Mr. Zigdon. As of June 3, 2020, 1,137,735 of these employee option shares are outstanding.

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 June 3, 2020, 749,868 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 as of June 3, 2020 certain information regarding the beneficial ownership by all shareholders known to us to own beneficially 5% or more of our Ordinary Shares. 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 June 3, 2020 to be outstanding and to be beneficially owned by the person holding the options or warrants 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 196,624,681 ordinary shares outstanding as of June 3, 2020.

Unless otherwise noted below, the address of each shareholder, director and executive officer is c/o Todos Medical Ltd., 1 HaMada St., Rehovot, 7670301 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.

Shareholder:	No. of Shares Beneficially Owned	Percentage Owned
Amarantus Bioscience Holdings, Inc. (1)	17,986,999	9.15%
Strategic Investment Holdings, Inc. (2)	30,100,072	15.31%

- (1) Gerald Commissiong is the Chief Executive Officer of Amarantus and in such capacity holds voting and dispositive power over the securities held by such entity.
- (2) Rob Rill is the Chief Executive Officer of Strategic Investment Holdings, Inc. and in such capacity holds voting and dispositive power over the securities held by such entity.

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 60 days from the date the option was granted, 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 30% of the Company, such that upon exercise of the option 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 held on April 29, 2019, the Company's shareholders voted to pass a resolution approving the Company's exercise of this option. While the Breakthrough option has not yet been exercised, the option has been extended by both parties and remains in effect.

On December 19, 2019, the Company entered into the Option Agreement with SIH, the sole owner of Ascenda, Ascenda, the sole owner of Provista and Provista. Pursuant to the Option Agreement, Ascenda granted the Company an exclusive option until March 31, 2020, subject to extension, to acquire all of the shares of Provista. In consideration for the option, the Company issued SIH 17,091,096 ordinary shares, or the equivalent of \$1 million of ordinary shares of the Company on the date of issuance. Subsequently, on April 2, 2020, the Company issued SIH an additional 13,008,976 ordinary shares in exchange for an extension of the exclusive option to June 30, 2020, which was the equivalent of an additional \$1 million

Record Holders

Based upon a review of the information provided to us by our transfer agent, as of June 3, 2020, there were a total of 98 holders of record of our shares, of which 18 record holders who hold 132,141,155 shares, or approximately 67.2% of our outstanding shares, had a registered address in the U.S., 54 holders had registered addresses in Israel, 18 holders had registered addresses in Singapore, 3 holders had registered addresses in Canada, 3 had registered addresses in the United Kingdom, 1 holder had a registered address in Germany, and 1 holder had a registered address in Cyprus.

B. Related Party Transactions

Other than the transactions discussed below, the transactions discussed in the section titled Recent Developments above, the joint venture with Amarantus discussed under “Breakthrough Diagnostics Acquisition,” and the Provista acquisition discussed under “Provista Diagnostics Acquisition,” since January 1, 2019, 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.

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.

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.

C. Interests of Experts and Counsel

Not applicable.

ITEM 8. FINANCIAL INFORMATION.

A. 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 June 12, 2020, except as set forth below.

The case of Strategic Global Research and Development, Inc. v. Amarantus Bioscience Holdings, Inc. and Todos Medical, Ltd. is pending in the United States District Court for the Eastern District of California, Eastern Division as case number 5:20-CV-0071.

The claims in the Plaintiff's complaint ("Complaint"), which was filed on January 13, 2020, are for alleged breach of contract and quantum meruit. In its Complaint, Plaintiff asserts that Todos is liable as the alter ego or joint venture partner of Amarantus Bioscience Holdings, Inc. ("Amarantus"), which was the actual party to the contract. Todos was not a party to the contract and was not mentioned as a beneficiary therein. The only evidence provided by Plaintiff so far of an alter ego/joint venture relationship appears to be that Todos paid or offered to pay some of the Plaintiff's bills for Amarantus. That evidence, standing alone, is not likely to be legally sufficient to hold Todos liable for the alleged debts of Amarantus. The Complaint does not appear to state any basis for Plaintiff to recover or collect its attorneys' fees.

After obtaining a consent order overturning an initial default for failure to timely answer, Defendants answered on February 28, 2020. In their answer, Defendants defended on the basis that Todos is neither a joint venture partner with Amarantus nor its alter ego. Defendants also defended on the basis that the Court appears to lack personal jurisdiction over Todos, making venue over Todos also improper. Defendants also asserted the defense that the Court lacks subject matter jurisdiction because the contract does not provide for late fees and, without late fees, the amount in controversy is less than \$75,000 and the Court cannot properly exercise jurisdiction based on diversity of citizenship. Defendants also defended on the basis that Plaintiff allegedly may have overbilled or double-billed for expenses, apparently charging only Amarantus for travel with may have been for the benefit of one or more of Plaintiff's other clients or customers. Defendants also asserted the defense that the Plaintiff's performance under the contract was deficient, in that the Plaintiff's failed to make a single sale or bring in a single new customer, client or investor. In addition, Plaintiff allegedly failed to give adequate priority to working for Amarantus. And, even if the late fees were agreed to, Defendants contend that they are an unenforceable penalty clause and not reasonable or appropriate liquidated damages.

The Plaintiff ("SGR&D") appears to be a one-man consulting firm that contracted to provide sales and marketing support and assistance to only to Amarantus. SGR&D claims it was not paid on time and is owed \$91,318.73, allegedly consisting of \$71,209.14 in unpaid consulting fees and late fees, plus \$20,109.59 in unreimbursed expenses for travel and the like plus late fees. Plaintiff does not appear to be asserting any claim for attorneys' fees.

On April 8, 2020, the Plaintiff's attorney sent a settlement proposal e-mail offering to settle for the full amount of the claim paid over-time at \$4,000 per month with 5% interest compounded monthly, with acceleration and confession of judgment upon default. Defendants have elected not to respond at present, until a lump-sum settlement proposal is fully funded with available funds.

Discovery is just commencing, and it is difficult to further evaluate the parties' positions or the merits thereof at present. While there does appear to be some e-mail correspondence promising to pay Plaintiff late fees, Defendants still have the potential defense that the proposed late fees are a penalty and not reasonable liquidated damages.

Because there is no claim for punitive damages or attorneys' fees, the only substantial risks and costs to continuing with the litigation rather than paying or settling the claim appear to be Defendants' own attorneys' fees (estimated at \$70,000 through trial) and the possibility of paying continuing late fees and/or pre-judgment interest.

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.

Some of our debt instruments prohibit us from paying cash dividends so long as they are outstanding.

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 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 tier of the OTC Markets 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. Although we are in the process of applying to have our Ordinary Shares and warrants listed on The Nasdaq Capital Market, no assurance can be given that we will successfully be able to list our securities on The Nasdaq Capital Market.

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. Our Amended Articles were filed as Exhibit 99.1 to the Company's current report on Form 6-K (File No. 333-209744) filed on March 30, 2017.

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 Articles, our Board of Directors may exercise all powers and take all actions that are not required under law or under our Amended Articles 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 Articles 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 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 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 2018 and 2019). In addition, an individual would be subject to an "Additional Tax" of 3% on his income exceeding NIS 641,880 (in 2018) or exceeding NIS 649,560 (in 2019). A corporation would be subject to capital gain at a rate of 23% (in 2018) or 23% (in 2019).

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 2018 and 2019), 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 641,880 (in 2018) or exceeding NIS 649,560 (in 2019).

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 of 1986, as amended, 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, no such ruling will be sought, 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 generally only considers U.S. Holders that will own our Ordinary Shares as capital assets. 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.

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 at the time of the sale, exchange, or other taxable disposition. 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. Because the value of our assets for purposes of the PFIC test will generally be determined by reference to the market price of our Ordinary Shares, our PFIC status may depend in part on the market price of our Ordinary Shares, which may fluctuate significantly. In addition, there may be certain ambiguities in applying the PFIC test to us. We have not performed an analysis of our PFIC status for our taxable year ended December 31, 2019, and no ruling from the IRS has been or will be sought with respect to our status as a PFIC. In addition, our actual PFIC status for our current taxable year (2020) 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, 2019 or any subsequent taxable year.

If we are a PFIC for any taxable year during which a U.S. Holder holds our Ordinary Shares, such U.S. Holders should be aware of certain tax consequences of investing directly or indirectly in us. Such 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, 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, thereby mitigating certain of the adverse consequences of PFIC status. If that election is made, the U.S. Holder generally would include as ordinary income in each taxable year that we are treated as a PFIC with respect to such U.S. Holder, 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.

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.

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.”

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. For each year that we are treated as a PFIC with respect to a U.S. Holder, such U.S. Holder who does not make a timely QEF election (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, or a Non-Electing U.S. Holder, 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 taxable years 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.

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, unless (1) we cease to be PFIC, and (2) such Non-Electing U.S. Holder makes a “deemed sale” election with respect to our Ordinary Shares. If such an election is made, such U.S. Holder will be deemed to have sold our Ordinary Shares held at their fair market value on the last day of the last taxable year in which we were a PFIC, and any gain from such deemed sale would be subject to taxation under the excess distribution regime described above. After the deemed sale election, a U.S. Holder’s Ordinary Shares with respect to which the deemed sale election was made will not be treated as shares in a PFIC unless we subsequently become a PFIC. 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).

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 24%. 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.

The Company's Singapore subsidiary had no activity in 2019.

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. Currently, all of our transactions are in United States dollars and Israeli shekels.

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

None.

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, 2019, or the Evaluation Date. Based on such evaluation, those officers have concluded that, as of the Evaluation Date, our disclosure controls and procedures are ineffective 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 not accumulated and communicated to management, including our principal executive and financial officers, in a manner sufficient to allow timely decisions regarding required disclosure, due to lack of sufficient internal accounting personnel, segregation of duties, lack of sufficient internal controls (including IT general controls) that encompass the Company as a whole with respect to entity and transactions level controls in order to ensure complete documentation of complex and non-routine transactions and adequate financial reporting.

Management has identified corrective actions to remediate such material weaknesses, and subject to fundraising, which includes hiring additional employees, Management intends to implement procedures to remediate such material weaknesses during the fiscal year 2020; however, the implementation of these initiatives may not fully address any material weakness or other deficiencies that we may have in our disclosure controls and procedures.

(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, 2019. 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, as of December 31, 2019, the ineffectiveness of the Company's internal control over financial reporting was due to identification of material weaknesses (i.e. lack of sufficient internal accounting personnel, segregation of duties, lack of sufficient internal controls (including IT general controls) that encompass the Company as a whole with respect to entity and transactions level controls) in order to ensure complete documentation of complex and non-routine transactions and adequate financial reporting during the year ended December 31, 2019.

Management has identified corrective actions to remediate such material weaknesses, subject to fundraising, which includes hiring additional employees. Management intends to implement procedures to remediate such material weaknesses during the fiscal year 2020; however, the implementation of these initiatives may not fully address any material weakness or other deficiencies that we may have in our disclosure controls and procedures.

(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, 2019, 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 Ms. Lauren Chung shall serve as our audit committee financial expert following the establishment of our audit committee by our Board of Directors. Ms. Chung has the following attributes: (i) an understanding of generally accepted accounting principles and financial statements; (ii) the ability to assess the general application of such principles in connection with the accounting for estimates, accruals and reserves; (iii) experience preparing, auditing, analyzing or evaluating financial statements that present a breadth and level of complexity of accounting issues that are generally comparable to the breadth and complexity of issues that can reasonably be expected to be raised by the registrant's financial statements, or experience actively supervising one or more persons engaged in such activities; (iv) an understanding of internal controls and procedures for financial reporting; and (v) an understanding of audit committee functions. Ms. Chung is independent of our management.

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, 2019 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, 2019 and 2018:

	Year Ended December 31,		
	2019	2018	2017
Audit Fees (1)	\$ 70,000	\$ 42,000	42,000
Audit Related Fees (2)	47,168	-	-
Tax Fees (3)	-	-	-
All other Fees	-	-	-
Total:	<u>\$ 117,168</u>	<u>\$ 42,000</u>	<u>\$ 42,000</u>

(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) "Audit related Fees" are fees for professional services rendered by our auditors for uplist process.

(3) "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 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.

<u>Exhibit</u>	<u>Description</u>
1.1	<u>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).</u>
1.2	<u>Charter of the Audit Committee of the Board of Directors*</u>
1.3	<u>Charter of the Compensation Committee of the Board of Directors*</u>
2.1	<u>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).</u>
4.1	<u>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).</u>
4.2	<u>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).</u>
4.3	<u>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).</u>
4.4	<u>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).</u>
4.5	<u>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).</u>

- 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 and incorporated herein by reference](#)
- 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 and incorporated herein by reference](#)
- 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*](#)
- 4.11 [Exclusive option agreement among the Company, Strategic Investment Holdings, LLC, Ascenda BioSciences LLC and Provista Diagnostics, Inc. dated January 6, 2020.*](#)
- 4.12 [2% Convertible Redeemable Note made by the Company in favor of Shmuel Rotbard in the original principal amount of \\$375,000 dated June 15, 2020.*](#)
- 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

*Previously filed.

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.

TODOS MEDICAL LTD.

Date: August 6, 2020

By: /s/ Gerald Commissiong

Gerald Commissiong, CEO
Chief Executive Officer and Director

TODOS MEDICAL LTD.

**FINANCIAL STATEMENTS
AS OF DECEMBER 31, 2019**

INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm	F-2
Balance Sheets as of December 31, 2019, and 2018	F-3
Statements of Operations for the Three years ended December 31, 2019, 2018 and 2017	F-4
Statements of Changes in Shareholders' Deficit for the three years ended December 31, 2019, 2018 and 2017	F-5 - F6
Statements of Cash Flows for the three years ended December 31, 2019, 2018 and 2017	F-7
Notes to Financial Statements	F-8 - F-43

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Board of Directors and Shareholders
Todos Medical Ltd.

Opinion on the financial statements

We have audited the accompanying balance sheets of Todos Medical Ltd. (the "Company") as of December 31, 2019 and 2018, the related statements of operations, changes in shareholders' deficit, and cash flows for each of the three years in the period ended December 31, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019, 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 1B to the financial statements, the Company has incurred net losses since its inception, and has not yet generated any revenues. As of December 31, 2019, there is an accumulated deficit of \$17,507,868 and shareholders' deficit of \$6,248,812. These conditions, along with other matters as set forth in Note 1B, 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 1B. 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
June 15, 2020

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

	Note	As of December 31,	
		2019	2018
ASSETS			
Current assets:			
Cash and cash equivalents		\$ 12,155	\$ 63,550
Restricted cash	2d	5,275	9,343
Other current assets		8,799	32,990
Total current assets		<u>26,229</u>	<u>105,883</u>
Non-current assets:			
Investment in affiliated company accounted for under equity method, net	3	*)-	-
Property and equipment, net	4	64,672	93,242
Total non-current assets		<u>64,672</u>	<u>93,242</u>
Total assets		<u>\$ 90,901</u>	<u>\$ 199,125</u>
LIABILITIES AND SHAREHOLDERS' DEFICIT			
Current liabilities:			
Loans, net	7	\$ 112,635	\$ 27,000
Accounts payable		414,460	163,174
Other current liabilities	5	799,625	211,435
Loans from shareholders	6	-	611,925
Liability for minimum royalties	9B	235,000	185,000
Total current liabilities		<u>1,561,720</u>	<u>1,198,534</u>
Non-current liabilities:			
Convertible bridge loans, net	7	\$ 3,427,207	\$ -
Loans from shareholders	6	310,477	-
Liability for minimum royalties	9B	188,000	188,000
Derivative warrants liability, net	8	752,309	28,525
Other current liabilities	9D	100,000	-
Total non-current liabilities		<u>4,777,993</u>	<u>216,525</u>
Commitments and contingent liabilities	9		
Shareholders' deficit:			
Ordinary Shares of NIS 0.01 par value each:	10		
Authorized: 1,000,000,000 shares at December 31, 2019 and 2018; Issued and outstanding:			
103,573,795 shares and 72,399,932 shares at December 31, 2019 and 2018, respectively		279,747	190,679
Additional paid-in capital		10,979,309	4,286,740
Accumulated deficit		(17,507,868)	(5,693,353)
Total shareholders' deficit		<u>(6,248,812)</u>	<u>(1,215,934)</u>
Total liabilities and shareholders' deficit		<u>\$ 90,901</u>	<u>\$ 199,125</u>

*) Representing an amount less than \$1,000.

STATEMENTS OF OPERATIONS
(U.S. dollars except share and per share amounts)

	Note	Year ended December 31,		
		2019	2018	2017
Research and development expenses	12	\$ 755,699	\$ 459,184	\$ 720,527
Marketing expenses	13	666,872	-	-
General and administrative expenses	14	2,092,645	919,694	617,087
Operating loss		(3,515,216)	(1,378,878)	(1,337,614)
Financing (income) expenses, net	15	5,333,498	(921,337)	(1,337,758)
Share in losses of affiliated company accounted for under equity method	3	2,965,801	-	-
Net loss		\$ 11,814,515	\$ 457,541	\$ 2,675,372
Basic and diluted net loss per share		\$ 0.13	\$ 0.01	\$ 0.04
Weighted average number of ordinary shares outstanding attributable to ordinary shareholders		92,024,188	70,869,924	68,587,261

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

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

	<u>Preferred shares</u>		<u>Ordinary shares</u>		<u>Additional paid-in capital</u>	<u>Accumulated deficit</u>	<u>Total Shareholders' deficit</u>
	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>			
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:							
Conversion of preferred shares into ordinary shares (Note 10B)	(3,351,850)	(9,475)	3,351,850	9,475	-	-	-
Exercise of warrants, net of issuance expenses and amount classified to equity upon exercise (Note 10C1)	-	-	1,665,000	4,625	1,058,475	-	1,063,100
Issuance of ordinary shares, net of issuance expenses (Note 10C2)	-	-	1,061,125	3,015	559,538	-	562,553
Exercise of stock options into ordinary shares (Note 10C3)	-	-	81,432	226	-	-	226
Issuance of ordinary shares to service providers	-	-	350,000	897	2,904	-	3,801
Stock-based compensation (Note 11)	18,379	51	-	-	109,957	-	110,008
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
Changes during the year ended December 31, 2018:							
Exercise of warrants, net of issuance expenses and amount classified to equity upon exercise (Note 10C4)	-	-	722,500	1,928	451,295	-	453,223
Exercise of stock options into ordinary shares (Note 10C5)	-	-	620,521	1,656	(1,656)	-	-
Issuance of units consisting of ordinary shares and stock warrants (Note 10C6)	-	-	800,000	2,134	78,211	-	80,345
Stock-based compensation (Note 11)	-	-	-	-	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

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

	Preferred shares		Ordinary shares		Additional paid-in capital	Accumulated deficit	Total Shareholders' deficit
	Shares	Amount	Shares	Amount			
Balance at December 31, 2018	-	\$ -	72,399,932	\$ 190,679	\$ 4,286,740	\$ (5,693,353)	\$ 1,215,934
Changes during the year ended December 31, 2019:							
Issuance of ordinary shares as consideration for unit consisting of investment in affiliated company and right to obtain control over affiliated company (Note 3)	-	-	17,986,999	51,391	2,466,789	-	2,518,180
Issuance of unit consisting of ordinary shares and stock warrants upon partial extinguishment of loans from shareholders (Note 6)	-	-	3,500,000	10,000	1,763,493	-	1,773,493
Partial conversion of convertible bridge loans into ordinary shares (Note 7)	-	-	1,811,864	5,177	330,344	-	335,521
Classification of derivative warrants liability into equity as result of partial conversion of convertible bridge loans into ordinary shares (Note 7)	-	-	-	-	60,365	-	60,365
Commitment for issuance of fixed number of ordinary shares and stock warrants upon modification of terms relating to convertible bridge loans transactions (Note 7)	-	-	-	-	162,405	-	162,405
Issuance of stock warrants to lenders upon convertible bridge loans transactions (Note 7)	-	-	-	-	290,875	-	290,875
Beneficial conversion feature upon modification of terms of convertible bridge loans (Note 7)	-	-	-	-	79,849	-	79,849
Commitment for issuance of fixed number of ordinary shares to service provider (Note 9F)	-	-	-	-	230,908	-	230,908
Issuance of ordinary shares (Note 10C7)	-	-	2,950,000	8,429	286,571	-	295,000
Issuance of ordinary shares to the Company's chairman of the Board of Directors (Note 10C8)	-	-	300,000	857	59,143	-	60,000
Issuance of ordinary shares as partial settlement of financial liability (Note 10C9)	-	-	125,000	357	12,143	-	12,500
Issuance of ordinary shares to service providers (Note 10B10)	-	-	4,500,000	12,857	742,143	-	755,000
Stock-based compensation (Note 11)	-	-	-	-	207,541	-	207,541
Net loss for the year	-	-	-	-	-	(11,814,515)	(11,814,515)
Balance at December 31, 2019	<u>-</u>	<u>\$ -</u>	<u>103,573,795</u>	<u>\$ 279,747</u>	<u>\$ 10,979,309</u>	<u>\$ 17,507,868</u>	<u>\$ 6,248,812</u>

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

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

	Year ended December 31		
	2019	2018	2017
Cash flows from operating activities:			
Net loss	\$ (11,814,515)	\$ (457,541)	\$ (2,675,372)
Adjustments required to reconcile net loss to net cash used in operating activities:			
Depreciation	29,643	25,502	24,083
Liability for minimum royalties	50,000	50,000	238,000
Stock-based compensation	1,253,449	47,672	113,758
Impairment of investment in affiliated company (Note 3)	1,345,180	-	-
Share in losses of affiliated company (Note 3)	447,621	-	-
Expiration of right to obtain control over affiliated company (Note 3)	1,173,000	-	-
Modification of terms relating to loans from shareholders (Note 6)	1,423,493	-	-
Exchange differences relating to loans from shareholders (Note 6)	48,552	(47,601)	66,658
Change in fair value of convertible bridge loans (Note 7)	2,321,867	-	-
Amortization of discounts and accrued interest on convertible bridge loans (Note 7)	958,741	-	-
Direct and incremental issuance costs allocated to First Warrant related to convertible bridge loans transactions paid with Warrants (Note 7)	11,055	-	-
Inducement related to warrants exercised (Note 8)	-	-	166,500
Change in fair value of derivative warrants liability and fair value of warrants expired (Note 8)	499,874	(925,910)	1,101,229
Decrease (increase) in other current assets	24,191	(13,236)	1,120
Increase in accounts payables	363,469	163,174	(21,874)
Increase in other current liabilities	588,190	101,644	81,488
Net cash used in operating activities	<u>(1,276,239)</u>	<u>(1,056,296)</u>	<u>(904,410)</u>
Cash flows from investing activities:			
Loans granted to affiliated company (Note 3)	(447,621)	-	-
Purchase of property and equipment	(1,073)	(15,370)	(3,596)
Net cash used in investing activities	<u>(448,694)</u>	<u>(15,370)</u>	<u>(3,596)</u>
Cash flows from financing activities:			
Proceeds from issuance of units consisting of convertible bridge loans and stock warrants, net (Note 7)	1,374,470	27,000	-
Proceeds from issuance of units consisting of ordinary shares and stock warrants (Note 10C2, Note 10C6 and Note 10C7)	295,000	100,000	562,604
Proceeds from exercise of stock options into ordinary shares, net (Note 10C3)	-	-	226
Proceeds from exercise of stock warrants into ordinary shares, net (Note 10C1 and Note 10C4)	-	324,258	599,400
Net cash provided by financing activities	<u>1,669,470</u>	<u>451,258</u>	<u>1,162,230</u>
Change in cash, cash equivalents and restricted cash	(55,463)	(620,408)	224,254
Cash, cash equivalents and restricted cash at beginning of year	72,893	693,301	439,077
Cash, cash equivalents and restricted cash at end of year	<u>\$ 17,430</u>	<u>\$ 72,893</u>	<u>\$ 693,301</u>
Supplemental disclosure of non-cash activities:			
Issuance of ordinary shares as consideration for unit consisting of investment in affiliated company and right to obtain control over affiliated company (Note 3)	<u>\$ 2,518,180</u>	<u>\$ -</u>	<u>\$ -</u>
Partial conversion of loans from shareholders into ordinary shares and stock warrant (Note 6)	<u>\$ 337,991</u>	<u>\$ -</u>	<u>\$ -</u>
Fair value of derivative warrants liability and convertible bridge loans classified into equity in connection with convertible bridge loans converted (Note 7)	<u>\$ 395,886</u>	<u>\$ -</u>	<u>\$ -</u>
Direct and incremental issuance costs related to convertible bridge loans transactions paid in Warrants (Note 7)	<u>\$ 68,145</u>	<u>\$ -</u>	<u>\$ -</u>
Commitment for issuance of fixed number of ordinary shares and stock warrants upon modification of terms relating to convertible bridge loans transactions (Note 7)	<u>\$ 162,405</u>	<u>\$ -</u>	<u>\$ -</u>
Beneficial conversion feature upon modification of terms of convertible bridge loans (Note 7)	<u>\$ 79,849</u>	<u>\$ -</u>	<u>\$ -</u>
Fair value of derivative warrants liability classified into equity in connection with warrants exercised during the period (Note 8)	<u>\$ -</u>	<u>\$ 128,965</u>	<u>\$ 297,200</u>
Issuance of ordinary shares as partial settlement of financial liability (Note 9D)	<u>\$ 12,500</u>	<u>\$ -</u>	<u>\$ -</u>
Conversion of preferred shares into ordinary shares (Note 10B)	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 9,424</u>

NOTES TO FINANCIAL STATEMENTS

NOTE 1 - GENERAL

A. Operations

Todos Medical Ltd. (the “Company”) was incorporated under the laws of the State of Israel and commenced its operations on April 22, 2010. The Company is a medical diagnostics company engaged in the development and commercialization of blood tests for the detection of immune-related diseases, beginning with cancer. The Company’s core technology centers on testing blood cells using a FTIR spectrometer to turn biological information into data (FTIR), and then using the Company’s proprietary TBIA data analytics platform to prospectively mine the data to develop algorithms that are indicative of the presence of cancer, and the tissue of origin in the body where the cancer is located (TBIA). TBIA is based upon technology originally invented by the researchers at BGU and Soroka, whose intellectual property has been licensed to the Company (see also Note 9B). Currently, the Company has received a CE Mark in the European Union authorizing the commercial use of the TBIA platform in the diagnosis of breast cancer and colon cancer. In addition, the Company has been issued patents in the United States, Europe and other international jurisdictions covering the use of TBIA to detect solid tumors.

On February 27, 2019, the Company entered into Shares Purchase and assignment of license agreement purchase to which the Company purchased 19.99% of the issued and outstanding common stock of Breakthrough Diagnostics, Inc. (“Breakthrough”). See also Note 3. Through Breakthrough, the Company has also entered the field of early detection of Alzheimer’s disease.

On January 27, 2016, the Company incorporated a wholly owned subsidiary in Singapore under the name of Todos Medical (Singapore) Pte Ltd. (“Todos Singapore”) for the purpose of purpose of advancing clinical trials of the Company’s core technology for breast cancer in Southeast Asia. As of December 31, 2019, 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 and Exchange Commission, and as of March 7, 2017, the Company’s shares began to be quoted on the OTCQB under the symbol “TOMDF”.

In connection with forming new entities subsequent to December 31, 2019, see also Note 18E.

A. Going concern uncertainty

The Company has devoted substantially all of its efforts to research and development of its products and raising capital to fund this development. The development and commercialization of the Company’s products are expected to require substantial further expenditures. To date, 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, 2019, the Company has incurred accumulated losses of \$17,507,868. As of December 31, 2019, the Company’s current liabilities exceed its current assets by \$1,535,491, and there is a shareholders’ deficit of \$6,248,812. The Company has generated negative operating cash flow for all periods. As of June 15, 2020, the total cash and cash equivalent balance (individual restricted cash) is approximately \$300,000, 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.

During the year ended December 31, 2017, the Company raised net amounts of \$226, \$599,400 and \$562,604 through exercise of stock options into ordinary shares, exercise of stock warrants into ordinary shares and private placement transactions, respectively (see also Note 8 and Note 10C, respectively). During the year ended December 31, 2018, the Company raised net amounts of \$27,000, \$324,258 and \$100,000 through issuance of financial instruments as part of convertible bridge loans transactions, exercise of stock warrants into ordinary shares and private placement transactions, respectively (see also Note 7, Note 8 and Note 10C, respectively). During the year ended December 31, 2019, the Company raised net amounts of \$1,374,470 and \$295,000 through issuance of financial instruments as part of convertible bridge loans and private placement transactions, respectively (see also Note 7 and Note 10C, respectively).

In connection with raising capital subsequent to December 31, 2019, see also Note 18C.

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 include (1) identification of and measurement of financial instruments in funding transactions; (2) Initial measurement of investment in affiliated company and subsequent equity method implications; (3) determination whether an acquired company represents a ‘business’; (4) initial and subsequent measurement of financial derivative asset to obtain control over affiliated company and (5) measurement of the fair value of equity awards.

A. Functional currency

The functional currency of the Company is the US dollar (“\$” or “dollar”), as the dollar is the primary currency of the economic environment in which the Company has operated and expects to continue to operate in the foreseeable future. The Company’s operations are currently conducted in Israel and most of the Israeli expenses are currently paid in new Israeli shekels (“NIS”); however, most of the expenses are denominated and determined in the dollar. Financing and investing activities including loans, equity transactions and cash investments, are made in the dollar.

In accordance with ASC 830, “Foreign Currency Matters”, balances denominated in or linked to foreign currency are stated on the basis of the exchange rates prevailing at the applicable balance sheet date. For foreign currency transactions included in the statement of operations, the exchange rates applicable on the relevant transaction dates are used. Gains or losses arising from changes in the exchange rates used in the translation of such transactions are presented within financing income or expenses.

A. 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.

A. 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.

	As of December 31,	
	2019	2018
Cash and cash equivalents	\$ 12,155	\$ 63,550
Restricted cash	5,275	9,343
Total cash, cash equivalents and restricted cash shown in statement of cash flows	\$ 17,430	\$ 72,893

A. Property 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 operations.

Rate of depreciation	%
Laboratory equipment	15
Furniture and equipment	7-15
Computers	33
Vehicle	15

NOTES TO FINANCIAL STATEMENTS (cont.)

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (CONT.)

A. 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.

A. Investment in affiliated company

Affiliated company is company held to the extent of 20% or more (which are not subsidiary), or company less than 20% held, which the Company can exercise significant influence over operating and financial policy of the affiliate.

The investment in affiliated company is accounted for by the equity method under ASC Subtopic 323-30, "Investments - Equity Method and Joint Ventures: Partnerships, Joint Ventures, and Limited Liability Entities". Upon initial recognition, the purchase price has been determined as residual amount which was equal to the fair value of the equity consideration that was paid by the Company less the fair value allocated to the right to obtain control over affiliated company as described in section 2H below. The purchase price was fully attributed to acquired In-Process Research and Development intangible asset ("IPR&D") which was assigned to the affiliated company.

Since at the closing date of the investment, the affiliated company was not considered as a business as no substantive process existed, and the IPR&D acquired is to be used in a research and development project which are determined not to have an alternative future use, the amount allocated to such IPR&D was charged to expense at the acquisition date. Consequently, based on purchase price allocation that was done by management by using the assistance of third-party appraiser, expenses were recognized in total amount of \$1,345,180 as part of "Share in Losses of Affiliated Company" line in operations in the accompanying statement of operations for the year ended December 31, 2019 (see also Note 3).

Accordingly, the Company recognizes its proportionate share of the affiliated company's net income or loss after the date of investment. When previous losses have reduced the common stock investment account to zero, the Company continues to report its share of equity method losses in its statement of operations to the extent of and as an adjustment to the adjusted basis of the other investments in the investee such as debt securities, long term loans or advances. Such additional equity method losses are applied to the other investments are based the seniority of the other investments (priority in liquidation) and on the percentage ownership interest in each type of other investment the Company holds (the 'relative holdings approach').

A. Right to obtain control over affiliated company

The Company accounted for the right to obtain control over affiliated company, as a non-current financial derivative asset according to the provisions of ASC 815-10, "Derivatives and Hedging - Overall" ("ASC 815-10"). The Company accounted for the right as a financial asset measured upon initial recognition and remeasured on subsequent periods at fair value by using the Black-Scholes Option Pricing Model, which requires inputs such as the underlying share asset value and share price volatility. These assumptions are reviewed on a regular basis and change in the estimated fair value of the outstanding right was recognized each reporting period as part of in the "Share in Losses of Affiliated Company" line in operations in the accompanying statement of operations, until such right is exercised or expired (see also Note 3).

NOTES TO FINANCIAL STATEMENTS (cont.)

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (CONT.)

A. 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 to amounts more likely than not to be realized.

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 2019 and 2018 financial statements and did not recognize any liability with respect to an unrecognized tax position in its balance sheets.

A. Convertible Bridge Loans

The Company has considered the provisions of ASC Topic 815-40, "Derivatives and Hedging - Contracts in Entity's Own Equity" and determined that the embedded conversion feature of the convertible bridge loan should not be bifurcated from the host instrument, as at the initial investment date the loan was considered as straight loan with maturity term which is under the control of the Company. Accordingly, upon initial recognition, the bridge loan was recognized based on the amount allocated as described in Note 2R less the applicable issuance cost. The difference between the face value of the bridge loan and the amount that was allocated to such bridge loan as part of the bundle of financial instruments that were granted to lenders, represents a discount which is amortized as finance expense to profit or loss by using effective interest method over the term of the bridge loan until its stated maturity. Following the maturity date and subject to the Company's discrete decision not to repay the loan for cash, the bridge loan became subject to the provision of ASC Topic 480 "Distinguishing Liabilities From Equity" as it represents an obligation to issue a variable number of shares (share-settled obligation). Thus, upon the lapse of the Company's right to repay the bridge loan for cash, the bridge loan is measured at fair value through profit or loss with changes presented within financing income or expense, as applicable.

A. Liability for employee rights upon retirement

The Company's liability for severance pay is pursuant to Section 14 of the Israeli Severance Compensation Act, 1963 ("Section 14"), pursuant to which all the Company's employees are included under Section 14, and are entitled only to monthly deposits, at a rate of 8.33% of their monthly salary, made in the employee's name with insurance companies. Under Israeli employment law, payments in accordance with Section 14 release the Company from any future severance payments in respect of those employees. The fund is made available to the employee at the time the employer-employee relationship is terminated, regardless of cause of termination. The severance pay liabilities and deposits under Section 14 are not reflected in the balance sheets as the severance pay risks have been irrevocably transferred to the severance funds. All deposits required through December 31, 2019 have been made.

A. Research and development expenses

Research and development expenses are charged to operations as incurred.

A. Royalty-bearing grants

Royalty-bearing grants from the Israeli Innovation Authority of the Ministry of Industry, Trade and Labor (the "IIA") 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 also Note 9A). The cumulative research and development grants received by the Company from inception through December 2019 amounted to \$272,237.

As of December 31, 2019, and 2018, the Company did not accrue for or pay any royalties to the IIA as no revenue has yet been generated.

NOTES TO FINANCIAL STATEMENTS (cont.)

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (CONT.)

A. Concentrations of credit risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents and restricted cash 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.

A. 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.

A. Fair Value Measurements

The Company measures and discloses fair value in accordance with the ASC Topic 820, Fair Value Measurements and Disclosures which 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 right to obtain control over affiliated company, convertible bridge loans (following the maturity date and thereafter) and the freestanding stock warrants issued to the units' owners (see also Note 2H, Note 2J above and Note 2T below) fall 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.

A. Basic and diluted net loss per ordinary share

The Company computes net loss per share in accordance with ASC 260, "Earning per Share", which requires presentation of both basic and diluted loss per share on the face of the statement of operations.

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. 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 certain stock warrants and using the if-converted method with respect to convertible bridge loans and certain stock warrants. 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. During the years ended December 31, 2019, 2018 and 2017 the total weighted average number of ordinary shares related to outstanding stock options, stock warrants and convertible bridge loans excluded from the calculation of the diluted loss per share was 23,069,233, 6,489,221 and 7,717,721, respectively.

NOTES TO FINANCIAL STATEMENTS (cont.)

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (CONT.)

O. Basic and diluted net 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, 2019, 2018 and 2017, are as follows:

	Year ended December 31,		
	2019	2018	2017
Loss for the year	\$ 11,814,515	\$ 457,541	\$ 2,675,372
Less: Loss attributed to preferred shares	-	-	31,950
Loss for the year attributable to ordinary shareholders	\$ 11,814,515	\$ 457,541	\$ 2,643,422
Weighted average number of ordinary shares outstanding attributable to ordinary shareholders	92,024,188	70,869,924	68,587,261

A. Allocation of proceeds and related issuance costs

When multiple instruments are issued in a single transaction (unit issuance), the total net proceeds from the transaction are allocated among the individual freestanding instruments identified. The allocation occurs after identifying all the freestanding instruments and the subsequent measurement basis for those instruments.

Financial instruments that are required to be substantively measured at fair value (such as derivative warrants liability) are measured at fair value and the remaining consideration is allocated to other financial instruments that are not required to be subsequently measured at fair value (such as convertible bridge loan and warrants eligible for equity classification), based on the relative fair value basis for such instruments.

The allocation of issuance costs to freestanding instruments was based on an approach that is consistent with the allocation of the proceeds, as described above.

Issuance costs allocated to the derivative warrant liability were immediately expensed, as discussed above. Issuance costs allocated to warrants stock classified as equity component are recorded as a reduction of addition paid-in capital. Issuance costs allocated to convertible bridge loan are recorded as discount of the host component and accreted up to face value of such loans using the effective interest method.

A. 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 share options are recognized in the statement of operations as an operating expense based on the fair value of the award at the grant date. The fair value of share options granted is estimated using the Black-Scholes option-pricing model. The inputs for the valuation analysis of the share options include several assumptions, of which the most significant are the expected stock price volatility and the expected option term. Expected volatility was calculated based upon historical volatility of peer companies in the same industry on weekly basis since the marketability of the Company is considered low. The expected option term represents the period that the Company's stock options are expected to be outstanding and is determined based on the simplified method until sufficient historical exercise data will support using expected life assumptions. The risk-free interest rate is based on the yield from U.S. treasury bonds with an equivalent term. The expected dividend yield assumption is based on the Company's historical experience and expectation of no future dividend payouts. The Company has historically not paid cash dividends and has no foreseeable plans to pay cash dividends in the future. 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.

Until December 31, 2018, Share-based payments awarded to consultants (non-employees) are accounted for in accordance with ASC Topic 505-50, "Equity-Based Payments to Non-Employees". Commencing January 1, 2019, following the adoption of ASU 2018-07 which aligns the measurement and classification guidance for share-based payments to nonemployees with the guidance for share-based payments to employees (with certain exceptions), share-based payments to non-employees are accounted in accordance with ASC 718.

NOTES TO FINANCIAL STATEMENTS (cont.)

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (CONT.)

A. Stock Warrants

The Second Warrant that was granted by the Company for lenders through convertible bridge loans transactions and stock warrants that were granted as result of modification of terms of certain convertible bridge loans transactions (see also Note 7) are classified as a component of permanent equity since they are freestanding financial instruments that are legally detachable and separately exercisable, contingently exercisable, do not embody an obligation for the Company to repurchase its own shares, and permit the holders to receive a fixed number of shares of common stock upon exercise for a fixed exercise price. In addition, the warrants must require physical settlement and may not provide any guarantee of value or return. Such warrants were initially recognized based on the allocation method described in Note 2R above as an increase to additional paid-in capital. When applicable, direct issuance expenses that were allocated to the above warrants were deducted from additional paid-in capital.

A. Derivative Warrants Liability

The Company accounts for warrants to purchase Ordinary Shares in connection with private placement transactions, held by investors, that include a fundamental transaction feature pursuant to which such warrants could be required to be settled in cash upon certain events which some of them are not considered solely within the control of the Company, as a non-current liability according to the provisions of ASC 815-40, "Derivatives and Hedging - Contracts in Entity's Own Equity" ("ASC 815-40"). The Company accounted for these warrants as a financial liability measured upon initial recognition and on subsequent periods at fair value by using the Black-Scholes Option Pricing Model.

The First Warrant that was granted by the Company for lenders through convertible bridge loans transactions (see also Note 7) entitle the lenders to exercise the First Warrant for a variable number of shares and thus the fixed-for-fixed criteria is not met. Accordingly, the First Warrant were classified as a non-current liability according to the provisions of ASC 815-40, "Derivatives and Hedging - Contracts in Entity's Own Equity" ("ASC 815-40"). The Company accounted for these warrants as a financial derivative liability measured upon initial recognition and on subsequent periods at fair value by using the Black-Scholes Option Pricing Model.

The fair value of the aforesaid warrants derivative 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 (income) expenses, net" line in operations in the accompanying statement of net loss, until such warrants are exercised or expired. When applicable, direct issuance expenses that were allocated to the above warrants were expensed as incurred.

A. Beneficial Conversion Features

Upon initial recognition or upon modification of a convertible instrument (such as the convertible bridge loans) the Company considered the provisions of ASC 815-40, "Derivatives and Hedging - Contracts in Entity's Own Equity" ("ASC 815-40"), and determined that the embedded conversion feature of the convertible bridge loan should not be separated from the host instrument. Furthermore, the Company applied ASC 470-20, "Debt - Debt with Conversion and Other Options" ("ASC 470-20"), which clarifies the accounting for instruments with BCFs or contingently adjustable conversion ratios and has applied the BCFs guidance to determine whether the conversion feature is beneficial to the lender.

The BCFs were calculated by allocating the proceeds received to the convertible bridge loans and to any detachable freestanding financial instrument (detachable warrants) included in the transaction, and by measuring the intrinsic value of the conversion option based on the effective conversion price as a result of the convertible bridge loans allocated proceeds.

The intrinsic value of the conversion option was recorded as an additional discount on the Convertible Bridge Loan with a corresponding amount credited directly to equity as additional paid-in capital. After the initial recognition, the discount is amortized as interest expense over the contractual term of the Convertible Bridge Loan.

NOTES TO FINANCIAL STATEMENTS (cont.)

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (CONT.)

A. Modification of stock-based compensation awards

A modification to the terms and/or conditions of an award (i.e. a change of award's fair value, vesting conditions or classification as an equity or a liability instrument) is accounted for as an exchange of the original award for a new award resulting in total compensation cost equal to the grant-date fair value of the original award, plus the incremental value of the modification to the award. The calculation of the incremental value is based on the excess of the fair value of the modified award based following the modification over the fair value of the original award measured immediately before its terms were modified.

A. Reclassification

Certain prior year amounts have been reclassified for consistency with the current year presentation. These reclassifications did not have any effect on the reported results of operations, shareholder's deficit or cash flows.

A. Recent Accounting Pronouncements

1 Accounting Standards Update 2016-02, "Leases (Topic 842): Section A - Leases: Amendments to the FASB Accounting Standards Codification; Section B - Conforming Amendments Related to Leases: Amendments to the FASB Accounting Standards Codification; Section C - Background Information and Basis for Conclusions"

Commencing January 1, 2019, the Company adopted ASC Update 2016-02, Leases (Topic 842), under which, lessees are required to recognize the following for all leases (with the exception of short-term leases) at the commencement date: 1. A lease liability, which is a lessee's obligation to make lease payments arising from a lease, measured on a discounted basis; and, 2. A right-of-use asset, which is an asset that represents the lessee's right to use, or control the use of, a specified asset for the lease term.

Under the new guidance, lessor accounting is largely unchanged. Certain targeted improvements were made to align, where necessary, lessor accounting with the lessee accounting model and Topic 606, Revenue from Contracts with Customers. The new lease guidance simplified the accounting for sale and leaseback transactions primarily because lessees must recognize lease assets and lease liabilities. Lessees will no longer be provided with a source of off-balance sheet financing.

As the existing real estate operating leases of the Company are in low value, this guidance had no material impact on the Company's financial statements.

2 Accounting Standard Update 2018-07, Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting

Commencing January 1, 2019, the Company adopted ASC Update 2018-07, "Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting" (ASU 2018-07). ASU 2018-07 aligns the measurement and classification guidance for share-based payments to nonemployees with the guidance for share-based payments to employees, with certain exceptions.

Consistent with the accounting requirement for employee share-based payment awards, awards within the scope of Topic 718 will be measured at grant-date fair value of the equity instruments that an entity is obligated to issue when the good has been delivered or the service has been rendered and any other conditions necessary to earn the right to benefit from the instruments have been satisfied. Equity-classified nonemployee share-based payment awards will be measured at the grant date.

With respect to awards with performance conditions ASU 2018-07 concludes that, consistent with the accounting for employee share-based payment awards, an entity will consider the probability of satisfying performance conditions when nonemployee share-based payment awards contain such conditions.

ASU 2018-07 also requires that the classification of equity classified nonemployee share-based payment awards will continue to be subject to the requirements of Topic 718 unless the award was modified after the good has been delivered, the service has been rendered, any other conditions necessary to earn the right to benefit from the instruments have been satisfied, and the nonemployee is no longer providing goods or services. This eliminates the requirement to reassess classification of such awards upon vesting.

Based on the limited grants of share-based payments to nonemployees as of the adoption date, it was determined that the adoption of ASU 2018-07 did not have a significant impact on the Company's financial statements.

NOTES TO FINANCIAL STATEMENTS (cont.)

NOTE 3 - INVESTMENT IN AFFILIATED COMPANY, NET

On February 27, 2019 (the “Effective Date”), following execution of the Convertible bridge loan transactions (see also Note 7), the Company signed a Definitive Joint Venture Agreement (the “Joint Venture Agreement”) and closed the Joint Venture Transaction, pursuant to which the Company issued 19.99% of its outstanding ordinary shares to Amarantus Bioscience Holdings, Inc. (“Amarantus”), a biotechnology holding company, in exchange for 19.99% of Breakthrough Diagnostics, Inc., a wholly-owned subsidiary of Amarantus (“Breakthrough”), and Amarantus assigned to Breakthrough exclusive license to develop and commercialize the LymPro Test®, an immune-based neurodiagnostic blood test for the detection of Alzheimer’s disease (the “License”). This share transaction was consummated at February 27, 2019 (the “Closing Date”) Following the Closing Date, the Company issued to Amarantus 17,986,999 ordinary shares (the “Equity Consideration”).

In addition, Amarantus granted the Company an exclusive option, in effect for 60-days from the Closing Date (the “Expiration Date”), to acquire the remaining 80.01% of Breakthrough Diagnostics in exchange for an additional 30.01% of the Company’s outstanding shares (the “Option Transaction”). Upon exercise of the Option Transaction, the Company would own 100% of the Subsidiary and Amarantus would own 49.99% of the Company. The Company is required to notify Amarantus in writing of its intention to exercise the Option, and the closing of the Option transaction shall take place within fourteen days of Amarantus’ receipt of such notice.

Under ASC Subtopic 323-30, “Investments - Equity Method and Joint Ventures: Partnerships, Joint Ventures, and Limited Liability Entities”, the management determined that the Company has the ability to exercise significant influence over operating and financial policies of Breakthrough and therefore an equity method was applied at the Closing Date at residual amount of \$1,345,180, which was the difference between the fair value of the total Equity Consideration that was paid by the Company in total amount of \$2,518,180 less the fair value of the Option Transaction of \$1,173,000, as was determined by the management by using the assistance of third-party appraiser.

At the Closing Date, Breakthrough was determined to be excluding substantive process as required under the definition of business in accordance with the provisions of ASC Topic 805 “Business Combination”. In addition, it was determined that the License represents IPR&D with no alternative future use. Consequently, the Company expensed immediately the allocated amount to the investment in affiliated company in amount of \$1,345,180. Following the Closing Date and through its Expiration Date, the Company has not exercised the Option Transaction and consequently the Option Transaction amounting to \$1,173,000 was expensed at the Expiration Date. Both amounts were recorded as part of “Share in Losses of Affiliated Company” line in operations in the accompanying statement of operations for the year ended December 31, 2019.

The changes in Level 3 asset associated with Option Transaction to obtain control over affiliated company are measured at fair value on a recurring basis. The following table summarizes the observable inputs used in the valuation of the Option Transaction asset as of the Closing Date:

	As of Closing Date	
Share price (U.S. dollars)	\$	5,385
Exercise price (U.S. dollars)	\$	5,423
Expected volatility		137.2%
Risk-free interest rate		2.44%
Dividend yield		-
Expected term (years)		0.16

The following tabular presentation reflects the Investment in affiliated company:

	As of December 31, 2019	
Investment in affiliated company, net (1)	\$	(447,621)
Non-current loans (2)		447,621
Total Investment in affiliated company, net	\$	-

NOTES TO FINANCIAL STATEMENTS (cont.)

NOTE 3 - INVESTMENT IN AFFILIATED COMPANY, NET (CONT.)

1. The investment in affiliated company as follows:

	Investment in Affiliated Company
As of the Closing Date	\$ 1,345,180
Less amortization of In-Process Research and Development asset	(1,345,180)
Less accumulated net losses	(447,621)
As of December 31, 2019	<u>\$ (447,621)</u>

1. As part of the Joint Venture Agreement, during the year ended December 31, 2019, the Company provided Breakthrough with an interest-free loan with no maturity date in total amount of \$447,621. Following the reduction of the investment in affiliated company to zero amount, the Company considered to recognized additional losses to other investments (non-current loans) based on the seniority of such other investments and the percentage ownership interest applicable for such other investment.

NOTE 4 - PROPERTY AND EQUIPMENT, NET

	As of December 31,	
	2019	2018
Laboratory equipment and others	\$ 151,260	\$ 151,260
Computers	8,253	7,180
Vehicle	5,204	5,204
Furniture and equipment	12,851	12,851
	<u>177,568</u>	<u>176,495</u>
Less - accumulated depreciation	(112,896)	(83,253)
Total property and equipment, net	<u>\$ 64,672</u>	<u>\$ 93,242</u>

Total depreciation expenses for the years ended December 31, 2019, 2018 and 2017 were \$29,643, \$25,502 and \$24,083, respectively.

NOTE 5 - OTHER CURRENT LIABILITIES

	As of December 31,	
	2019	2018
Accrued payroll and related taxes	\$ 172,648	\$ 111,076
Provision for vacation	36,819	12,807
Accrued expenses	590,158	87,552
	<u>\$ 799,625</u>	<u>\$ 211,435</u>

NOTES TO FINANCIAL STATEMENTS (cont.)

NOTE 6 - LOANS FROM SHAREHOLDERS

During the years 2011-2014, the Company received loans from two separate shareholders. The loans matured 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.

On November 20, 2018, the Company entered into Assignment of a Loan Agreement (the "Assignment Agreement") with two of its shareholders (the "Assigners"), pursuant to which the Assigners assigned their loan amounted to \$350,000 (the "Loan") to S.B. Nihul Mekarkein Ltd. and Sorry Doll Ltd (collectively the "Assignees"). According to the terms of the Assignment Agreement, it was agreed that upon shareholders' approval the Loan is eligible for conversion into 3,500,000 Ordinary Shares of the Company at a conversion price of \$0.10 per share (the "Shares"). In addition, it was agreed that upon shareholders' approval the Assignees are entitled to an option to purchase 7,000,000 Ordinary Shares of the Company at a price-per-share of \$0.20 for exercise period of five years from the signing of the Assignment Agreement (the "Option").

On April 29, 2019 (the "Commitment Date"), the Company held its Annual General Meeting of Shareholders, at which the shareholders of the Company approved inter alia the aforesaid related-party loan conversion transaction including the Option grant.

At the Commitment Date, the Company by assistance of third-party appraiser measured the fair value of the Option in total amount of \$1,108,493 by using Black-Scholes-Merton pricing model in which the assumptions that have been used are as follows: expected dividend yield of 0%; risk-free interest rate of 2.31%; expected volatility of 127.8%, and Option exercise period based upon the stated terms. In addition, at the Commitment Date, the fair value of the Shares was \$665,000 which was based on the closing share price of the Company. Consequently, the Company recorded loss from extinguishment of loans from shareholders as part of "Financing income (expenses), net" line in operations in the accompanying statement of operations in total amount of \$1,423,493.

As of December 31, 2019, the remaining outstanding loans from shareholders in total amount of \$310,477 have been classified as non-current liability as result of execution of loan conversion agreement that was entered into effect in May 2020 under which the loan will be converted into shares of the Company based on the terms in the Assignment Agreement (see also Note 18D3).

The following tabular presentation reflects the reconciliation of the carrying amount of the loans from shareholders as of December 31, 2019 and 2018:

	As of December 31,	
	2019	2018
Opening balance, classified as a current liability	\$ 611,925	\$ 659,526
Less: Partial conversion of loans from shareholders	(350,000)	-
Plus: Exchange differences relating to loans from shareholders	48,552	(47,601)
Closing balance, classified as a non-current liability	\$ 310,477	\$ 611,925

NOTES TO FINANCIAL STATEMENTS (cont.)

NOTE 7 - CONVERTIBLE BRIDGE LOANS, NET

During the years ended December 31, 2019 and 2018, the Company entered into certain Convertible Bridge Loan Agreements (the “Loan Agreements”), under which the Company obtained an aggregate net cash amount of \$1,442,250 and \$27,000, respectively, (which representing 90% of the gross Principal Amount of the loans) (the “Net Principal Amount”) from several private lenders (the “Lenders”), in order to use for the Company’s working capital needs and finance the Company’s activities through the consummation of a proposed public offering and its planned up listing to the NASDAQ Capital Market.

The Principal Amount has been originally issued with 10% discount of aggregated amount of \$163,250, bear interest at a flat rate of 10% (the “Interest”) and have a maturity date of 6-months period after receipt of the Loans funds (the “Maturity Date”). The Company will be required to pay 10% penalty upon repayment of the Principal Amount prior to the Maturity Date. Upon the Maturity Date of the loans, the Company will be required to repay the Principal Amount of the Loan and unpaid Interest for cash. From the initial recognition and until the Maturity Date, the loans are presented as current liability. Subject to the Company’s discrete decision not to repay the Principal Amount and unpaid Interest for cash, the Principal Amount and the unpaid Interest shall become convertible into the Company’s Ordinary Shares following the Maturity Date and thereafter at a conversion price equal to 70% of the average closing bid price of the Company’s Ordinary Shares in the 5-days prior to the conversion date. In the event the Company’s defaults under the Agreements, the conversion price shall be reduced to 60% of the average closing bid price of the Company’s Ordinary Shares in the 15-days prior to the conversion date. Following the Maturity Date, the convertible loans are reclassified to non-current liability.

As part of the transaction, the Company issued to the Lenders Convertible Promissory Notes (the “Notes”) and two freestanding ordinary share purchase warrants for the purchase of ordinary shares (the “First Warrant” and the “Second Warrant”, respectively and together “Warrants”).

The First Warrant provides the Lenders with 25% warrant coverage, with the warrant exercise price to be equal to the offering price in the Company’s proposed public offering, or, in the event the Principal Amount are converted into ordinary 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 Principal Amount. The term of the First Warrant is three years from the date of the determination of the exercise price. The First Warrant may be exercised by cash payment or through cashless exercise by the surrender of warrant shares having a value equal to the exercise price of the portion of the warrants being exercised. Each warrant may be exercised by cash payment or through cashless exercise by the surrender of warrant shares having a value equal to the exercise price of the portion of the warrants being exercised. The First Warrant permits the lenders to receive a variable number of shares of common stock upon exercise and therefore was accounted for as non-current financial derivative. See also Note 8.

The Second Warrant provides the Lenders an additional 25% warrant coverage, under the same terms as the aforesaid warrant, except the exercise price which is equal to 150% of the closing bid price of the Company’s shares on the day prior to the closing of the bridge loan transaction. The Second Warrant permits the lenders to receive fixed number of shares of common stock upon exercise and therefore was classified as additional paid-in capital versus discount on the Notes.

At the initial date, the management by assistance of third-party appraiser measured the First Warrant at fair value in total amount of \$205,075. The remaining amount of the net proceeds were allocated in total amount of \$938,151 and \$326,024 to the Notes and Second Warrant, respectively, based on their relative fair value. See also Note 2R.

Commencing the initial recognition date through December 31, 2019, Principal Amount and unpaid Interest in total amount of \$335,521 have been converted into 1,811,864 Ordinary shares. Following such partial conversion of bridge loans into ordinary shares, the exercise price of certain portion of the First Warrant has been determined as a fixed price and accordingly the applicable amount of \$60,365 was reclassified into additional paid-in capital. See also Note 8.

In addition, on December 17, 2018 (the “Effective Date”), the Company entered into Engagement Agreement (the “Agreement”) with Alternative Execution Group LLC (“AEXG”) whereby AEXG will render non-exclusive advice and service to the Company concerning equity and/or debt financing with certain Related Parties as defined in the Agreement.

In consideration for AEXG’s non-exclusive services with respect to the aforesaid Loan Agreements, during the year ended December 31, 2019, the Company incurred cash and non-cash expenses in form of stock warrants (“Placement Agent Warrant”) in total aggregate amount of \$158,400 which was allocated to the identified components (i.e. convertible bridge loans, First Warrant and Second Warrant) consistent with the allocation of the proceeds issuance expenses. Consequently, an amount of \$101,142 out of which was recorded as additional discount of the convertible bridge loans at the outset of the transactions.

NOTES TO FINANCIAL STATEMENTS (cont.)

NOTE 7 - CONVERTIBLE BRIDGE LOANS, NET

The following tabular presentation reflects the reconciliation of the carrying amount of the convertible bridge loans during the year ended December 31, 2019:

	As of December 31, 2019
Opening balance	\$ -
Plus: Net principal amount received	1,469,250
Less: Debt issuance costs	(101,142)
Less: Fair value of derivative First and Second Warrants	(531,099)
Plus: Amortization of discounts and accrued interest on convertible bridge loans	958,741
Less: Partial conversion of convertible bridge loans into equity	(335,521)
Less: Modification of terms relating to convertible bridge loans transactions	(354,889)
Plus: Change in fair value of convertible bridge loans	2,321,867
Closing balance	<u>\$ 3,427,207</u>

On February 20, 2020, the Company entered into convertible note extension agreements and lock-up agreements with certain institutional investors who participated in the Company's Loan Agreements. See also Note 18C1A.

Commencing January 1, 2020 through the release date of these financial statement, the Company entered into certain new convertible bridge loan transactions under which the Company obtained an aggregate net amount of \$900,000. See also Note 18C1B and Note 18C1C.

Commencing January 1, 2020 through the release date of these financial statement, Principal Amount and unpaid Interest in total amount of \$553,973 have been converted into 36,668,926 Ordinary shares. See also Note 18C1D.

Amendments to Loan Agreements

- A.** On December 2, 2019, the Company entered into convertible note extension agreement and lock-up agreement with one of the lenders whereby it was determined to extend the original Maturity Date of applicable Note until February 14, 2020 (the "Amended Maturity Date") in exchange for (1) waiver of the conversion feature of the applicable Note and accrued Interest prior to the Amended Maturity Date, unless such conversion is either (1) at the Fixed Conversion Price as defined in the amendment or (2) upon an Event of Default in which case the Maturity Date shall be accelerated and the Note shall be convertible at the Alternate Conversion Price as defined in the amendment (2) the Interest shall be amended to be at a rate of 24% and (3) issuance of 500,000 stock warrants to purchase the same number of ordinary shares, at an exercise price equal to \$0.15 per stock warrant at any time after the issuance date and up to five years thereafter.
- B.** On December 10, 2019, the Company entered into convertible note extension agreement and lock-up agreement with another lender whereby it was determined to extend the original Maturity Date of applicable Note until February 2020 (the "Amended Maturity Date") in exchange for (1) waiver of the conversion feature of the applicable Principal Amount and accrued Interest prior to the Amended Maturity Date, but the lender has at any time after the effectiveness of the Company's Registration Statement on Form F-1 that is being filed pursuant to the Company's proposed public offering and Uplisting (including immediately prior to an Event of Default) the option to convert the applicable Principal Amount and accrued Interest into the units that are being registered pursuant to the Company's proposed public offering and Uplisting (the "Units"), at a conversion price equal to 70% of the price of the Units in such public offering, subject to the availability of Units registered pursuant to the Company's registration statement for such public offering and (2) issuance of 350,000 newly issued restricted ordinary shares, par value NIS 0.01 each and issuance of 1,666,667 stock warrants to purchase the same number of ordinary shares, at an exercise price equal to \$0.15 per stock warrant at any time commencing six months after the issuance date and up to three years thereafter.

The management has determined by using the assistance of third-party appraiser that the fair value of the modified loan plus the fair value of the ordinary shares and stock warrants approximately amounted to the fair value of the convertible bridge loans prior to the modification date. The Company reduced the non-current balance of the convertible bridge loan in total amount of \$354,889 and recorded an amount of \$24,500 and \$137,905 which represented the fair value at the commitment date of ordinary shares to be issued and issued stock warrants, respectively, as an increase of additional paid-in capital. In addition, due to waiver of the conversion feature and the new Amended Maturity Date that was determined, the fair value of the applicable loans in total amount of \$192,484 (which was off-set by embedded BCF in total amount of \$79,849 which was recorded versus increase of additional paid-in capital) was classified as current liability on the balance sheet as of December 31, 2019.

NOTES TO FINANCIAL STATEMENTS (cont.)

NOTE 8 - 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 that were issued under Private Placement transactions to the fair value of 600,000, 4,518,406 and 3,106,000 warrants issued during the years ended December 31, 2018, 2016 and 2015, respectively. These warrants were classified as financial 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).

In addition, the Company allocated approximately \$205,075 for the year ended December 31, 2019, of proceeds from its units that were issued under convertible bridge loans transactions to the fair value of First Warrant issued during the year ended December 31, 2019 (see also Note 7). In addition, the Company has an obligation to issue warrants in total amount of \$80,000 to the placement agent in connection with the convertible bridge loans transactions (see also Note 7). These warrants are classified as financial liability because of provisions in such warrants that that permit the holders to receive a variable number of shares of common stock upon exercise (see also Note 2S).

The remaining outstanding warrants and terms as of December 31, 2019 and 2018 is as follows:

<u>Issuance date</u>	<u>Outstanding as of December 31, 2018</u>	<u>Outstanding as of December 31, 2019</u>	<u>Exercise Price</u>	<u>Exercisable as of December 31, 2019</u>	<u>Exercisable Through</u>
Series (2015)	1,502,500	1,502,500	\$ 0.5	1,502,500	April 2021
Series (2016)	2,628,406	375,000	\$ 0.5	375,000	March 2022
Series (2018)	600,000	600,000	\$ 0.125	600,000	November 2021
First Warrant	-	(*)	(*)	-	(**)
	<u>4,730,906</u>	<u>2,477,500</u>		<u>2,477,500</u>	

(*) The number of First Warrant instruments has not been determined as the First Warrant provides the Lenders with 25% warrant coverage, with the warrant exercise price to be equal to the offering price in the Company's proposed public offering, or, in the event the Loan Amount are converted into ordinary 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 Amount. However, based on the share price of the Company as of December 31, 2019, the number of the First Warrant would have been 20,896,789 shares.

(**) The exercise period is three years from the date of the determination of the exercise price.

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 non-current financial 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 derivative warrant liability at December 31, 2019 and 2018, was \$752,309 and \$28,525, 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, expected stock price volatility, expected term of the warrants and other assumptions. Expected volatility was calculated based upon historical volatility of peer companies in the same industry on weekly basis since the marketability of the Company is considered low. Risk-free interest rates are derived from the yield on U.S. Treasury debt securities. Dividend yields are based on 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 measurement date.

In April 2017, the Company offered to the warrants holders to lower the warrants' exercise price from \$0.5 per share to \$0.4 per share for 8 weeks period. As a result of such offer, in May 2017, certain holders exercised 1,665,000 warrants into the same number of ordinary shares for cash consideration of \$666,000. The inducement fair value was measured in an amount of \$166,500 which was recognized as financing expense in accompanying Company's Statement of Operations for the year ended December 31, 2017. As of the exercise date, the fair value of the warrants exercised which amounted to \$297,200 (after the effect of the inducement) was reclassified to equity rather than derivative warrant liabilities.

In May 2018, the Company offered to the warrants holders an option to convert 25% of the warrants into shares in exchange for extending the period exercise of their warrants for an additional 3 years. As a result of such offer, in May 2018, certain holders exercised 722,500 warrants into the same number of Ordinary Shares for gross cash consideration of \$361,250 (see also Note 10C4). During the year ended December 31, 2019, stock warrants have not been exercised.

NOTES TO FINANCIAL STATEMENTS (cont.)

NOTE 8 - DERIVATIVE WARRANTS LIABILITY (cont.)

The following table summarizes the observable inputs used in the valuation of the derivative warrant liabilities as of December 31, 2019 and 2018:

	As of December 31, 2019			As of December 31, 2018		
	Series (2015)	Series (2016)	Series (2018)	Series (2015)	Series (2016)	Series (2018)
	Share price (U.S. dollars)	\$ 0.040	\$ 0.040	\$ 0.040	\$ 0.094	\$ 0.094
Exercise price (U.S. dollars)	\$ 0.50	\$ 0.50	\$ 0.125	\$ 0.5	\$ 0.5	\$ 0.125
Expected volatility	109.15%	122.46%	102.92%	63%	63%	63%
Risk-free interest rate	1.59%	1.58%	1.58%	2.92%	2.92%	2.92%
Dividend yield	-	-	-	-	-	-
Expected term (years)	1.35	2.21	1.58	2.4	0.47	2.88

	First Warrant	
	Closing Date	As of December 31, 2019
Share price (U.S. dollars)	\$ 0.12-\$0.26	\$ 0.040
Exercise price (U.S. dollars)	\$ 0.12-\$0.26	\$ 0.018
Expected volatility	125.31%-129.94%	102.55%-125.71%
Risk-free interest rate	1.74%-2.56%	1.58%-1.62%
Dividend yield	-	-
Expected term (years)	2.38	1.96-2.99
Probability for uplisting	75%	75%

	Series (2015)	Series (2016)	Series (2018)	First Warrant	Placement Agent Warrant	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	(88,803)	(40,162)	-	-	-	(128,965)
Expired	(178,498)	-	-	-	-	(178,498)
Issued	-	-	19,655	-	-	19,655
Changes in fair value	(281,119)	(466,293)	-	-	-	(747,412)
Balances at December 31, 2018	\$ 5,996	\$ 2,874	\$ 19,655	\$ -	\$ -	\$ 28,525
Amount classified to equity upon determination of the exercise price (*)	-	-	-	(60,365)	-	(60,365)
Expired	-	(88)	-	-	-	(88)
Issued	-	-	-	205,075	79,200(**)	284,275
Changes in fair value	(3,901)	-	(13,351)	517,213	-	499,874
Balances at December 31, 2019	\$ 2,095	\$ 2,786	\$ 6,304	\$ 661,923	\$ 79,200	\$ 752,309

(*) Following the partial conversion of certain convertible bridge loans into ordinary shares (see also Note 7), the exercise price of certain portion of the First Warrant has been determined as a fixed price and accordingly the applicable amount was reclassified into additional paid-in capital.

(**) The fair value of the Placement Agent Warrant is equal to 8% of the total proceeds received by the Company from introduced investor and/or lenders by the Placement Agent (see also Note 7).

NOTES TO FINANCIAL STATEMENTS (cont.)

NOTE 9 - COMMITMENTS AND CONTINGENT LIABILITIES

A. Israeli Innovation Authority

Commencing 2012 through 2013, the Company received grants of \$162,017 from the IIA (Israeli Innovation Authority) 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. In 2016, the IIA approved further grants (under the same terms) up to maximum amount of approximately \$185,000, of which the Company received \$110,220 in 2016. The receipt of such amounts is dependent on numerous conditions being met. Amounts were not received in 2019 and 2018. The Company is required to pay royalties to IIA at a rate of 3% in the first 3-years period and 3.5% commencing 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.

As of December 31, 2019, and 2018, the Company did not accrue for or pay any royalties to the IIA as no revenue has yet been generated.

A. B.G. Negev Technologies and Applications Ltd. and Mor Research Applications Ltd.

At inception date, the Company entered into a License Agreement ("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) ("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 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 thereafter - \$50,000 per year.

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

1. the regular royalties based on the royalty rates as described above and
2. 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 Agreement term is unlimited but each party is entitled to terminate the Agreement as a result of material breach or failure to comply with 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 during a period of 7-years following the transaction effective date, 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 the Agreement other than in accordance with the Termination for Cause provisions. As of December 31, 2019, the Company did not reach a determination regarding viability of commercialization of the leukemia licensed products.

NOTES TO FINANCIAL STATEMENTS (cont.)

NOTE 9 - COMMITMENTS AND CONTINGENT LIABILITIES

B. B.G. Negev Technologies and Applications Ltd. and Mor Research Applications Ltd. (Cont.)

However, since the 7-year period ended prior to December 31, 2019, 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 \$423,000 of which \$235,000 is considered a current liability and \$188,000 is considered non-current liability. 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.

On May 20, 2020, the Company and the Licensors agreed on an amendment to the license agreement, according to which the minimum royalties payable to the Licensors in respect of the years 2015 until 2020 in an aggregate amount of \$250,000 shall be paid in cash on December 31 2020.

1. In January 2015, the Company signed a one-year lease agreement for office space leasing 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 Israeli Customer Price Index (CPI) based on the CPI published on February 15, 2015, which until December 31, 2019, has not changed significantly. The total expected future lease commitments from January 2020 through January 2021 are approximately \$22,000. In addition, the aforesaid lease was renewed by the Company on February 1, 2020 for additional one year.

The payments above are associated with lease of premises with low value and therefore are out of scope of ASC 842 "Leases". Consequently, leasing payments are recognized on a straight-line basis as an expense in the accompanying statements of operations.

1. MDM Worldwide Inc.

On June 21, 2018, the Company had entered into an Investor Relations Agreement with MDM Worldwide Solution Inc. ("MDM") whereby the Company agreed to pay MDM a monthly fee of \$12,000 for IR services.

On July 17, 2019, the Board of Directors approved the conversion of up to \$100,000 owed by the Company to MDM into ordinary shares, at a conversion price of \$0.10 per share, for an issuance of up to 1,000,000 shares to MDM. Consequently, during the year ended December 31, 2019, the Company issued 125,000 ordinary shares of NIS 0.01 par value as settlement of financial liability to MDM in total amount of \$12,500. See also Note 10C9.

In addition, an amount of \$100,000 have been classified as non-current liability as result of execution of new exchange agreement that was entered into effect in May 2020 under which this amount will be converted into shares of the Company based on the terms in the exchange agreement (see also Note 18D1).

1. Care G.B. Plus Ltd.

On December 20, 2018 (the "Effective Date"), the Company entered into Marketing and Reseller Agreement with Care G.B. Plus Ltd ("Care G.B.") whereby the Company granted Care G.B. an exclusive right to market, distribute and resell the Company's breast cancer screening products to customers located in and taking delivery in the State of Israel, including the Palestinian Authority (the "Product", "Exclusivity" and "Territory", respectively). On April 29, 2019, the Company held its Annual General Meeting of Shareholders, at which the shareholders of the Company approved inter alia the aforesaid Marketing and Reseller Agreement.

Commencing the second anniversary of the Marketing and Reseller Agreement, Care G.B.'s Exclusivity is subject to Care G.B. achieving annual milestones to be set by both parties ("Annual Milestones"). If Care G.B. is not achieving at least 50% of the Annual Milestones, the Company has its own discretion either to cancel Care G.B.'s Exclusivity or terminate the Marketing and Reseller Agreement. Through December 31, 2019, the annual milestones for Care GB were not set established as the Company was waiting to finish the development of the product in the Territory.

The Agreement became effective at the Effective Date and continue in effect for 5-year period from Care G.B.'s first purchase order of the Products issued to the Company (the "Initial Term"). Upon the Initial Term completion, provided that Care G.B. has achieved the Annual Milestones, the Marketing and Reseller Agreement term shall be automatically renewed for additional 5-year. Thereafter, at the end of each renewal term, the Marketing and Reseller Agreement shall renew for additional 2-year unless one of the parties provides the other party with prior written non-renewal notice.

NOTES TO FINANCIAL STATEMENTS (cont.)

NOTE 9 - COMMITMENT AND CONTINGENT LIABILITIES (cont.)

1. Orot Plus Ltd.

On March 28, 2019 (the "Effective Date"), the Company entered into Distribution Agreement with Orot Plus Ltd. ("Orot") whereby the Company appointed Orot as its exclusive market generator for importing, marketing and distributing for Products as defined in the Distribution Agreement in Romania and Austria (the "Territories").

The Distribution Agreement commenced at the Effective Date and shall be in effect for a period of four and five years from the Effective Date with respect to Romania and Austria, respectively (the "Term"). The Term will be extending automatically for an additional period of three years unless terminated by either party at the end of the Term by giving the other party termination notice in writing at least 90 days prior to the Term end.

Both parties have commercial cooperation according to the terms of the Distribution Agreement, under which Orot is committed to minimum purchase quantities of the Products according to the supply price as defined in the Distribution Agreement.

It was agreed that during the first six months of the Term (the "Preliminary Period"), Orot will set up the infrastructure for the marketing, selling and distribution of the Products in the Territories (the "Preliminary Stage"). Orot will bear all costs of the Preliminary Stage. The Company will provide Orot with the Products free of charge to be used for non-revenue producing purposes in furtherance of the Preliminary Stage. In consideration for the expenses made by Orot until the end of the Preliminary Stage, the Company shall issue to Orot Ordinary Shares of the Company of NIS 0.01 par value each, in an amount equal to the Preliminary Stage Expenses based on Preliminary Stage budget of \$180,000 divided by the average closing price of the shares during the thirty days period immediately prior to the Effective Date (the "Issued Shares"). The Issued Shares will be issued to Orot within 14 days as of the end of the Preliminary Period. The Issued Shares will be subject to a lock-up 6-months period as of the end of the Preliminary Period in accordance with the terms of the lock-up agreement.

In addition, in the event Orot satisfies with a three monthly sales milestones as defined in the Distribution Agreement, the Company will issue to Orot on the date on which Orot achieve each respective monthly sales milestone, warrants to purchase a number of ordinary shares of the Company par value NIS 0.01 per share equal to 0.5% of the Company's issued and outstanding shares as of the Effective Date, with the exercise price to be determined once Orot achieves its first commercial sale of the Products to an unaffiliated third party (the "First Commercial Sale Date"). The warrants' exercise price shall be equal to 80% of the average closing sale price of the Company's ordinary shares during the five days period immediately prior to the First Commercial Sale Date. The warrants' exercise period shall be 24 months from their grant date. The shares issuance upon exercise of the warrants shall be subject to a lock-up period of six months as of the date of such issuance in accordance with the terms of the warrants. Through December 31, 2019, the monthly sales milestones have not been met.

Moreover, in the event the Company satisfies with following aggregate milestones: (a) signing the Distribution Agreement and (b) signing of a distribution agreement between the Company and Orot with respect to additional territories (i.e. Japan and Poland) ("Milestones"), Orot will issue the Company on the date in which the Company achieve each respective Milestone, warrants to purchase a number of ordinary shares of Orot, par value NIS 0.01 per share, equal to 0.5% of Orot's issued and outstanding shares at the Effective Date. The warrants' exercise price shall be calculated based on Orot's valuation of \$7,000,000. The warrants' exercise period shall be 24 months from their grant date. Through December 31, 2019, the Milestones have not been met.

The Distribution Agreement is explicitly determining that upon breach of the Distribution Agreement by the Company within the first three years following the preliminary period, Orot will be entitled to one-time termination payment as defined in the Distribution Agreement plus reimbursement of the cost.

On October 10, 2019, the Company entered into supplement to the aforesaid Distribution Agreement with Orot, whereby it was determined that in exchange for completion of the Preliminary Stage, the Company will issue to Orot, on account of the Issued Shares, such number of ordinary shares of Orot in total amount equal to \$180,000 divided by the lower of: (a) 20% discount on the average closing price of the shares during the 30 days period immediately prior to March 28, 2019, (b) the average closing price of the shares during the 10 days period immediately prior to the date hereof, (c) the lowest price per share that will apply in any equity investment (including the issuance of convertible securities) in the Company prior to the issuance of the shares under this section to Orot.

NOTES TO FINANCIAL STATEMENTS (cont.)

NOTE 9 - COMMITMENT AND CONTINGENT LIABILITIES (cont.)

F. Orot Plus Ltd.

The modification to the number of Issued Shares was accounted for as an exchange of the original Issued Shares for a new Issued Shares resulting in total compensation cost equal to the grant date fair value of the Issued Shares of \$180,000, plus incremental value of the modification amounted to \$38,773. Consequently, during the year ended December 31, 2019, the Company recorded stock-based compensation expenses in total amount of \$218,773 as part of "Research and Development Expenses" line in operations in the accompanying statement of operations.

On January 13, 2020, 3,600,000 Issued Shares have been issued, reflecting price per share of \$0.05.

1. Orion Capital Advisors, LLC

On May 16, 2019, the Company entered into Business Development Agreement with Orion Capital Advisors, LLC ("BDC") whereby BDC will provide business development service to the Company which include inter alia (a) review and advice concerning the technical design of existing and planned products or services; (b) business development assistance including terms of possible transactions and suggestions during negotiations; (c) sales assistance through the development of business models and sales strategy; (d) advice regarding financing, review of proposed term sheets, capitalization planning and, where appropriate, participation in negotiations; (e) strategic consulting regarding product planning, market development, marketing and public relations; (f) consulting on corporate structure, employee stock option structure, warrant arrangements and intellectual property planning; (g) introductions to potential strategic partners and other alliance candidates; (h) introductions to prospective customers for the Company's products or services.

The term of the Business Development Agreement commenced on May 16, 2019 and through August 16, 2019.

Upon execution of the Business Development Agreement, the Company issued 500,000 ordinary shares of the Company par value NIS 0.01 per share to BDC and recorded stock-based compensation expenses in total amount of \$115,000 as part of "General and Administrative Expenses" line in operations in the accompanying statement of operations, representing a price per share of \$0.23 at the commitment date.

1. Udi Zelig

On November 24, 2019 (the "Effective Date"), the Company entered into CTO Consulting Agreement with Orot Plus Ltd. (the "Service Provider"), whereby the Service Provider will provide Chief Technology Officer services based on work plan focus on commercialization of breast cancer products (the "CTO Services") by Mr. Udi Zelig (the "Consultant") on behalf of the Service Provider.

In consideration for the Service Provider's performance of the CTO Services, the Company will issue to the Service Provider ordinary shares of the Company valued at two times the monthly agreed upon value (excluding VAT) of the CTO Services which is NIS 13,000 (the "CTO Fee"). The shares will be subject to a lock-up period of six months as of their issuance. In addition, the Company will cover the pre-approved business expenses to the Service Provider and the Consultant in the performance of the CTO Services.

The CTO Consulting Agreement became effective at the Effective Date and continue in effect until terminated.

During the year ended December 31, 2019, the Company recorded stock-based compensation expenses in total amount of \$12,135 as part of "Research and Development expenses" line in operations in the accompanying statement of operations which reflects the CTO Services provided by the Consultant for the period commencing the Effective Date through December 31, 2019. On January 14, 2020, the Company issued 242,697 ordinary shares of the Company par value NIS 0.01 per share as compensation for the CTO Services in December 2019.

1. Steeltown Consulting Group, LLC

On March 28, 2019, the Company entered into Business Development Agreement with Steeltown Consulting Group, LLC (the "Consultant") whereby the Consultant will provide business development service as defined in the Agreement. In exchange the Company shall issue to the Consultant number of 500,000 ordinary shares of the Company par value NIS 0.01 per share.

The term of the Business Development Agreement commenced on March 28, 2019 through 6-month period.

During the year ended December 31, 2019, the Company recorded stock-based compensation expenses in total amount of \$70,000 as part of "General and Administrative Expenses" line in operations in the accompanying statement of operations in exchange for issuance of the above 500,000 ordinary shares of NIS 0.01 par value, representing a price per share of \$0.14 at the commitment date.

NOTES TO FINANCIAL STATEMENTS (cont.)

NOTE 9 - COMMITMENT AND CONTINGENT LIABILITIES (cont.)

1. AI and J Media Inc

On March 28, 2019, the Company entered into Media Advertising Agreement with AI and J Media Inc. (the “Consultant”) whereby the Consultant will introduce the Company to potential sources of media, marketing agreement(s) and/or other strategic alliances which may benefit the Company in the performance of implementing its business plan(s), including but not limited to radio and television media spots; various media publications; and internet podcasts (the “Service”). The Company agreed to pay a fee to Consultant for the Services in cash and equity awards according to payment schedule as defined in the Media Advertising Agreement.

The Media Advertising Agreement term commenced on March 28, 2019 and continue through Service completion.

During the year ended December 31, 2019, the Company recorded marketing expenses in total amount of \$565,000, an amount of \$420,000 out of which was recorded as stock-based compensation expenses in exchange for issuance of 3,000,000 ordinary shares of NIS 0.01 par value, representing a price per share of \$0.14 at the commitment date.

1. Dawson James Securities

On September 17, 2019 (the “Effective Date”), the Company entered into Engagement Agreement with Dawson James Securities (“Dawson”), pursuant to which the Company appointed Dawson as its exclusive financial and sole management underwriter in connection with proposed public offering to raise up to \$7 million (the “Offering”). Dawson will be provided with an underwriting discount or spread of up to 9.0% of the Offering price. In addition, Dawson is entitled to (1) non-accountable expense allowance of 1% of the proceeds received by the Company at the closing from the securities sales (excluding any subsequent closings for the sale of the over-allotment securities) and (2) warrants (the “Placement Agent’s Warrants”) to purchase that number of Securities equal to 5% of the aggregate number of securities sold in the Offering. The Placement Agent’s Warrants will be exercisable at any time and from time to time, in whole or in part, during the five-year period commencing six months from the closing of the Offering, at a price per share equal to 125% of the price per Security issued in the Offering. The Placement Agent’s Warrant will provide for a cashless exercise provision, registration rights (including a one-time demand registration right and unlimited piggyback rights) and customary anti-dilution provisions (for stock dividends and splits and recapitalizations).

Dawson is entitled to the above fees with respect to any public or private offering or other financing or capital-raising transaction of any kind (“Tail Financing”) to the extent that such financing or capital is provided to the Company by investors whom Dawson had introduced to the Company during 6-months period commencing the Effective Date (the “Engagement Period”), as well as any investors that participated in the Offering if such Tail Financing is consummated at any time during the Engagement Period or within the 12-month period following the expiration or termination of the Engagement Agreement or the completion of the Offering (the “Tail Period”). If the Offering is completed for 12-month period from the Offering date, Dawson is entitled to right of first refusal to act as lead managing underwriter or book runner, or as lead placement agent, for any and all future equity, equity-linked or debt (excluding commercial bank debt) offerings during such period, of the Company, or any successor to or any Company’s subsidiary. Notwithstanding the foregoing, in the event of public or private sale of securities during the foregoing 12-month period, Dawson is entitled to receive as its compensation at least 50% of the compensation payable to the underwriters or placement agents. During the 12-month period described, if the Company makes any equity, equity-linked or debt (excluding commercial bank debt) offerings, Dawson is permitted to participate at a 50% level as a placement agent or underwriter for such Offering.

Through December 31, 2019, the Company has no obligation regarding aforesaid Engagement Agreement with Dawson.

On April 6, 2020, the Company entered into new engagement agreement with Dawson. See also Note 18F9.

NOTES TO FINANCIAL STATEMENTS (cont.)

NOTE 9 - COMMITMENT AND CONTINGENT LIABILITIES (cont.)

1. First Choice International Company, Inc.

On September 24, 2019, the Company entered into Consulting Agreement with First Choice International Company, Inc. (the "First Choice") whereby First Choice provided consulting services to the Company that include assist the Company with its plans to expand its business; and (ii) furnish additional ongoing management and business consulting services aimed at enhancing Company's opportunities. In exchange the Company issued to the Consultant an amount equal to 500,000 shares of restricted common stock. Consequently, during the year ended December 31, 2019, the Company recorded stock-based compensation expenses in total amount of \$50,000 as part of "General and Administrative Expenses" line in operations in the accompanying statement of operations in exchange for issuance of 500,000 ordinary shares of NIS 0.01 par value, representing a price per share of \$0.10 at the commitment date.

In addition, it was determined that upon achievement of certain milestones (the "Performance Milestones") an additional 1,000,000 shares of restricted common stock will be issued. As the Performance Milestones was achieved in January 2020, the Company's management determined the likelihood for consummation of the Performance Milestones as of December 31, 2019 was probable. Consequently, during the year ended December 31, 2019, the Company recorded as additional stock-based compensation expenses in total amount of \$100,000 as part of "General and Administrative Expenses" line in operations in the accompanying statement of operations in exchange for commitment to issue 500,000 ordinary shares of NIS 0.01 par value, representing a price per share of \$0.10 at the commitment date.

On February 6, 2020, the Company and First Choice entered into first amendment of the Consulting Agreement under which it was determined inter alia that the Term of the Consulting Agreement was extended until and including June 30, 2020. See also Note 18F1.

1. Financial Buzz Media Networks LLC

On December 2, 2019, the Company entered into PR and Media Service Provider Agreement with Financial Buzz Media Networks LLC (the "Financial Buzz"), whereby media and PR marketing services which including, but are not limited to implementation of an PR and financial media marketing strategy (the "Media Service"), will be provided by Financial Buzz. In consideration for the Media Services, the Company shall issue a total of 5,000,000 fully vested Ordinary Shares of NIS 0.01 par value to Financial Buzz upon execution of the PR and Media Service Provider Agreement. The fair value of these shares amounted to \$750,000, representing a price per share of \$0.15 at the commitment date.

The term of the PR and Media Service Provider Agreement is for a period of four months without automatic extensions.

Through December 31, 2019, the Company has not issued the aforesaid shares and services were not rendered by Financial Buzz. Subsequent to December 31, 2019 but before the release of these financial statements, the services were rendered by Financial Buzz and 2,500,000 ordinary shares have been issued.

1. Provista Diagnostics, Inc

On December 19, 2019 (the "Effective Date"), the Company entered into an exclusive Option Agreement (the "Option Agreement") with Strategic Investment Holdings, LLC, Ascenda BioSciences LLC and Provista Diagnostics, Inc. ("Provista") pursuant to which at any time after the Effective Date through March 31, 2020 the Company has the right but not the obligation to require Provista to acquire a number of ordinary shares of the Company equal to a value of \$10,000,000 at the volume weighted average price ("VWAP") of the last 20 trading days prior to exercise of the option, provided that the Company's ordinary shares are listed on a national exchange at the time of the closing of the transaction (the "Call Option"). It was agreed that with respect to the Option exercise, the Company will issue number of ordinary shares of the Company equal to a value of \$1,000,000 at the VWAP of the last 20 trading days prior to execution of the Option Agreement. In addition, it was agreed that the Call Option may be extended by the Company to June 30, 2020 by issuance of additional number of ordinary shares equal to a value of \$1,000,000 at the VWAP of the last 20 trading days prior to exercising the extension of the Call Option (the "Call Option Extension").

The Call Option and the Call Option Extension have been exercised by the Company in 2020. See also Note 18E1).

NOTES TO FINANCIAL STATEMENTS (cont.)

NOTE 9 - COMMITMENT AND CONTINGENT LIABILITIES (cont.)

1. Employment Agreement with Dr. Wee Yue Chew

On March 16, 2017, 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 inter alia 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).

To date, Todos Singapore is inactive and has not realized any profits.

NOTE 10 - SHAREHOLDERS' DEFICIT

1. Ordinary Shares:

The Ordinary Shares confer upon the holders thereof all rights accruing to a shareholder of the Company, as provided in these Articles, including, inter alia, the right to receive notices of, and to attend meetings of shareholders; for each share held, the right to one vote at all meetings of shareholders; and to share equally, on a per share basis, in such dividend and other distributions to shareholders of the Company as may be declared by the Board of Directors in accordance with these Articles and the Companies Law, and upon liquidation or dissolution of the Company, in the distribution of assets of the Company legally available for distribution to shareholders in accordance with the terms of applicable law and these Articles. All Ordinary Shares rank pari passu in all respects with each other.

1. 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 the then Chief Executive Officer of the Company ("Mr. Zigdon").

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.

NOTES TO FINANCIAL STATEMENTS (cont.)

NOTE 10 - SHAREHOLDERS' DEFICIT

1. Issuance of Ordinary Shares:

2. In 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, in 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 accompanying Company's statement of operations.

At the exercise date, 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.

1. In October 2017, the Company signed a share purchase agreement with certain investors for \$625,000 in exchange for issuance of 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.
2. During the year ended December 31, 2017, 81,432 stock options have been exercised into the same number of ordinary shares at an exercise price of NIS0.01.
3. In 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. The total direct and incremental costs paid regarding this transaction were approximately \$36,992.
4. On August 15, 2018, a certain consultant converted 620,521 stock options into the same number of ordinary shares at an exercise price of NIS0.01.
5. 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. An amount of \$19,655 was allocated to derivative warrant liability (see also Note 8) and the remaining amount was allocated to the shares.
6. During the year ended December 31, 2019, the Company signed a share purchase agreement with certain new investors for \$295,000 in cash in exchange for 2,950,000 ordinary shares of NIS 0.01 par value, which representing price per share of \$0.10.
7. On April 14, 2019 ("Commitment Date"), the Company's compensation Committee approved the issuance of 300,000 ordinary shares of NIS 0.01 par value to the then Chief Executive Officer for his service as the chairman of the Board of Directors. Consequently, at the Commitment Date, the Company recorded stock-based compensation expense as part of "General and Administrative" line in operations in the accompanying statement of operations in total amount of \$60,000, which representing price per share of \$0.2 at the commitment date.
8. In May 2019, the Company issued 125,000 ordinary shares to certain service provider as partial settlement of financial liability in total amount of \$12,500. See also Note 9D.
9. During the year ended December 31, 2019, the Company entered into several service agreements with certain service providers, whereby the Company issued 4,500,000 ordinary share of NIS 0.01 par value in exchange for services that have been rendered. Consequently, the Company recorded related stock-based compensation expense of \$420,000 and \$335,000 as part of "Marketing Expenses" and "General and Administrative Expenses" lines in operations in the accompanying statement of operations, respectively, based on the fair value of the issued shares at each applicable commitment date, which representing an average price per share of \$0.15. See also Note 9.

NOTES TO FINANCIAL STATEMENTS (cont.)

NOTE 11 - 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 Company's Board of Directors may award stock options to purchase its ordinary shares to designated participants. Subject to the terms and conditions of the 2015 Plan, the Company's 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 grant of up to 6,000,000 options to purchase ordinary shares subject to adjustments set in the 2015 Plan. As of December 31, 2019, there were 3,732,429 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, 2019 and 2018:

	Number of Options	Weighted Average Exercise Price
Outstanding at December 31, 2017 and 2018	1,758,316	0.003
Granted (*)	1,129,836	0.120
Forfeited or expired	(620,581)	0.003
Outstanding at December 31, 2019	2,267,571	0.061
Exercisable at December 31, 2019	1,879,705	0.073

(*) On March 25, 2019, the Company's Board of Directors approved the employment agreement (the "Agreement") with Dr. Herman Weiss, ("Dr. Weiss") whereby will serve as the Company's Chief Executive Officer effective retroactive commencing August 1, 2018, in exchange for compensation package that include inter alia stock 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 grant date, in accordance with the vesting schedule under which 25% of the stock options will vest on grant and the remaining 75% of the stock options will vest upon consummation of the Company's planned public offering ("Performance Milestone"). On April 29, 2019 (the "Commitment Date"), the Company held its Annual General Meeting of Shareholders, at which the Company's shareholders approved inter alia the aforesaid Agreement.

The likelihood that the Performance Milestone for consummation of the Company's planned public offering was determined to be remote due to termination of Dr. Weiss from his position as the Company's Chief Executive Officer at the beginning of January 2020 (see also Note 18B). Thus, During the year ended December 31, 2019, stock-based compensation expense has not been recorded with respect to the Performance Milestone.

At the Commitment Date, the Company by assistance of third-party appraiser measured the fair value of 1,129,836 stock options which are not subject to Performance Milestone in total amount of \$207,541 by using Black-Scholes-Merton pricing model in which the assumptions that have been used are as follows: expected dividend yield of 0%; risk-free interest rate of 2.54%; expected volatility of 125.2%, and stock options exercise period based upon the stated terms. Consequently, the Company recorded stock-based compensation expense in such amount as part of "General and Administrative Expenses" line in operations in the accompanying statement of operations.

As of December 31, 2019, the aggregate intrinsic value for the stock options outstanding and exercisable according to \$0.04 price per share was \$42,551 and \$28,045, respectively, with a weighted average remaining contractual life of 5 years.

Stock-based compensation expenses incurred for employees (and directors) and non-employees, for the years ended December 31, 2019, 2018 and 2017, amounted to \$1,253,449 (\$1,045,908 out of which allocated to ordinary shares issued or to fixed number of ordinary shares to be issued (see also Note 9F, Note 10C8 and Note 10C10)), \$47,672 and \$113,758 (\$3,801 out of which allocated to ordinary shares issued), respectively.

NOTES TO FINANCIAL STATEMENTS (cont.)

NOTE 12 - RESEARCH AND DEVELOPMENT EXPENSES

	Year ended December 31		
	2019	2018	2017
Salaries and related expenses	\$ 291,606	\$ 178,486	\$ 144,250
Stock-based compensation (Note 9F)	230,908	12,077	22,883
Professional fees	65,506	22,271	18,888
Laboratory and materials	35,472	70,779	143,644
Patent expenses	51,491	82,367	65,654
Rent and maintenance	32,895	40,146	41,673
Liability for minimum royalty expenses (Note 9B)	-	-	238,000
Depreciation	29,643	25,650	24,083
Insurance and other expenses	18,178	27,408	21,452
	<u>\$ 755,699</u>	<u>\$ 459,184</u>	<u>\$ 720,527</u>

NOTE 13 - MARKETING EXPENSES

	Year ended December 31		
	2019	2018	2017
Stock-based compensation (Note 10C10)	\$ 420,000	\$ -	\$ -
Professional fees	246,872	-	-
	<u>\$ 666,872</u>	<u>\$ -</u>	<u>\$ -</u>

NOTE 14 - GENERAL AND ADMINISTRATIVE EXPENSES

	Year ended December 31		
	2019	2018	2017
Salaries and related expenses	\$ 325,879	\$ 190,207	\$ 67,541
Stock-based compensation (Note 10C8, Note 10C10 and Note 11)	602,541	35,595	90,875
Communication and investor relations	106,886	230,194	83,836
Professional fees	943,175	269,980	224,407
Insurance and other expenses	114,164	193,718	150,428
	<u>\$ 2,092,645</u>	<u>\$ 919,694</u>	<u>\$ 617,087</u>

NOTES TO FINANCIAL STATEMENTS (cont.)

NOTE 15 - FINANCING (INCOME) EXPENSES, NET

	Year ended December 31		
	2019	2018	2017
Change in fair value of warrants liability and fair value of warrants expired (Note 8)	\$ 499,874	\$ (925,910)	\$ 1,101,229
Inducement related to warrants exercised (Note 8)	-	-	(166,500)
Change in fair value of convertible bridge loans following to Maturity Date (Note 7)	2,321,867	-	-
Loss from extinguishment of loans from shareholders (Note 6)	1,423,493	-	-
Direct and incremental issuance costs allocated to First Warrant (Note 7)	22,109	-	-
Amortization of discounts and accrued interest on convertible bridge loans (prior to Maturity Date) (Note 7)	958,741	-	-
Change in liability to minimum royalties (Note 9B)	50,000	50,000	-
Exchange rate differences and other finance income (expenses)	57,414	(45,427)	(70,029)
Financing (income) expenses, net	\$ 5,333,498	\$ 921,337	\$ 1,337,758

NOTES TO FINANCIAL STATEMENTS (cont.)

NOTE 16 - TAXES ON INCOME

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

1. 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 in effect from 2018 onwards is 23%.
2. The Company has final (considered final) tax assessments through the 2013 tax year.
3. As of December 31, 2019, the Company has carried forward losses for Israeli income tax purposes of approximately \$6.9 million which can be offset against future taxable income for an indefinite period of time.
4. Deferred income taxes reflect the net tax effects of net operating loss and temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets are as follows:

Composition of deferred tax assets:	As of December, 31	
	2019	2018
Net operating loss carry-forward	\$ 1,585,272	\$ 991,987
Research and development credits	112,149	63,439
Others	8,556	2,946
Net deferred tax asset before valuation allowance	1,705,976	1,058,371
Valuation allowance	(1,705,976)	(1,058,371)
Net deferred tax assets	\$ -	\$ -

	Year Ended December 31,		
	2019	2018	2017
Tax rate	23%	23%	24%
Tax expense (benefit) at statutory rate	\$ 2,054,113	\$ 105,234	\$ 642,090
Tax rate differential	-	-	28,057
Change in taxes from permanent differences in stock-based compensation	639,504	10,964	27,301
Change in taxes from permanent difference in derivative warrants liabilities and convertible loans	858,307	(212,959)	304,254
Change in temporary differences	111,480	-	-
Others	1,925	-	-
Loss carryforwards	442,897	307,229	282,478
Income tax expense (benefit)	\$ -	\$ -	\$ -

In assessing the realization of deferred tax assets, management considers whether it is more likely than not that all or some portion of the deferred tax assets will not be realized. The ultimate realization of the deferred tax assets is dependent upon the generation of future taxable income during the periods in which temporary differences are deductible and net operating losses are utilized. Based on consideration of these factors, the Company recorded a full valuation allowance at December 31, 2019 and 2018.

1. For the years ended December 31, 2019, 2018 and 2017, the following table reconciles the statutory income tax rate to the effective income tax rate:

NOTES TO FINANCIAL STATEMENTS (cont.)

NOTE 17 - RELATED PARTIES

- A. On July 30, 2018, the Company's Board of Directors resolved that Dr. Herman Weiss will cease to serve as the Company's current Chairman of the Board of Directors and appointed him as the Company's Chief Executive Officer, 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.

On March 25, 2019, 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:

- *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.

On April 29, 2019 (the "Commitment Date"), the Company held its Annual General Meeting of Shareholders, at which the shareholders of the Company approved inter alia the compensation package for Dr. Weiss.

For the years ended December 31, 2019 and 2018, the Company recorded expenses with respect to the aforesaid compensation package OF Dr. Herman Weiss for his services as the Chief Executive Officer in total amount of \$463,582 (\$207,541 out of which as stock-based compensation (see also Note 11)) and \$82,967, respectively.

On January 5, 2020, the Company appointed Mr. Gerald Commissiong as Chief Executive Officer and Director of the Company effective immediately. Additionally, in conjunction with the appointment of Mr. Commissiong as Chief Executive Officer, Dr. Herman Weiss left his position as the Company's previous Chief Executive Officer and will focus solely on his new role as Chairman of the Board. See also Note 18B.

- B. 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.
- C. With respect to Reseller Agreement with Care G.B. Plus Ltd. which is also the Company's shareholder - see also Note 9E.

NOTES TO FINANCIAL STATEMENTS (cont.)

NOTE 18 - SUBSEQUENT EVENTS

1. COVID-19

Beginning in early 2020, there has been an outbreak of coronavirus (COVID-19), initially in China and which has spread to other jurisdictions, including locations where the Company does or plans to do business. The full extent of the outbreak, related business and travel restrictions and changes to behavior intended to reduce its spread are uncertain as of the date of the financial statements as this continues to evolve globally. Therefore, the full extent to which coronavirus may impact the Company's results of operations, liquidity or financial position is uncertain. This outbreak has already had a material disruption on the operations of the Company and its suppliers. Management continues to monitor the impact that the COVID-19 pandemic is having on the Company and the economies in which the Company operates. The Company anticipates that its future results of operations, including the results for 2020, and its liquidity and financial position will be materially impacted by the coronavirus outbreak. However, given the speed and frequency of continuously evolving developments with respect to this pandemic, the Company cannot reasonably estimate the magnitude of the impact to its results of operations, and, if the outbreak continues on its current trajectory, such impacts could grow and become material to its liquidity or financial position. To the extent that the Company's suppliers continue to be materially and adversely impacted by the coronavirus outbreak, this could reduce the availability, or result in delays, of materials or supplies to the Company, which in turn could materially interrupt the Company's business operations, including its research and development activities.

1. Resignation of Officer and Appointment of New Directors and Officers

On January 5, 2020, the Company appointed Mr. Gerald Commissiong as Chief Executive Officer and Director of the Company. In addition, Mr. Daniel Hirsch was promoted to Chief Financial Officer and appointed a Director of the Company on January 5, 2020. Mr. Hirsch previously served as the Company's Director of Investor Relations. Mr. Commissiong and Mr. Hirsch were appointed primarily to transition the Company's headquarters from Israel to the United States.

Currently, Mr. Commissiong is director and president and Chief Executive Officer of Amaranthus Bioscience Holdings, Inc. and is interim Chief Executive Officer of Breakthrough Diagnostics, Inc., the Company's joint venture with Amaranthus. See also Note 3.

Concurrent with Gerald Commissiong's appointment as Chief Executive Officer, Dr. Herman Weiss resigned as Chief Executive Officer of the Company and will focus solely on his new role as Chairman of the Board.

1. Funds raising

1. Convertible Bridge Loans Agreements

1. On February 20, 2020, the Company entered into Convertible Note Extension Agreements (the "Amendments") with certain institutional investors who participated in the Company's previously announced financing round of 2019, under which it was agreed to extend the maturity of those notes to August 14, 2020 (the "Amended Maturity Date"). The institutional investors shall not be entitled to convert the Loan Principal plus Interest prior to the Amended Maturity Date, unless such conversion is either (1) at the Fixed Conversion Price as defined in the Amendments or (2) upon an event of default in which case the Maturity Date shall be accelerated and the Note shall be convertible at the Alternate Conversion Price as defined in the Amendments.

In addition to the warrants issued to the institutional investors pursuant to the Agreement, the Company issues to the institutional investors a third Warrant (the "Third Warrant") providing the institutional investors with a right to purchase 20,792,380 Third Warrant Shares, at an exercise price equal to \$0.10 per Third Warrant Share. The Investor may exercise the Third Warrant after the issue date and up to 5 years thereafter.

Moreover, the Company has entered into lock-up agreements with the institutional investors that preclude them from selling common shares in the market until August 20, 2020.

NOTES TO FINANCIAL STATEMENTS (cont.)

NOTE 18 - SUBSEQUENT EVENTS

C. Funds raising

1. Convertible Bridge Loans Agreements

1. Commencing January 1, 2020 through the release date of these financial statement, the Company entered into certain Convertible Bridge Loan Agreements (the "Loan Agreements"), under which the Company obtained an aggregate gross amount of \$835,714, (the "Loan Amount") from several private lenders (the "Lenders"), in order to use for the Company's working capital needs and finance the Company's activities through the consummation of a proposed public offering and its planned up listing to the NASDAQ Capital Market.

The Loan Amount has been originally issued with 30% discount of aggregated amount of \$250,714, bear interest at a flat rate of 10% (the "Interest"). Having said that, upon occurrence of any uncured Event of Default as defined in the Loan Agreements, and in the event that Lenders at their sole discretion elect to allow the Company to continue with repayment of the Loan Amount and Interest after an Event of Default, the Interest rate on the unpaid Loan Amount will be change to 18% or the highest interest rate currently allowable under Nevada law for loans of this amount (the "Default Interest Rate").

The Loan Amount has maturity date as defined in the Loan Agreements (the "Maturity Date"). The Company will be required to pay 20% penalty upon repayment of the Loan Amount prior to the Maturity Date.

At the earlier of the effective date of Registration Statement as defined in the Loan Agreements or 6 months after the Effective Date, the Lenders at their sole option, may convert the outstanding Loan Amount, or any portion of the Loan Amount, and any accrued interest, in whole or in part, into shares of the common stock of the Company (the "Common Stock"). Any amount so converted will be converted into common stock of the Company at a price equal to the lower of (1) the closing market price on the date of closing and (2) 50% of the lowest trading price on the primary trading market on which the Company's Common Stock is quoted for the last 10 trading days immediately prior to but not including the Conversion Date ("Conversion Price").

The Lenders shall have a right of participation up to 40% of any future financing (excluding strategic transactions) for a period of 2 years.

The Company shall pay a monthly liquidated damages of \$12,500 if the Registration Statement is not filed by the earlier of (i) 75 days of the Effective Date or (ii) 30 days after uplisting of the Company's Common Stock to a national securities exchange and / or declared effective within 180 days from the Effective Date of the Loan Agreements, which damages shall accrue each month until the applicable breach (failure to timely file, failure to timely have declared effective, or both) has been cured.

Upon the occurrence of any uncured Event of Default, the Holder at any time, at its sole discretion, may elect to immediately (without prior notice) convert the outstanding Loan Amount, or any portion of the Loan Amount, and any accrued Interest, in whole or in part, into shares of the Common Stock, according to the terms of the Loan Agreements.

As part of the transaction, the Company issued 24,776,758 warrants to purchase of the same number of ordinary shares at an exercise price of \$0.10 per share. The warrants shall be cashless exercisable with full ratchet anti-dilution for a period of 5-years from the issuance date.

1. On June 15, 2020 (the "Issuance Date"), the Company entered into a Securities Purchase Agreement pursuant to which it issued a 2% Convertible Redeemable Note ("Note"). Under the Note, the Company received net cash of \$315,000 (which representing 84% of the gross Principal Amount of the note) from a private lender (the "Holder").

The Note was issued with 16% original issue discount totaling \$60,000, bears interest at a flat rate of 2% and has a maturity date of June 15, 2021 (the "Maturity Date") on which all principal and interest is due and payable in one payment. During the first 40 days after the Issuance Date, the Company has the right to redeem the Note at a price equal to 125% of the Note's face amount.

NOTES TO FINANCIAL STATEMENTS (cont.)

NOTE 18 - SUBSEQUENT EVENTS (cont.)

C. Funds raising

1. Convertible Bridge Loans Agreements (Cont.)

- C. The Holder is entitled, at its option, at any time, to convert all or any amount of the principal face amount of the Note and the accumulated Interest then outstanding into the Company's ordinary shares at a price equal to 80% of the lower of (i) the lowest closing bid price on the trading day prior to the Issuance Date or (ii) the lowest trading price of the ordinary shares as reported by the trading market on which the Company's shares are traded, for the 20 prior trading days including the day upon which a conversion notice is received (the "Conversion Price").

Upon occurrence of a Sale Event as defined in the Note, the Company shall, upon request of the Holder, redeem the Note in cash in an amount equal to 150% of the principal amount, plus accrued but unpaid interest through the date of redemption, or at the election of the Holder, such Holder may convert the unpaid principal amount of the Note and the unpaid interest into ordinary shares of the Company at the Conversion Price immediately prior to such Sale Event.

Upon the occurrence of an Event of Default (as defined in the Note), the Note shall accrue interest at the lower of (i) 24% per annum or (ii) the highest rate of interest permitted by law. In addition, the Company will be subject to the penalty described in paragraph 8 of the Note.

1. As noted in Note 7, commencing January 1, 2020 through the signing date of these financial statement, Loan Amount and Interest of \$553,973 have been converted into 36,668,926 Ordinary shares.

2. Subscription Agreements

In March 2020, the Company entered into subscription agreements with several investors under which the Company raised gross funds in total amount of \$30,000 in exchange for the issuance of units consisting of 1,500,000 ordinary shares of the Company and 1,339,284 warrants to purchase the same number of ordinary shares of the Company at an exercise price of \$0.10. These warrants may be eligible for exercise over a period of four years from the issuance date and are subject to standard anti-dilution provisions. In addition, the Company may be subject to liquidated damages upon failure to timely deliver shares upon exercise of the warrants.

1. Settlement of debts

1. MDM Worldwide Solution, Inc.

As noted in Note 9E, on April 13, 2020, the Company entered into exchange agreement under which the Company agreed to exchange partial amount of the outstanding trade debt of \$100,000 held by MDM Worldwide Solution, Inc. for issuance of 5,000,000 ordinary shares of the Company at an exchange price of \$0.02 per share. The ordinary shares have been issued on May 14, 2020.

As result of the execution of the Agreement, as of December 31, 2019, the outstanding loans from shareholders amounted to \$100,000 have been classified as non-current liability on the balance sheet.

1. Toledo Advisors, LLC

On May 1, 2020, the Company entered into a letter agreement with Toledo Advisors, LLC ("Toledo") pursuant to which the Company agreed to convert aggregate principal number of Notes of the Company of \$119,296 plus \$2,845 of accrued interest into 6,107,026 ordinary shares of the Company at a conversion price of \$0.02 per share. Upon Conversion the principal amount of the notes and all accrued interest shall no longer be outstanding and any and all defaults shall be cured.

1. As noted in Note 6, on May 10, 2020, the Company entered into Loan Conversion Agreement (the "Agreement") with its shareholders pursuant to which the Company will convert the then outstanding loan amounting to \$350,000 into 8,750,000 ordinary shares of the Company at a conversion price of \$0.04 per share. Upon conversion of the loan, the Company shall be released from all its obligations and liabilities with respect to the loan, which shall be deemed to have been paid in full. The ordinary shares have been issued on May 19, 2020.

As result of the execution of the Agreement, as of December 31, 2019, the outstanding loans from shareholders amounted to \$310,477 have been classified as non-current liability on the balance sheet.

NOTES TO FINANCIAL STATEMENTS (cont.)

NOTE 18 - SUBSEQUENT EVENTS (cont.)

1. Establishment or purchasing of Additional Entities

1. Provista Diagnostics, Inc.

As noted in Note 9N, in January 2020 and subject to the term of the Option Agreement, the Company exercised the Call Option by issuance of 17,091,096 ordinary shares. In April 2020, the Company exercised the Call Option Extension by issuance of 13,008,976 ordinary shares.

In addition, on May 11, 2020, the Company held Special Meeting of Stockholders under which it was approved inter alia that upon the Company's consummation of proposed public offering the Company will complete the purchasing of the outstanding shares Provista.

1. Todos Medical USA

On January 29, 2020, the Company's Board of Directors determined to open a U.S. subsidiary named Todos Medical USA for the purpose of conducting business as medical importer and distributor focused on the distribution the Company's testing products and services to customers in the North America and Latin America. In addition, Todos Medical USA has formed the subsidiary Corona Diagnostics, LLC (see also Note 18D3 below), for the purpose of marketing COVID-19 related products in the United States and contracting with Provista Diagnostics, Inc. (see also Note 18D1 above) to validate potential products the Company is contemplating distributing and creating marketing materials for the testing products based upon those validations.

1. Emerald Organic Products, Inc.

On March 23, 2020 Todos Medical USA entered into Joint Venture Agreement (the "Agreement") with Emerald Organic Products, Inc., a Nevada corporation ("Emerald"), for the formation of Emerald Viral Diagnostics Joint Venture, Inc. (the "Joint Venture") in order to manage, operate and distribute viral testing currently controlled by Todos Medical USA. It was agreed inter alia that (1) Todos Medical USA will contribute diagnostic testing under its control that will be useful in detecting Coronavirus / COVID-19 ("Viral Testing"). Todos Medical USA will contribute the expertise and know-how to the Joint Venture necessary to validate the products for distribution; (2) Emerald will contribute capital for validation as per the budget as described in the Agreement and be responsible for developing and implementing the necessary financial structures for the distribution of the Viral Testing; (3) interest in the Joint Venture shall be 51% owned and controlled by Emerald and 49% owned and controlled by Todos Medical USA; (4) Emerald shall be entitled to receive priority distributions from the Joint Venture up to the amount of any cash capital contributions made by Emerald; (5) the Board of Managers will initially consist of three board members: Two members shall be appointed by Emerald and one member shall be appointed by Todos Medical USA; (6) the Joint Venture shall commence the date hereof and shall continue until the earlier of (i) 25 years or (ii) mutual agreement of Todos Medical USA and Emerald to dissolve.

On April 24, 2020, Todos Medical USA entered into the Amended and Restated Collaboration Agreement with Emerald, pursuant to which Todos became the owner of 100% of the equity of the Joint Venture (Corona Diagnostics, LLC) and agreed to integrate its COVID-19 tests with Emerald's telemedicine (Carie Health, Inc.) and independent pharmacy business Bonsa Health, Inc. to create a full solution to help facilitate the screening and diagnosis of individuals potentially to identify each indication's COVID-19 Polymerase Chain Reaction (PCR) and/or antibody testing status to facilitate return to work programs in the United States.

NOTES TO FINANCIAL STATEMENTS (cont.)

NOTE 18 - SUBSEQUENT EVENTS (cont.)

1. Service Agreements

1. First Choice International Company, Inc.

As described in Note 9L, on February 6, 2020, the Company and First Choice entered into first amendment of the Agreement under which it was agreed that the Term of the Agreement was extent until and including June 30, 2020 (the "Expected Term") and the Consultant shall continue to perform services including the additional services related to the expansion and addition of business lines during the Expanded Term.

1. Orion Capital Advisors, LLC

On February 10, 2020, the Company entered into Business Development Agreement (the "Agreement") with Orion Capital Advisors, LLC ("BDC") whereby BDC will provide business development service to the Company which include inter alia (a) review and advice concerning the technical design of existing and planned products or services; (b) business development assistance including terms of possible transactions and suggestions during negotiations; (c) sales assistance through the development of business models and sales strategy; (d) advice regarding financing, review of proposed term sheets, capitalization planning and, where appropriate, participation in negotiations; (e) strategic consulting regarding product planning, market development, marketing and public relations; (f) consulting on corporate structure, employee stock option structure, warrant arrangements and intellectual property planning; (g) introductions to potential strategic partners and other alliance candidates; (h) introductions to prospective customers for the Company's products or services.

Upon signing the Agreement, the Company shall issue to BDC 2,500,000 restricted shares of common stock.

The term of this Agreement shall commence on February 10, 2020 and shall continue through August 10, 2020.

1. AS Iber Israel Ltd

On February 11, 2020 (the "Effective Date"), the Company entered into Engagement Agreement (the "Agreement") with AS Iber Israel Ltd ("AS Iber Israel") whereby AS Iber Israel will render services to the Company concerning equity and/or debt financing transactions in exchange of the following considerations:

1. Success fee equal in amount to 10% plus VAT of the total value of the benefit, monetary or otherwise derived by the Company shall be earned in connection with any other activities as defined in the Agreement, plus 10% in share at the same value as the investment.
2. Success fee equal in amount to 7% plus VAT of the total of any success fee earned in connection with any pre and/or post IPO and/or M&A activity whether directly arranged by AS Iber Israel and/or by any registered dealer introduced to the Company by AS Iber Israel who will be entitled to earn this fee in connection with any transaction that is either completed and/or initiated by the registered dealer for a period of 24 months after the initial introduction.

The Agreement shall be effective as of the Effective Date and shall remain in effect for a period of 24 months following the Effective Date.

NOTES TO FINANCIAL STATEMENTS (cont.)

NOTE 18 - SUBSEQUENT EVENTS (cont.)

F. Service Agreements (cont.)

1. 3D Biomedicine Science and Technology Co. Limited

On March 17, 2020 (the “Effective Date”), Todos Medical USA entered into Distribution Agreement (the “Agreement”) with 3D Biomedicine Science and Technology Co. Limited (“3DMed”), whereby at the Effective Date 3DMed hereby appointed Todos Medical USA as its non-exclusive agent for importing, marketing and distributing of the Products as defined in the Agreement in specific countries (the “Territories”). The Agreement shall be in effect for a period of one year from the Effective Date (the “Term”) and will be extending automatically for an additional period of three years unless terminated by either party at the end of the Term by giving the other party termination notice in writing at least 90 days prior to the Term end.

At the initial of the Agreement, the Company will validate the performance of the Products provided by 3DMed (the “Validation Stage”). If the Validation Stage result will be accepted by the Company, both parties will have further commercial cooperation according to the terms of the Agreement, under which the Company will be committed to minimum purchase quantities of the Products according to the supply price as defined in the Agreement.

Having said that, in consideration for the reduced the supply price, the Company will issue to 3DMed restricted ordinary shares amounted to \$250,000 at the end of the Validation Stage upon successful completion of the Validation. The shares will be priced as of the closing date of March 13, 2020.

At the date of the signing on these financial statements, the Validation Stage is still in progress.

1. Gibraltar Brothers and Associates LLC

On March 19, 2020 (the “Effective Date”), Todos Medical USA entered into Distribution Agreement (the “Agreement”) with Gibraltar Brothers and Associates LLC (“Gibraltar”), whereby at the Effective Date Gibraltar hereby appointed Todos Medical USA as its exclusive agent for importing, marketing and distributing of the Products as defined in the Agreement in specific countries (the “Territories”). The Agreement shall be in effect for a period of one year from the Effective Date (the “Term”) and will be extending automatically for an additional period of three years unless terminated by either party at the end of the Term by giving the other party termination notice in writing at least 90 days prior to the Term end.

During the first three months of the Term (the “Preliminary Period”), the Company will set up the infrastructure for the marketing, selling and distribution of the Products in the Territories (the “Preliminary Stage”). The Company will bear all costs of the Preliminary Stage. Gibraltar will provide the Company with the Products free of charge to be used for non-revenue producing purposes in furtherance of the Preliminary Stage.

Both parties have commercial cooperation according to the terms of the Agreement, under which the Company will be committed to minimum purchase quantities of the Products according to the supply price as defined in the Agreement.

1. Zhengzhou Fortune Bioscience Co. Ltd

On April 18, 2020, Todos Medical USA entered into an Original Equipment Manufacturing (OEM) agreement with Zhengzhou Fortune Bioscience Co. Ltd. (Zhengzhou) for the manufacture of immunochromatography-based colloidal gold SARS-nCoV-2 fingerprick IgM/IgG and IgA/IgM/IgG – IgD/IgE rapid antibody test (Zhengzhou Colloidal Gold). Zhengzhou has applied for Emergency Use Authorization (EUA) with the United States Food & Drug Administration (US FDA).

NOTES TO FINANCIAL STATEMENTS (cont.)

NOTE 18 - SUBSEQUENT EVENTS (cont.)

F. Service Agreements (cont.)

1. Gnomegen, LLC

On May 7, 2020 (the “Effective Date”), Todos Medical USA entered into an Exclusive Distribution Agreement (the “Agreement”) with Gnomegen LLC (“Gnomegen”) whereby at the Effective Date Gnomegen hereby appointed Todos Medical USA as its exclusive agent for importing, marketing and distributing of SARS-nCoV-2 PCR test kits in specific countries (the “Territories”) as defined in the Agreement. The Agreement shall be in effect for a period of two years from the Effective Date (the “Term”) and will be extending automatically for an additional period of three years unless terminated by either party at the end of the Term by giving the other party termination notice in writing at least 90 days prior to the Term end.

Todos Medical USA is committed to minimum purchase quantities of the Products according to the supply price as defined in the Agreement.

Gnomegen has received Emergency Use Authorization (EUA) with the United States Food and Drug Administration (US FDA).

1. Zhengzhou

On May 12, 2020, Todos Medial USA entered into a Non-Exclusive Distribution Agreement (the Agreement”) with Zhengzhou Fortune Bioscience Co., Ltd. (“Zhengzhou”), pursuant to which Todos Medial USA has been appointed as distributor of Zhengzhou’s Products as defined in the Agreement in United States. Zhengzhou has applied for Emergency Use Authorization (EUA) with the United States Food and Drug Administration (US FDA).

1. Dawson James Securities

On April 6, 2020 (the “Effective Date”), the Company entered into an engagement agreement with Dawson James Securities (“Dawson”) to act as lead or managing placement agent on a best efforts basis in connection with any public or private offering or other financing or capital-raising transaction of any kind (“Tail Financing”) to the extent that such financing or capital is provided to the Company by investors whom Dawson had introduced to the Company during a period of 60 days commencing the Effective Date (the “Engagement Period”) if such Tail Financing is consummated at any time during the Engagement Period or within the 12-month period following the expiration or termination of Agreement or the completion of the offering (the “Tail Period”). If the offering is completed, for a period of 12 months from the offering date, the Company grants Dawson the right of first refusal to act as lead managing underwriter or book runner, or as lead placement agent, for any and all future equity, equity-linked or debt (excluding commercial bank debt) offerings during such period, of the Company, or any successor to or any subsidiary of the Company.

In consideration for the services to be rendered by Dawson, the Company will pay to Dawson a placement agent fee of 8% of the gross proceeds received in the Offering; provided that such fee will be reduced to 7% for investors introduced to Dawson by the Company. As additional compensation for Dawson’s services, the Company shall issue to Dawson or its designees at the closing of the offering (“Closing”) warrants (the “Placement Agent’s Warrants”) to purchase that number of Securities equal to 5% of the aggregate number of securities sold in the offering. The Placement Agent’s Warrants will be exercisable at any time and from time to time, in whole or in part, during the five-year period commencing six months from the closing of the offering, at a price per share equal to 125% of the price per Security issued in the offering. The Placement Agent’s Warrant will provide for a cashless exercise provision, registration rights (including a one-time demand registration right and unlimited piggyback rights) and customary anti-dilution provisions (for stock dividends and splits and recapitalizations).

NOTES TO FINANCIAL STATEMENTS (cont.)

NOTE 18 - SUBSEQUENT EVENTS (cont.)

G. Contingencies

Strategic Global Research and Development, Inc

On February 13, 2020 Strategic Global Research and Development, Inc (“Strategic” or “SGR&D”), brought suit against Amaranthus and the Company in the United States District Court for the Central District of California Eastern Division for failure to pay for consulting services with respect to sales and marketing support and assistance that were contracted on April 12, 2018.

SGR&D claims it was not paid on time and is owed \$91,319, allegedly consisting of \$71,209 in unpaid consulting fees and late fees, plus \$20,110 in unreimbursed expenses for travel and the like plus late fees. On April 8, 2020, SGR&D’s attorney sent a settlement proposal e-mail offering to settle for the full amount of the claim paid over-time at \$4,000 per month with 5% interest compounded monthly, with acceleration and confession of judgment upon default. Defendants have elected not to respond at present, until a lump-sum settlement proposal is fully funded with available funds.

Based on opinion of management and the advice of the legal counsel of the Company, at this stage the outcome of the litigation is inherently unpredictable

**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, Gerald Commissiong, certify that:

1. I have reviewed this Annual Report on Form 20-F/A 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/ Gerald Commissiong
Chief Executive Officer

Date: August 6, 2020

**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, Daniel Hirsch, certify that:

1. I have reviewed this Annual Report on Form 20-F/A 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/ Daniel Hirsch
Chief Financial Officer

Date: August 6, 2020

**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, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of Gerald Commissiong and Daniel Hirsch 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/ Gerald Commissiong

Gerald Commissiong
Chief Executive Officer

Date: August 6, 2020

/s/ Daniel Hirsch

Daniel Hirsch
Chief Financial Officer

Date: August 6, 2020
