UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 20-F

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

OR

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended **December 31, 2015**

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 _____
Commission file number _____

Kitov Pharmaceuticals Holdings Ltd.
(Exact name of Registrant as specified in its charter)

N/A
(Translation of Registrant's name into English)

Israel
(Jurisdiction of incorporation or organization)

One Azrieli Center, Round Building, 23rd Floor, Tel Aviv, 6701101, Israel
(Address of principal executive offices)

Simcha Rock, Chief Financial Officer
One Azrieli Center, Round Building, 23rd Floor, Tel Aviv, 6701101, Israel

Tel: +972-54-4490673; Fax: +972-77-3180015
(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

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

Title of class	Name of each exchange on which registered
American Depositary Shares, each representing 20 Ordinary Shares (1)	**Nasdaq Capital Market**
Ordinary Shares, no par value (2)	**N/A**
Warrants to purchase our American Depositary Shares	**Nasdaq Capital Market**

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

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

None

(Title of Class)

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act:

None

(Title of Class)

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: **77,755,641 Ordinary Shares, no par value (including 21 shares held in treasury**)

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 1934.

Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

☒ Yes ☐ No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes ☐ No ☐

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

Large Accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☒

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

U.S. GAAP ☐
International Financing 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 ☒

APPLICABLE ONLY TO ISSUERS INVOLVED IN BANKRUPTCY PROCEEDINGS DURING THE PAST FIVE YEARS)

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Sections 12, 13 or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court.

Yes ☐ No ☐

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Unless the context otherwise requires, all references to:

- “Kitov Holdings,” refers to Kitov Pharmaceuticals Holdings Ltd.,
- “we,” “us,” “our,” and similar designations refer to Kitov Pharmaceuticals Holdings Ltd., together with its wholly-owned subsidiary, Kitov Pharmaceuticals Ltd.,
- “Kitov Pharmaceuticals” refers to Kitov Pharmaceuticals Ltd., the wholly owned subsidiary of Kitov Pharmaceuticals Holdings Ltd.,
- the terms “shekels”, “Israeli shekels” and “NIS” refer to New Israeli Shekels, the lawful currency of the State of Israel,
- the terms “dollar”, “US$” or “$” refer to U.S. dollars, the lawful currency of the United States of America,
- the terms “Euro” or “€” refer to the Euro, the lawful currency of the European Union member states,
- references to “ordinary shares,” “our shares” and similar expressions refer to the Registrant’s Ordinary Shares, no par value per share,
- references to “ADS” refer to the Registrant’s American Depositary Shares,
- references to “public warrants” refer to the Registrant’s warrants listed on the Nasdaq Capital Market under the symbol KTOVW,
- references to the “Companies Law” are to Israel’s Companies Law, 5759-1999, as amended,
- references to the “SEC” are to the United States Securities and Exchange Commission,
- references to the “NASDAQ” or “Nasdaq” are to the Nasdaq Capital Market, and
- references to the “TASE” are to the Tel Aviv Stock Exchange.

Glossary of Industry Terms

Additionally, for convenience, the following terms used in this Annual Report Form 20-F are defined as follows:

"cGMP"	**Current Good Manufacturing Practice** - the rules and standards defined by the regulatory authorities for the production of drugs at the quality required for use in human beings.
"Clinical"	Measureable effect or trial performed in human beings.
"FDA"	United States Food and Drug Administration
"Formulation"	All the inactive materials contained in a final medical product.
"Generic Product"	A product developed by others than the original innovator, yet contains the same active substance as the original product; a generic product may be completely identical to the original product or differ from the original product, based on the active substance contained in the original product. Limits of the difference from the original product within which the product may be recognized by the regulations as generic are determined separately for each product by the related regulatory authorities during the approval process. Regulatory recognition of a product as a generic product is performed through the majority of approval procedures adapted to this type of product, which differ from the approval procedures applied to a new chemical entity (NCE).
"HTN"	Hypertension.
"IND"	**Investigational New Drug -** a new trial drug approved by the FDA for clinical trials in human beings.
"NCE"	**New Chemical Entity** - a new chemical product, approved through a unique regulatory procedure that differs from the approval procedure of the existing products.
"NDA"	**New Drug Application -** an application submitted to the FDA to approve marketing a new drug.
"Preclinical"	Measureable effect or trial performed on cells or animals.
"Pharmacokinetics" "PK"	The specific properties of a certain preparation, absorption, distribution and material disappearance from the body; the pharmacokinetic indices provide, among other things, information on the extent and time of the patient's exposure to the material.
"Therapeutic effect"	Measurable change in the clinical condition of patients, resulting from the use of a certain medical drug or preparation.

FORWARD-LOOKING STATEMENTS

Some of the statements under the sections entitled "Item 3. Key Information — D. Risk Factors," "Item 4. Information on the Company," "Item 5. Operating and Financial Review and Prospects" and elsewhere in this Annual Report on Form 20-F may include forward looking statements. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. In some cases, you can identify forward-looking statements by terms including "anticipates", "believes", "could", "estimates", "expects", "intends", "may", "plans", "potential", "predicts", "projects", "should", "will", "would", and similar expressions intended to identify forward-looking statements. Forward-looking statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. 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 and other sources that we have not independently verified. You should not put undue reliance on any forward-looking statements. Unless we are required to do so under U.S. federal securities laws or other applicable laws, we do not intend to update or revise any forward-looking statements.

Factors that could cause our actual results to differ materially from those expressed or implied in such forward-looking statements include, but are not limited to:

- the initiation, timing, progress and results of our preclinical and clinical trials, and other development efforts;
- our ability to successfully complete our clinical trials;
- our receipt of regulatory approvals for our therapeutic candidates, and the timing of other regulatory filings and approvals;
- the clinical development, commercialization, and market acceptance of our therapeutic candidates;
- our ability to establish and maintain corporate collaborations;
- the interpretation of the properties and characteristics of our therapeutic candidates and of the results obtained with our therapeutic candidates in preclinical studies or clinical trials;
- the implementation of our business model, strategic plans for our business and therapeutic candidates;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our therapeutic candidates and our ability to operate our business without infringing the intellectual property rights of others;
- estimates of our expenses, future revenues capital requirements and our needs for additional financing;
- competitive companies, technologies and our industry; and
- the political and security situation in Israel on our business.

You should review carefully the risks and uncertainties described under the heading "Item 3. Key Information – D. Risk Factors" in this Annual Report on Form 20-F for a discussion of these and other risks that relate to our business and investing in our ADSs and warrants. The forward-looking statements contained in this Annual Report on Form 20-F are expressly qualified in their entirety by this cautionary statement.

PART I

ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS

A. **Directors and Senior Management**

Not applicable

B. **Advisors**

Not applicable

C. **Auditors**

Not applicable

ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE

Not applicable.

ITEM 3. KEY INFORMATION

A. Selected Financial Data

SELECTED CONSOLIDATED FINANCIAL AND OTHER DATA

The following tables present our selected consolidated statements of operations for the three years ended December 31, 2015, 2014 and 2013, and our selected consolidated statements of financial position as of December 31, 2015 and 2014. Our selected consolidated statements of operations for the three years ended December 31, 2015, 2014 and 2013, and our selected consolidated statements of financial position as of December 31, 2015 and 2014 have been derived from our audited consolidated financial statements included elsewhere in this Annual Report on Form 20-F. We prepare our consolidated financial statements in accordance with IFRS as issued by the IASB. Our historical results are not necessarily indicative of results to be expected in any future periods. You should read this information together with the section of this Annual Report on Form 20-F entitled "Item 5. Operating and Financial Review and Prospects" and our audited consolidated financial statements and related notes included elsewhere in this Annual Report on Form 20-F.

	Year Ended December 31,		
	2015	**2014**	**2013**
	(U.S. Dollars in thousands, except per share and weighted average shares data)		
Statement of Operations:			
Research and development expenses	2,560	3,192	109
General and administrative expenses	1,509	1,269	1,061
Other expenses	-	720	1,383
Operating loss	4,069	5,181	2,553
Financing expense, net	133	71	75
Loss for the period	4,202	5,252	2,628
Loss per ordinary share:[(1)]			
Basic and diluted	(0.22)	*(1.17)	(1.60)
Weighted average number of ordinary shares used in computing basic and diluted loss per share (in thousands):	19,250	*4,482	*1,641

* Unless otherwise indicated, all information contained in this Annual Report on Form 20-F gives retrospective effect to a consolidation of our share capital at a ratio of 1:13, which was effected on November 30, 2014, or the Consolidation, so that: (A) each 13 ordinary shares of Kitov Holdings were consolidated into one ordinary share of Kitov Holdings; and (B) each of the Company's options (tradable and non-tradable) outstanding immediately prior to the consolidation of the share capital was adjusted by multiplying the number of ordinary shares into which such option was exercisable by 1/13 (rounded to 0.07692).

	As of December 31,		
	2015	2014	2013
	(U.S. Dollars, in thousands)		
Balance Sheet Data:			
Cash and cash equivalents	10,558	1,313	193
Working capital (*)	9,606	773	(946)
Total assets	10,812	1,759	311
Total liabilities	(1,383)	(986)	(1,257)
Accumulated deficit	(14,054)	(9,852)	(4,600)
Total equity (deficit)	9,429	773	(946)

(*) Working capital is defined as current assets less current liabilities

(1) Basic loss per ordinary share is calculated by dividing the loss attributable to shareholders by the weighted average number of ordinary shares outstanding during the period. There are no differences between basic and diluted loss per ordinary share since there are no dilutive potential ordinary shares.

On July 11, 2013, Kitov Holdings (then known as Mainrom Line Logistics Ltd., a public shell company listed on the TASE with no assets, debt and/or liabilities) acquired the issued and outstanding shares of Kitov Pharmaceuticals. As part of the acquisition, Mainrom Line Logistics Ltd. changed its name to Kitov Pharmaceuticals Holdings Ltd. The acquisition was accounted for under IFRS as issued by the IASB, as a reverse merger, and therefore the consolidated financial statements of Kitov Holdings presented in this Annual Report on Form 20-F include the financial results of Kitov Pharmaceuticals for the three years ended December 31, 2015, 2014 and 2013 and of Kitov Holdings for the period from July 11, 2013 to December 31, 2015. See Item 7. Major Shareholder and Related Party Transactions – B. Related Party Transactions – Share Transfer Agreement with Kitov Pharmaceuticals" for more information.

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 we describe below, in addition to the other information set forth elsewhere in this Annual Report on Form 20-F, including our consolidated financial statements and the related notes beginning on page F-1, before deciding to invest in our ordinary shares, our American Depositary Shares or our warrants. These material risks could adversely impact our results of operations, possibly causing the trading price of our ordinary shares, American Depositary Shares and our warrants to decline, and you could lose all or part of your investment.

Risks Related to Our Financial Condition and Capital Requirements

We are a clinical development stage biopharmaceutical company with a history of operating losses. We expect to incur significant additional losses in the future and may never be profitable.

We are a clinical development stage biopharmaceutical company, and we are focused on the development of innovative pharmaceutical products. Both of our current therapeutic candidates are in the clinical development stage, and neither has been approved for marketing or is being marketed or commercialized. Our therapeutic candidates require additional clinical trials or other testing before we can obtain the regulatory approvals in order to initiate commercial sales. For professional considerations and in order to manage our financial and human resources, we are currently advancing the development of KIT-302, and after its completion, we will consider the further development of KIT-301. We have incurred losses from commencement of our pharmaceutical research and development activities through December 31, 2015 of approximately $13.9 million as a result of research and development activities, clinical trial related activities, listing for trading and fund raising related activities, general administrative and other expenses. We may incur significant additional losses as we continue to focus our resources on advancing our therapeutic candidates. Our ability to generate revenue and achieve profitability depends mainly upon our ability, alone or with others, to successfully develop our therapeutic candidates and obtain the required regulatory approvals in various territories and then commercialize our therapeutic candidates. We may be unable to achieve any or all of these goals with regard to our therapeutic candidates. As a result, we may never be profitable or achieve significant or sustained revenues.

Our limited operating history as a pharmaceutical research and development company makes it difficult to evaluate our business and prospects.

We have a limited operating history as a pharmaceutical research and development company, and our operations to date have been limited primarily to acquiring therapeutic candidates, research and development, raising capital and recruiting scientific and management personnel and third party partners. We have not yet demonstrated an ability to commercialize or obtain regulatory approval for any of our therapeutic candidates. Consequently, any predictions about our future performance may not be accurate, and you may not be able to fully assess our ability to complete development or commercialize our therapeutic candidates, obtain regulatory approvals, or achieve market acceptance or favorable pricing for our therapeutic candidates.

We will need to raise additional capital to achieve our strategic objectives of developing and commercializing additional therapeutic candidates, and our failure to raise sufficient capital would significantly impair our ability to fund our future operations, develop our therapeutic candidates, attract development or commercial partners and retain key personnel.

Our financial statements for the years ended December 31, 2014 and 2013 contained an explanatory paragraph in the footnotes as to our ability to continue as a going concern. In November 2015, we closed a public offering of our ADSs and public warrants on NASDAQ for an aggregate of approximately $13 million. Prior to this offering we funded our operations primarily through offerings of our securities on the TASE and private loans. We believe our existing cash and cash equivalents will be sufficient to meet our anticipated cash requirements through at least the next twelve months. Our business presently generates no revenues, and we plan to continue expending substantial funds in research and development, including clinical trials. We plan to fund our future operations through commercialization and out-licensing of our therapeutic candidates and either debt or equity financing. However, we cannot be certain that we will be able to raise capital on commercially reasonable terms or at all, or that our actual cash requirements will not be greater than anticipated. We may have difficulty raising needed capital or securing a development or commercialization partner in the future as a result of, among other factors, our lack of revenues from commercialization of the therapeutic candidates, as well as the inherent business risks associated with our company and present and future market conditions. In addition, global and local economic and geopolitical conditions may make it more difficult for us to raise needed capital or secure a development or commercialization partner in the future and may impact our liquidity. If we are unable to obtain future financing, we may be forced to delay, reduce the scope of, or eliminate one or more of our research, development or commercialization programs related to our therapeutic candidates, any of which may have a material adverse effect on our business, financial condition and results of operations. Moreover, to the extent we are able to raise capital through the issuance of debt or equity securities, it could result in substantial dilution to existing shareholders.

Our long term capital requirements are uncertain and subject to numerous risks.

We estimate that so long as no significant revenues are generated from our therapeutic candidates, we will need to raise substantial additional funds to acquire, develop and/or commercialize both of our current therapeutic candidates and any additional therapeutic candidates, as our current cash and short-term investments are not sufficient to complete the research and development of both of our current therapeutic candidates and any additional therapeutic candidates and fund our related expenses. Our long term capital requirements are expected to depend on many potential factors, including, among others:

- the regulatory path of each of our therapeutic candidates;
- our ability to successfully commercialize our therapeutic candidates, including securing commercialization agreements with third parties and favorable pricing and market share;
- the progress, success and cost of our clinical trials and research and development programs;
- the costs, timing and outcome of regulatory review and obtaining regulatory approval of our therapeutic candidates and addressing regulatory and other issues that may arise post-approval;
- the costs of obtaining and enforcing our issued patents and defending intellectual property-related claims;
- the costs of developing sales, marketing and distribution channels; and
- our consumption of available resources more rapidly than currently anticipated, resulting in the need for additional funding sooner than anticipated.

If we are unable to commercialize or out-license our therapeutic candidates or obtain future financing, we may be forced to delay, reduce the scope of, or eliminate one or more of our research and development programs related to the therapeutic candidates, which may have a material adverse effect on our business, financial condition and results of operations.

Risks Related to Our Business and Regulatory Matters

If we and/or our potential commercialization partners are unable to obtain FDA or other foreign regulatory authority approval for our therapeutic candidates, we and/or our potential commercialization partners will be unable to commercialize our therapeutic candidates.

To date, we have not marketed, distributed or sold any therapeutic candidate or other product. Our therapeutic candidates are subject to extensive governmental laws, regulations and guidelines relating to development, clinical trials, manufacturing and commercialization of drugs. We may not be able to obtain regulatory approval for any of our therapeutic candidates in a timely manner or at all.

Any material delay in obtaining, or the failure to obtain, required regulatory approvals will increase our costs and materially and adversely affect our ability to generate future revenues. Any regulatory approval to market a therapeutic candidate may be subject to limitations on the indicated uses for marketing the therapeutic candidate or may impose restrictive conditions of use, including cautionary information, thereby limiting the size of the market for the therapeutic candidate. We also are, and will be, subject to numerous regulatory requirements from both the FDA and foreign state agencies that govern the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. Moreover, approval by one regulatory authority does not ensure approval by other regulatory authorities in separate jurisdictions. Each jurisdiction may have different approval processes and may impose additional testing requirements for our therapeutic candidates than other jurisdictions. Additionally, the FDA or other foreign regulatory bodies may change their approval policies or adopt new laws, regulations or guidelines in a manner that delays or impairs our ability to obtain the necessary regulatory approvals to commercialize our therapeutic candidates.

Clinical trials may involve a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. We and/or our potential commercialization partners will not be able to commercialize our therapeutic candidates without completing such trials.

We have limited experience in conducting and managing the clinical trials that are required to commence commercial sales of our therapeutic candidates. Clinical trials are expensive, complex, can take many years to complete and have uncertain outcomes. We cannot predict whether we, independently or through third parties, will encounter problems with any of the completed, ongoing or planned clinical trials that will cause delays, including suspension of clinical trials, delays in recruiting patients into the clinical trials, or delay of data analysis or release of the final report. The clinical trials of our therapeutic candidates may take significantly longer to complete than is estimated. Failure can occur at any stage of the testing, and we may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent commercialization of our current or future therapeutic candidates.

In connection with the clinical trials for our therapeutic candidates and other therapeutic candidates that we may seek to develop in the future, either on our own or through licensing or partnering agreements, we face various risks, including but not limited to:

- delays in securing clinical investigators or trial sites for the clinical trials;
- delays in receiving import or other government approvals to ensure appropriate drug supply;
- delays in obtaining institutional review board (human ethics committee) and other regulatory approvals to commence a clinical trial;
- negative or inconclusive results from clinical trials;
- the FDA or other foreign regulatory authorities may disagree with the number, design, size, conduct or implementation of our clinical studies;
- an inability to monitor patients adequately during or after treatment;
- problems with investigator or patient compliance with the trial protocols;
- a therapeutic candidate may not prove safe or efficacious;
- there may be unexpected or even serious adverse events and side effects from the use of a therapeutic candidate;
- the results with respect to any therapeutic candidate may not confirm the positive results from earlier preclinical studies or clinical trials;
- the results may not meet the level of statistical significance required by the FDA or other foreign regulatory authorities;
- the results will justify only limited and/or restrictive uses, including the inclusion of warnings and contraindications, which could significantly limit the marketability and profitability of the therapeutic candidate;
- the clinical trials may be delayed or not completed due to the failure to recruit suitable candidates or if there is a lower rate of suitable candidates than anticipated or if there is a delay in recruiting suitable candidates; and
- changes to the current regulatory requirements related to clinical trials which can delay, hinder or lead to unexpected costs in connection with our receiving the applicable regulatory approvals.

A number of companies in the pharmaceutical and biotechnology industries, including those with greater resources and experience than us, have suffered significant setbacks in advanced clinical trials, even after seeing promising results in earlier clinical trials. As such, we do not know whether any clinical trials we may conduct will demonstrate adequate efficacy and safety sufficient to obtain regulatory approval to market our therapeutic candidates. If any of the clinical trials of any therapeutic candidate do not produce favorable results, our ability to obtain regulatory approval for the therapeutic candidate may be adversely impacted, which will have a material adverse effect on our business, financial condition and results of operations.

If we do not establish collaborations for our therapeutic candidates or otherwise raise substantial additional capital, we will likely need to alter our development and any commercialization plans.

Our drug development programs and the potential commercialization of our therapeutic candidates will require additional cash to fund expenses. As such, our strategy includes selectively partnering or collaborating with multiple pharmaceutical and biotechnology companies to assist us in furthering development and potential commercialization of our therapeutic candidates, in some or all jurisdictions. We may not be successful in collaborations with third parties on acceptable terms, or at all. In addition, if we fail to negotiate and maintain suitable development or commercialization agreements, we may have to limit the size or scope of our activities or we may have to delay one or more of our development or commercialization programs. Any failure to enter into development or commercialization agreements with respect to the development, marketing and commercialization of any therapeutic candidate or failure to develop, market and commercialize such therapeutic candidate independently will have an adverse effect on our business, financial condition and results of operation.

Any collaborative arrangements that we establish may not be successful or we may otherwise not realize the anticipated benefits from these collaborations. We do not control third parties with whom we have or may have collaborative arrangements, and we rely on them to achieve results which may be significant to us. In addition, any future collaboration arrangements may place the development and commercialization of our therapeutic candidates outside our control, may require us to relinquish important rights or may otherwise be on terms unfavorable to us.

Our collaborative arrangements require us to rely on external consultants, advisors, and experts for assistance in several key functions, including clinical development, manufacturing, regulatory, market research, and intellectual property. We do not control these third parties, but we rely on them to achieve results, which may be significant to us. Relying upon collaborative arrangements to develop and commercialize our therapeutic candidates subject us to a number of risks, including:

- we may not be able to control the amount and timing of resources that our collaborators may devote to our therapeutic candidates;
- should a collaborator fail to comply with applicable laws, rules, or regulations when performing services for us, we could be held liable for such violations;
- our collaborators may experience financial difficulties or changes in business focus;
- our collaborators partners may fail to secure adequate commercial supplies of our therapeutic candidates upon marketing approval, if at all;
- our collaborators partners may have a shortage of qualified personnel;
- we may be required to relinquish important rights, such as marketing and distribution rights;
- business combinations or significant changes in a collaborator's business strategy may adversely affect a collaborator's willingness or ability to complete its obligations under any arrangement;
- under certain circumstances, a collaborator could move forward with a competing therapeutic candidate developed either independently or in collaboration with others, including our competitors; and
- collaborative arrangements are often terminated or allowed to expire, which could delay the development and may increase the cost of developing our therapeutic candidates.

If any of these scenarios materialize, they could have an adverse effect on our business, financial condition or results of operations.

Our business plan is based largely upon the combination of drugs that have not been previously combined. Unexpected difficulties or delays in perfecting the combination of such drugs or in successfully marketing such combination drugs could have an adverse effect on our business, financial condition and results of operations.

We are focused on the development of combinations of existing drugs for the simultaneous treatment of pain caused by osteoarthritis and hypertension.

Since these existing drugs have not previously been combined into one therapeutic agent, we cannot be certain whether the combination will work as intended. In particular, we do not know whether the combination will be bio-equivalent to the separate component drugs, and we cannot be certain that the formulation and manufacturing process for the combination drugs will develop as planned. In addition, we cannot be certain that the market will consider our combination drug to be superior to treatment with the separate drug components. Any delays in perfecting the combination, the production of the combination, or in market acceptance of the combination could have an adverse effect on our business, financial condition and results of operations.

We rely on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily, including, but not limited to, failing to meet established deadlines for the completion of such clinical trials.

We do not have the ability independently to conduct clinical trials for our product candidates, and we rely on third parties, such as contract research organizations, medical institutions, contract laboratories, current and potential development or commercialization partners, clinical investigators and independent study monitors, to perform this function. Our reliance on these third parties for clinical development activities reduces our control over these activities. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. Although we have, in the ordinary course of business, entered into agreements with these third parties, we continue to be responsible for confirming that each of our clinical trials is conducted in accordance with its general investigational plan and protocol. Moreover, the FDA requires us to comply with regulations and standards, commonly referred to as good clinical practices, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the trial participants are adequately protected. Our reliance on third parties does not relieve us of these responsibilities and requirements. To date, we believe our contract research organizations and other similar entities with which we are working have performed well. However, if these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be required to replace them. Although we believe that there are a number of other third-party contractors we could engage to continue these activities, it may result in a delay of the affected trial and additional costs. Accordingly, we may be delayed in obtaining regulatory approvals for our therapeutic candidates and may be delayed in our efforts to successfully commercialize our therapeutic candidates for targeted diseases.

In addition, we rely substantially on third-party data managers for the clinical trial data that we present to regulatory authorities in order to obtain marketing authorizations. Although we attempt to audit and control the quality of third party data, we cannot guarantee the authenticity or accuracy of such data, nor can we be certain that such data has not been fraudulently generated. There is no assurance that these third parties will pass FDA or regulatory audits, which could delay or prohibit regulatory approval.

If third parties do not manufacture our therapeutic candidates in sufficient quantities, in the required timeframe, and at an acceptable cost, clinical development and commercialization of our therapeutic candidates would be delayed.

We do not currently own or operate manufacturing facilities, and we rely, and expect to continue to rely, on third parties to manufacture clinical and commercial quantities of our therapeutic candidates. Our reliance on third parties includes our reliance on them for quality assurance related to regulatory compliance. Our current and anticipated future reliance upon others for the manufacture of our therapeutic candidates may adversely affect our future profit margins, if any, and our ability to develop therapeutic candidates and commercialize any therapeutic candidates on a timely and competitive basis.

We may not be able to maintain our existing or future third party manufacturing arrangements on acceptable terms, if at all. If for some reason our existing or future manufacturers do not perform as agreed or expected, or our existing or future manufacturers otherwise terminate their arrangements with us, we may be required to replace them. Although we are not substantially dependent upon our existing manufacturing agreements since we could replace them with other third party manufacturers, we may incur added costs and delays in identifying, engaging, qualifying and training any such replacements.

We rely on third party contract vendors to manufacture and supply us with high quality active pharmaceutical ingredients, or API, in the quantities we require on a timely basis.

We currently do not manufacture any API ourselves. Instead, we rely on third-party vendors for the manufacture and supply of our APIs that are used to formulate our therapeutic candidates. While there are many potential API suppliers in the market, if these suppliers are incapable or unwilling to meet our current or future needs on acceptable terms or at all, we could experience a delay in conducting additional clinical trials of our therapeutic candidates and incur additional costs.

While there may be several alternative suppliers of API in the market, we have not conducted extensive investigation into the quality or availability of their APIs. As a result, we can provide no assurances that supply sources will not be interrupted from time to time. Changing API suppliers or finding and qualifying new API suppliers can be costly and take a significant amount of time. Many APIs require significant lead time to manufacture. There can also be challenges in maintaining similar quality or technical standards from one manufacturing batch to the next.

If we are not able to find stable, reliable supplies of our API, we may not be able to produce enough supplies of our therapeutic candidates, which could affect our business, financial condition and results of operation.

We anticipate continued reliance on third-party manufacturers if we are successful in obtaining marketing approval from the FDA and other regulatory agencies for any of our therapeutic candidates.

To date, our therapeutic candidates have been manufactured in relatively small quantities for formulation development and clinical trials by third-party manufacturers and our therapeutic candidates may be developed in the future for preclinical and clinical trials, as may be required. If the FDA or other regulatory agencies approve any of our therapeutic candidates for commercial sale, we expect that we would continue to rely, at least initially, on third-party manufacturers to produce commercial quantities of our approved therapeutic candidates. These manufacturers may not be able to successfully increase the manufacturing capacity for any of our approved therapeutic candidates in a timely or economic manner, or at all. Significant scale-up of manufacturing may require additional validation studies, which the FDA must review and approve. If they are unable to successfully increase the manufacturing capacity for a therapeutic candidate, or we are unable to establish alternative manufacturing capabilities, the commercial launch of any approved therapeutic candidates may be delayed or there may be a shortage in supply.

We and our third-party manufacturers are, and will be, subject to regulations of the FDA and other foreign regulatory authorities.

We and our contract manufacturers are, and will be, required to adhere to laws, regulations and guidelines of the FDA and other foreign regulatory authorities setting forth Current Good Manufacturing Practices. These laws, regulations and guidelines cover all aspects of the manufacturing, testing, quality control and recordkeeping relating to our therapeutic candidates. We and our manufacturers may not be able to comply with applicable laws, regulations and guidelines. We and our manufacturers are and will be subject to unannounced inspections by the FDA, state regulators and similar foreign regulatory authorities outside the U.S. Our failure, or the failure of our third-party manufacturers, to comply with applicable laws, regulations and guidelines could result in the imposition of sanctions on us, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our therapeutic candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of our therapeutic candidates, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect regulatory approval and supplies of our therapeutic candidates and materially and adversely affect our business, financial condition and results of operations.

Even if we obtain regulatory approvals, our therapeutic candidates will be subject to ongoing regulatory review. If we fail to comply with continuing U.S. and applicable foreign laws, regulations and guidelines, we could lose those approvals, and our business would be seriously harmed.

Even if our therapeutic candidates receive regulatory approval, we or our potential commercialization partners, as applicable, will be subject to ongoing reporting obligations, including pharmacovigilance, and the therapeutic candidates and the manufacturing operations will be subject to continuing regulatory review, including inspections by the FDA and other foreign regulatory authorities. The results of this ongoing review may result in the withdrawal of a therapeutic candidate from the market, the interruption of the manufacturing operations or the imposition of labeling or marketing limitations. Since many more patients are exposed to drugs following their marketing approval, serious but infrequent adverse reactions that were not observed in clinical trials may be observed during the commercial marketing of the therapeutic candidate. In addition, the manufacturer and the manufacturing facilities that we or our potential commercialization partners use or will use to produce any therapeutic candidate will be subject to periodic review and inspection by the FDA and other foreign regulatory authorities. Later discovery of previously unknown problems with any therapeutic candidate, manufacturer or manufacturing process, or failure to comply with rules and regulatory requirements, may result in actions such as:

- restrictions on such therapeutic candidate, manufacturer or manufacturing process;
- warning letters from the FDA or other foreign regulatory authorities;
- withdrawal of the therapeutic candidate from the market;
- suspension or withdrawal of regulatory approvals;
- refusal to approve pending applications or supplements to approved applications that we or our potential commercialization partners submit;
- voluntary or mandatory recall;
- fines;
- refusal to permit the import or export of our therapeutic candidates;
- product seizure or detentions;
- injunctions or the imposition of civil or criminal penalties; or
- adverse publicity.

If we, or our current or potential commercialization partners, suppliers, third party contractors or clinical investigators are slow to adapt, or are unable to adapt, to changes in existing regulatory requirements or the adoption of new regulatory requirements or policies, we or our potential commercialization partners may lose marketing approval for any of our therapeutic candidates if any of our therapeutic candidates are approved, resulting in decreased or lost revenue from milestones, product sales or royalties.

Modifications to our therapeutic candidates, or to any other therapeutic candidates that we may develop in the future, may require new regulatory clearances or approvals or may require us or our current or potential development and commercialization partners, as applicable, to recall or cease marketing these therapeutic candidates until clearances are obtained.

Modifications to our therapeutic candidates, after they have been approved for marketing, if at all, or to any other pharmaceutical product or medical device that we may develop in the future, may require new regulatory clearance or approvals, and, if necessitated by a problem with a marketed product, may result in the recall or suspension of marketing of the previously approved and marketed product until clearances or approvals of the modified product are obtained. The FDA and other foreign regulatory authorities require pharmaceutical product and device manufacturers initially to make and document a determination of whether or not a modification requires a new approval, supplement or clearance. A manufacturer may determine in conformity with applicable laws, regulations and guidelines that a modification may be implemented without pre-clearance by the FDA or other foreign regulatory authorities; however, the FDA or other foreign regulatory authorities can review a manufacturer's decision and may disagree. The FDA or other foreign regulatory authorities may also on their own initiative determine that a new clearance or approval is required. If the FDA or other foreign regulatory authorities require new clearances or approvals of any pharmaceutical product for which we or our current or potential development and commercialization partners previously received marketing approval, we or our current or potential development and commercialization partners may be required to recall such therapeutic candidate and to stop marketing the therapeutic candidate as modified, which could require us or our current or potential development and commercialization partners to redesign the therapeutic candidate and cause a material adverse effect on our business, financial condition and results of operations.

While we have negotiated a special protocol assessment, or SPA, agreement with the FDA relating to the Phase III clinical trial protocol for KIT-302, this agreement does not guarantee approval of KIT-302 or any other particular outcome from regulatory review of the study or the drug candidate.

We have reached an agreement with the FDA to conduct the Phase III clinical trial for KIT-302 pursuant to an SPA agreement. The FDA's SPA process is designed to facilitate the FDA's review and approval of drugs by allowing the FDA to evaluate the proposed design and size of Phase III trials that are intended to form the primary basis for determining a therapeutic candidate's efficacy. Upon specific request by a clinical trial sponsor, the FDA will evaluate the protocol and respond to a sponsor's questions regarding, among other things, primary efficacy endpoints, trial design and data analysis plans, within 45 days of receipt of the request. The FDA ultimately assesses whether the protocol design and planned analysis of the trial are acceptable to support regulatory approval of the therapeutic candidate with respect to its effectiveness and safety against the indication studied. All agreements and disagreements between the FDA and the sponsor regarding an SPA agreement must be clearly documented in an SPA letter or the minutes of a meeting between the sponsor and the FDA. Nevertheless, an SPA agreement does not guarantee approval of a therapeutic candidate, and even if the FDA agrees to the design, execution and analysis proposed in protocols reviewed under the SPA process, the FDA may revoke or alter its agreement in certain circumstances. In particular, an SPA agreement is not binding on the FDA if public health concerns emerge that were unrecognized at the time of the SPA agreement, other new scientific concerns regarding product safety or efficacy arise, the sponsor company fails to comply with the agreed upon trial protocols, or the relevant data, assumptions or information provided by the sponsor in a request for the SPA change or are found to be false or omit relevant facts. In addition, even after an SPA agreement is finalized, the SPA agreement may be modified, and such modification will be deemed binding on the FDA review division, except under the circumstances described above, if the FDA and the sponsor agree in writing to modify the protocol and such modification is intended to improve the study. The FDA retains significant latitude and discretion in interpreting the terms of the SPA agreement and the data and results from any study that is the subject of the SPA agreement. A revocation or alteration in our existing SPA agreement could significantly delay or prevent approval of our application. Our SPA agreement with the FDA does not ensure that KIT-302 will receive marketing approval or that the approval process will be faster than conventional regulatory procedures. Further, we cannot assure you that the reported results of our Phase III clinical trial of KIT-302 will result in any FDA approval for KIT-302. While we believe that our Phase III clinical trial has been completed in accordance with the SPA agreement, and that the data generated met the endpoints that have been agreed in the SPA agreement to represent adequate evidence of effectiveness, if the FDA revokes or alters its agreement under the SPA agreement, or if the FDA interprets the data collected from the clinical trial differently than we do, the FDA may not deem the data sufficient to support an application for regulatory approval, which could materially adversely affect our business, financial condition and results of operations.

We depend on our ability to identify and acquire or in-license therapeutic candidates to achieve commercial success.

Our therapeutic candidates were all acquired by us from third parties. We evaluate internally and with external consultants each potential therapeutic candidate. However, there can be no assurance as to our ability to accurately or consistently select therapeutic candidates that have the highest likelihood to achieve commercial success.

Our business could suffer if we are unable to attract and retain key employees or directors.

The loss of the services of members of senior management or other key personnel could delay or otherwise adversely impact the successful completion of our planned clinical trials or the commercialization of our therapeutic candidates or otherwise affect our ability to manage our company effectively and to carry out our business plan. We do not maintain key-man life insurance for any of our personnel. Although we have entered into employment or consultancy agreements with all of the members of our senior management team, members of our senior management team may resign at any time. High demand exists for senior management and other key personnel in the pharmaceutical industry. There can be no assurance that we will be able to continue to retain and attract such personnel.

Our growth and success also depend on our ability to attract and retain additional highly qualified scientific, technical, business development, marketing, managerial and finance personnel. We experience intense competition for qualified personnel, and the existence of non-competition agreements between prospective employees and their former employers may prevent us from hiring those individuals or subject us to liability from their former employers. In addition, if we elect to independently commercialize any therapeutic candidate, we will need to expand our marketing and sales capabilities. While we attempt to provide competitive compensation packages to attract and retain key personnel, many of our competitors are likely to have greater resources and more experience than we have, making it difficult for us to compete successfully for key personnel. Compensation packages for certain of our senior office holders are subject to approval of our compensation committee (or the audit committee acting in lieu of a compensation committee pursuant to the Companies Law) and board of directors and in certain instances of our shareholders as well. We may not be able to achieve the required corporate approvals for proposed compensation packages, further making it difficult for us to compete successfully with privately owned companies in order to attract and retain key personnel. If we cannot attract and retain sufficiently qualified technical employees on acceptable terms, we may not be able to develop and commercialize competitive therapeutic candidates. Further, any failure to effectively integrate new personnel could prevent our business from successfully growing.

We are an international business, and we are exposed to various global and local risks that could have an adverse effect on our business.

We operate our business in multiple international jurisdictions. Such operations could be affected by changes in foreign exchange rates, capital and exchange controls, expropriation and other restrictive government actions, changes in intellectual property legal protections and remedies, trade regulations and procedures and actions affecting approval, production, pricing, and marketing of, reimbursement for and access to, our products, as well as by political unrest, unstable governments and legal systems and inter-governmental disputes. Any of these changes could adversely affect our business.

Risks Related to Our Industry

Even if our therapeutic candidates receive regulatory approval or do not require regulatory approval, they may not become commercially viable products.

Even if our therapeutic candidates are approved for commercialization, they may not become commercially viable products. For example, if we or our potential commercialization partners receive regulatory approval to market a therapeutic candidate, approval may be subject to limitations on the indicated uses or subject to labeling or marketing restrictions which could materially and adversely affect the marketability and profitability of the therapeutic candidate. In addition, a new therapeutic candidate may appear promising at an early stage of development or after clinical trials but never reach the market, or it may reach the market but not result in sufficient product sales, if any. A therapeutic candidate may not result in commercial success for various reasons, including:

- difficulty in large-scale manufacturing, including yield and quality;
- low market acceptance by physicians, healthcare payers, patients and the medical community as a result of lower demonstrated clinical safety or efficacy compared to other products, prevalence and severity of adverse side effects, or other potential disadvantages relative to alternative treatment methods;
- insufficient or unfavorable levels of reimbursement from government or third-party payers, such as insurance companies, health maintenance organizations and other health plan administrators;
- infringement on proprietary rights of others for which we or our potential commercialization partners have not received licenses;
- incompatibility with other therapeutic candidates;
- other potential advantages of alternative treatment methods and competitive forces that may make it more difficult for us to penetrate a particular market segment;
- ineffective marketing and distribution support;
- lack of significant competitive advantages over existing products on the market;
- lack of cost-effectiveness; or
- timing of market introduction of competitive products.

Physicians, various other health care providers, patients, payers or the medical community in general may be unwilling to accept, utilize or recommend any of our approved therapeutic candidates. If we are unable, either on our own or through third parties, to manufacture, commercialize and market our proposed formulations or therapeutic candidates when planned, or develop commercially viable therapeutic candidates, we may not achieve any market acceptance or generate revenue.

The market for our therapeutic candidates is rapidly changing and competitive, and new drug delivery mechanisms, drug delivery technologies, new drugs and new treatments which may be developed by others could impair our ability to maintain and grow our business and remain competitive.

The pharmaceutical and biotechnology industry is highly competitive, and we face significant competition from many pharmaceutical, biopharmaceutical and biotechnology companies that are researching and marketing products designed to address the indications for which we are currently developing therapeutic candidates or for which we may develop therapeutic candidates in the future. There are various other companies that currently market or are in the process of developing products that address all of the indications or diseases treated by our therapeutic candidates. For information regarding our competition, See "Item 4. Information on the Company B. Business Overview - Competition and Market."

New drug delivery mechanisms, drug delivery technologies, new drugs and new treatments that have been developed or that are in the process of being developed by others may render our therapeutic candidates noncompetitive or obsolete, or we may be unable to keep pace with technological developments or other market factors. Some of these technologies may have an entirely different approach or means of accomplishing similar therapeutic effects compared to our therapeutic candidates. Technological competition from pharmaceutical and biotechnology companies, universities, governmental entities and others is intense and is expected to increase. Many of these entities have significantly greater research and development capabilities, human resources and budgets than we do, as well as substantially more marketing, manufacturing, financial and managerial resources. These entities represent significant competition for us. Acquisitions of, or investments in, competing pharmaceutical or biotechnology companies by large corporations could increase such competitors' financial, marketing, manufacturing and other resources.

The potential widespread acceptance of therapies that are alternatives to ours may limit market acceptance of our formulations or therapeutic candidates, even if commercialized. Many of our targeted diseases and conditions can also be treated by other medications or drug delivery technologies. These treatments may be widely accepted in medical communities and have a longer history of use. The established use of these competitive drugs may limit the potential for our therapeutic candidates to receive widespread acceptance if commercialized.

If third-party payers do not adequately reimburse customers for any of our therapeutic candidates that are approved for marketing, they might not be purchased or used, and our revenues and profits will not develop or increase.

Our revenues and profits will depend heavily upon the availability of adequate reimbursement for the use of our approved therapeutic candidates, if any, from governmental or other third-party payers, both in the U.S. and in foreign markets. Reimbursement by a third-party payer may depend upon a number of factors, including the third-party payer's determination that the use of an approved therapeutic candidate is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective, including compared to approved alternate therapies; and
- neither experimental nor investigational.

Obtaining reimbursement approval for a therapeutic candidate from each government or other third-party payer is a time-consuming and costly process that could require us or our current or potential development and commercialization partners to provide supporting scientific, clinical and cost-effectiveness data for the use of our therapeutic candidates to each payer. Even when a payer determines that a therapeutic candidate is eligible for reimbursement, the payer may impose coverage limitations that preclude payment for some uses that are approved by the FDA or other foreign regulatory authorities. Reimbursement rates may vary according to the use of the therapeutic candidate and the clinical setting in which it used, may be based on payments allowed for lower-cost products that are already reimbursed, may be incorporated into existing payments for other products or services, and may reflect budgetary constraints or imperfections in Medicare, Medicaid or other data used to calculate these rates.

In the U.S., there have been, and we expect that there will continue to be, federal and state proposals to constrain expenditures for medical products and services which may affect payments for our therapeutic candidates in the U.S. We believe that legislation that reduces reimbursement for our therapeutic candidates could adversely impact how much or under what circumstances healthcare providers will prescribe or administer our therapeutic candidates, if approved. This could materially and adversely impact our business by reducing our ability to generate revenue, raise capital, obtain additional collaborators and market our therapeutic candidates, if approved. At this stage, we are unable to estimate the extent of the direct or indirect impact of any such federal and state proposals.

Further, the Centers for Medicare and Medicaid Services frequently change product descriptors, coverage policies, product and service codes, payment methodologies and reimbursement values. Third-party payers often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and both the Centers for Medicare and Medicaid Services and other third-party payers may have sufficient market power to demand significant price reductions.

Legislative or regulatory reform of the healthcare system in the United States may harm our future business.

On March 23, 2010, President Obama signed the "Patient Protection and Affordable Care Act" (P.L. 111-148) and on March 30, 2010, the President signed the "Health Care and Education Reconciliation Act" (P.L. 111-152), collectively commonly referred to as the "Healthcare Reform Law." The Health Reform Law included a number of new rules regarding health insurance, the provision of health care, and conditions to reimbursement for healthcare services provided to Medicare and Medicaid patients. Through the rule making process, substantial changes have been and continue to be made to the current system for paying for healthcare in the United States, including changes made in order to extend medical benefits to those who lack insurance coverage. Extending coverage to a large population could substantially change the structure of the health insurance system and the methodology for reimbursing medical services and drugs. This legislation is one of the most comprehensive and significant reforms ever experienced by the United States in the healthcare industry and is expected to have meaningful ramifications on tens of millions of citizens in the United States. This legislation is expected to impact the scope of healthcare insurance, the insurance refunds from the insurance companies and possibly also the costs of medical products. Additionally, the Healthcare Reform Law's provisions are designed to encourage providers to find cost savings in their clinical operations. Pharmaceuticals represent a significant portion of the cost of providing care. Through modified reimbursement rates and other incentives, the United States government is requiring that providers identify the most cost-effective services, supplies and pharmaceuticals. This environment has caused changes in the purchasing habits of providers and resulted in specific attention to the pricing negotiation, product selection and utilization review surrounding pharmaceuticals. To the extent that our therapeutic candidates are at some point reimbursable by U.S federal government programs, this attention may result in our therapeutic candidates being chosen less frequently or the pricing being substantially lowered. However, the effect of the legislation is difficult to predict and, at this stage, we are unable to estimate the full extent of the direct and/or indirect impact of the legislation on us.

These structural changes could entail modifications to the existing system of private payors and government programs (such as Medicare, Medicaid and State Children's Health Insurance Program), creation of a government-sponsored healthcare insurance source, or some combination of both, as well as other changes. Restructuring the coverage of medical care in the United States could impact the reimbursement for prescribed drugs and pharmaceuticals, such as those we and our development and/or commercialization partners are currently developing. If reimbursement for our approved therapeutic candidates, if any, is substantially reduced in the future, or rebate obligations associated with them are substantially increased, our business could be materially and adversely impacted.

Extending medical benefits to those who currently lack coverage will likely result in substantial cost to the United States federal government, which may force significant additional changes to the healthcare system in the United States. Much of the funding for expanded healthcare coverage may be sought through cost savings. While some of these savings may come from realizing greater efficiencies in delivering care, improving the effectiveness of preventive care and enhancing the overall quality of care, much of the cost savings may come from reducing the cost of care. Cost of care could be reduced by decreasing the level of reimbursement for medical services or products (including those pharmaceuticals currently being developed by us or our development and/or commercialization partners), or by restricting coverage (and, thereby, utilization) of medical services or products. In either case, a reduction in the utilization of, or reimbursement for, any therapeutic candidate for which we receive marketing approval in the future could have a materially adverse effect on our financial performance.

Several States and private entities initially mounted legal challenges to the healthcare reform legislation, and they continue to litigate various aspects of the legislation. On July 26, 2012, the United States Supreme Court generally upheld the healthcare reform legislation as constitutional. However, the Supreme Court held that the legislation improperly required the States to expand their Medicaid programs to cover more individuals. As a result, the States have a choice as to whether they will expand the numbers of individuals covered by their respective State Medicaid programs. Some States have determined that they will not expand their Medicaid programs and will develop other cost saving and coverage measures to provide care to currently uninsured residents. Many of these efforts to date have included the institution of Medicaid managed care programs. The manner in which these cost saving measures are implemented could have a materially adverse effect on our financial performance. Further, the healthcare regulatory environment has seen significant changes in recent years and is still in flux. We cannot predict the impact on our business of future legal challenges to the healthcare reform legislation or other changes to the current laws and regulations.

We are subject to additional federal and state laws and regulations relating to our business, and our failure to comply with those laws could have a material adverse effect on our results of operations and financial conditions.

In the event that we were to market products in the United States, we would be subject to additional healthcare regulation and enforcement by the federal government and the states in which we conduct or will conduct our business. The laws that may affect our ability to operate include, but are not limited to, the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under government healthcare programs such as the Medicare and Medicaid programs;
- the federal Anti-Inducement Law (also known as the Civil Monetary Penalties Law), which prohibits a person from offering or transferring remuneration to a Medicare or State health care program beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of any item or service for which payment may be made, in whole or in part, by Medicare or a State health care program;
- the Ethics in Patient Referrals Act of 1989, commonly referred to as the Stark Law, which prohibits physicians from referring Medicare or Medicaid patients for certain designated health services where that physician or its family member has a financial relationship with the entity providing the designated health service, unless an exception applies;
- federal false claims laws that prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other government healthcare programs that are false or fraudulent;
- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers.

Further, the recently enacted Healthcare Reform Law, among other things, amends the intent requirement of the federal anti-kickback and criminal healthcare fraud statutes. A person or entity can now be found guilty of fraud or an anti-kickback violation without actual knowledge of the statute or specific intent to violate it. In addition, the Healthcare Reform Law provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statue constitutes a false or fraudulent claim for purposes of the False Claims Act (31 U.S.C. 3729–3733). Possible sanctions for violation of these anti-kickback laws include monetary fines, civil and criminal penalties, exclusion from Medicare, Medicaid and other government programs and forfeiture of amounts collected in violation of such prohibitions. Any violations of these laws, or any action against us for violation of these laws, even if we successfully defend against it, could result in a material adverse effect on our reputation, business, results of operations and financial condition.

The Healthcare Reform Law also imposes reporting requirements on certain medical devices and pharmaceutical manufacturers, among others, to make annual public disclosures of certain payments or other transfers of value to physicians and teaching hospitals and ownership or investment interests held by physicians or their immediate family members. Failure to submit required information may result in civil monetary penalties of up to an aggregate of $150,000 per year (or up to an aggregate of $1 million per year for "knowing failures"), for all payments, transfers of value or ownership or investment interests that are not reported. Manufacturers were required to begin data collection on August 1, 2013 and report such data to the Centers for Medicare & Medicaid Services (CMS) by March 31 each year. CMS made the data publicly available on its searchable database beginning in September 2014.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians for marketing, medical directorships, and other purposes. Some states, such as California, Massachusetts and Vermont, mandate implementation of corporate compliance programs, along with the tracking and reporting of gifts, compensation and other remuneration to physicians, and some states limit or prohibit such gifts.

The scope and enforcement of these laws is uncertain and subject to change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. We cannot predict the impact on our business of any changes in these laws. Federal or state regulatory authorities may challenge our current or future activities under these laws. Any such challenge could have a material adverse effect on our reputation, business, results of operations, and financial condition. Any state or federal regulatory review of us, regardless of the outcome, would be costly and time-consuming.

We could be exposed to significant drug product liability claims, which could be time consuming and costly to defend, divert management attention and adversely impact our ability to obtain and maintain insurance coverage.

The clinical trials that we conduct, and the testing, manufacturing, marketing and commercial sale of our therapeutic candidates, involve and will involve an inherent risk that significant liability claims may be asserted against us. We currently have a clinical trial liability policy that includes coverage for our clinical trials. Should we decide to seek additional insurance against such risks before our product sales commence, there is a risk that such insurance will be unavailable to us, or if it can be obtained at such time, that it will be available only at an unaffordable cost. Even if we obtain insurance, it may prove inadequate to cover claims or litigation costs, especially in the case of wrongful death claims. Product liability claims or other claims related to our therapeutic candidates, regardless of their outcome, could require us to spend significant time and money in litigation or to pay significant settlement amounts or judgments. Any successful product liability or other claim may prevent us from obtaining adequate liability insurance in the future on commercially desirable or reasonable terms. An inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the commercialization of our products and therapeutic candidates. A product liability claim could also significantly harm our reputation and delay market acceptance of our therapeutic candidates.

Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. An economic downturn could result in a variety of risks to our business, including weakened demand for our therapeutic candidates and our inability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our partners and suppliers, possibly resulting in supply disruption, or cause future customers to delay making payments for our products. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

Our business involves risks related to handling regulated substances which could severely affect our ability to conduct research and development of our therapeutic candidates.

In connection with our current or potential development and commercialization partners' research and clinical development activities, as well as the manufacture of materials and therapeutic candidates, we and our current or potential development and commercialization partners are subject to foreign, federal, state and local laws, rules, regulations and policies governing the use, generation, manufacture, storage, air emission, effluent discharge, handling and disposal of certain materials, biological specimens and wastes. We and our current or potential development and commercialization partners may be required to incur significant costs to comply with environmental and health and safety regulations in the future. Our research and clinical development, as well as the activities of our manufacturing and current or potential development and commercialization partners, both now and in the future, may involve the controlled use of hazardous materials, including but not limited to certain hazardous chemicals. We cannot completely eliminate the risk of accidental contamination or injury from these materials. In the event of such an occurrence, we could be held liable for any damages that result and any such liability could exceed our resources.

Risks Related to Intellectual Property and Legal Proceedings

We may be unable to adequately protect or enforce our rights to intellectual property, causing us to lose valuable rights. Loss of patent rights may lead us to lose market share and potential profits.

Our success depends, in part, on our ability, and the ability of our current or potential development and commercialization partners to obtain patent protection for our therapeutic candidates, maintain the confidentiality of our trade secrets and know how, operate without infringing on the proprietary rights of others and prevent others from infringing our proprietary rights.

We try to protect our proprietary position by, among other things, filing U.S., European, and other patent applications related to our therapeutic candidates, inventions and improvements that may be important to the continuing development of our therapeutic candidates.

Because the patent position of pharmaceutical companies involves complex legal and factual questions, we cannot predict the validity and enforceability of any patents we may obtain with certainty. Our competitors may independently develop drug delivery technologies or products similar to ours or design around or otherwise circumvent any patents that may be issued to or licensed by us. Our pending patent applications, and those that we may file in the future or those we may license from third parties may not result in patents being issued. If these patents are issued, they may not provide us with proprietary protection or competitive advantages. The degree of future protection to be afforded by our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage.

Patent rights are territorial; thus, the patent protection we have sought will only extend, if issued, to those countries, if any, in which we will be issued patents. Even so, the laws of certain countries do not protect our intellectual property rights to the same extent as do the laws of the U.S. and the European Union. Competitors may successfully challenge any of our patents, produce similar drugs or products that do not infringe such patents, or produce drugs in countries where we have not applied for patent protection or that do not respect such patents. Furthermore, it is not possible to know the scope of claims that will be allowed in published applications and it is also not possible to know which claims of granted patents, if any, will be deemed enforceable in a court of law.

After the completion of development and registration of any future patents, third parties may still act to manufacture or market our therapeutic candidates in infringement of our patent protected rights. Such manufacture or marketing of our therapeutic candidates in infringement of any patent-protected rights is likely to cause us damage and lead to a reduction in the prices of our therapeutic candidates, thereby reducing our potential profits.

We may invest a significant amount of time and expense in the development of our therapeutic candidates only to be subject to significant delay and patent litigation before they may be commercialized. In addition, due to the extensive time needed to develop, test and obtain regulatory approval for our therapeutic candidates, any patents that may be issued that protect our therapeutic candidates may expire early during commercialization. This may reduce or eliminate any market advantages that such patents may give us. Following patent expiration, we may face increased competition through the entry of generic products into the market and a subsequent decline in market share and profits.

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

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

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

Legal proceedings or third-party claims of intellectual property infringement and other legal challenges may require us to spend substantial time and money and could prevent us from developing or commercializing our therapeutic candidates. An adverse result in these infringements and other legal challenges could have a material adverse effect on our business, results of operations and financial condition.

The development, manufacture, use, offer for sale, sale or importation of our therapeutic candidates may infringe on the claims of third-party patents or other intellectual property rights. The nature of claims contained in unpublished patent filings around the world is unknown to us, and it is not possible to know which countries patent holders may choose for the extension of their filings under the Patent Cooperation Treaty, or other mechanisms. We may also be subject to claims based on the actions of employees and consultants with respect to the usage or disclosure of intellectual property learned at other employers. The cost to us of any intellectual property litigation or other infringement proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation or defense of intellectual property litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Intellectual property litigation and other proceedings may also absorb significant management time. Consequently, we are unable to guarantee that we will be able to manufacture, use, offer for sale, sell or import our therapeutic candidates in the event of an infringement action.

In the event of patent infringement claims, or to avoid potential claims, we may choose or be required to seek a license from a third party and would most likely be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we were able to obtain a license, the rights may be non-exclusive, which could potentially limit our competitive advantage. Ultimately, we could be prevented from commercializing a therapeutic candidate or be forced to cease some aspect of our business operations if, as a result of actual or threatened patent infringement or other claims, we are unable to enter into licenses on acceptable terms. This inability to enter into licenses could harm our business significantly.

From time to time, we may be involved in various lawsuits and legal proceedings other than intellectual property infringement actions, concerning such laws as corporate and securities laws, business laws, product liability laws, and environmental laws. On December 3, 2015, we announced that we received a lawsuit and motion to approve the lawsuit as a class action lawsuit pursuant to the Class Action Lawsuits Law 5766-2006 (Motion) which was filed against us and our directors at the Tel Aviv District Court (Economic Division). The Motion asserts claims for damages to the holders of our securities listed on the TASE, arising due to the initial public offering of our securities in the U.S. during November 2015. This Motion could result in significant legal defense costs and high punitive damage payments. Although we maintain directors' and officers' liability insurance, with an extension to cover the Company as well, the insurance companies may reject our claims for coverage under the policy or the coverage may not be adequate to cover future claims. Additionally, we may be unable to maintain our existing directors' and officers' liability insurance in the future at satisfactory rates or adequate amounts. We have been advised by our attorneys that the likelihood of the Company not incurring any financial obligation as a result of the class action exceeds the likelihood that the Company will incur a financial obligation. At this preliminary stage however, we are unable, with any degree of certainty, to make any other evaluations or any other assessments with respect to the Motion's probability of success or the scope of potential exposure, if any. For more information see "Item 8 – Financial Information – Legal Proceedings".

It is difficult to foresee the results of legal actions and proceedings currently involving us or those which may arise in the future, and an adverse result in these matters could have a material adverse effect on our business, results of operations and financial condition. In addition, any legal or administrative proceedings which we are subject to could require the significant involvement of our senior management, and may divert management attention from our business and operations.

We may be subject to other patent-related litigation or proceedings that could be costly to defend and uncertain in their outcome.

In addition to infringement claims against us, we may in the future become a party to other patent litigation or proceedings before regulatory agencies, including interference or re-examination proceedings filed with the U.S. Patent and Trademark Office (USPTO) or opposition proceedings in other foreign patent offices regarding intellectual property rights with respect to our therapeutic candidates, as well as other disputes regarding intellectual property rights with our current and potential development and commercialization partners, or others with whom we have contractual or other business relationships. Post-issuance oppositions are not uncommon and we and our current and potential development and commercialization partners will be required to defend these opposition procedures as a matter of course. Opposition procedures may be costly, and there is a risk that we may not prevail.

Risks Related to our Operations in Israel

We conduct our operations in Israel and therefore our results may be adversely affected by political, economic and military instability in Israel and its region.

We are incorporated under the laws of the State of Israel, our principal offices are located in central Israel and some of our officers, employees, consultants and directors are residents of Israel. Accordingly, political, economic and military conditions in Israel and the surrounding region 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 Arab neighbors. Any hostilities involving Israel or the interruption or curtailment of trade within Israel or between Israel and its trading partners could adversely affect our operations and results of operations and could make it more difficult for us to raise capital. In 2008, 2012, and again in the summer of 2014, Israel was engaged in an armed conflict with Hamas, a militia group and political party operating in the Gaza Strip, and during the summer of 2006, Israel was engaged in an armed conflict with Hezbollah, a Lebanese Islamist Shiite militia group and political party. These conflicts involved missile strikes against civilian targets in various parts of Israel, and negatively affected business conditions in Israel. Political uprisings and civil resistance demonstrations in various countries in the Middle East, including Egypt and Syria, have affected the political stability of those countries. It is not clear how this instability, will develop and how it will affect the political and security situation in the Middle East. This instability may lead to deterioration of the political relationships that exist between Israel and these countries, and have raised concerns regarding security in the region and the potential for armed conflict. The tension between Israel and Iran or extremist groups in the region, such as Hamas in Gaza and Hezbollah in Lebanon, may escalate in the future and turn violent, which could affect the Israeli economy generally and us in particular. Any armed conflicts, terrorist activities or political instability in the region could adversely affect business conditions and could harm our results of operations. Parties with whom we may do business have sometimes declined to travel to Israel during periods of heightened unrest or tension, forcing us to make alternative arrangements when necessary. The conflict situation in Israel could cause situations where medical product certifying or auditing bodies could not be able to visit manufacturing facilities of our subcontractors in Israel in order to review our certifications or clearances, thus possibly leading to temporary suspensions or even cancellations of our product clearances or certifications. The conflict situation in Israel could also result in parties with whom we have agreements involving performance in Israel claiming that they are not obligated to perform their commitments under those agreements pursuant to force majeure provisions in such agreements.

Our commercial insurance does not cover losses that may occur as a result of events associated with the security situation in the Middle East. Although the Israeli government currently covers the reinstatement value of direct damages that are caused by terrorist attacks or acts of war, we cannot assure you that this government coverage will be maintained. Any losses or damages incurred by us could have a material adverse effect on our business. Any armed conflicts or political instability in the region would likely negatively affect business conditions and could harm our results of operations.

Further, in the past, the State of Israel and Israeli companies have been subjected to an economic boycott. Several countries still restrict business and trade activity with the State of Israel and with Israeli companies, and additional countries may impose restrictions on doing business with Israel and Israeli companies if hostilities in the region continue or intensify. Such restrictions may seriously limit our ability to sell our products to customers in those countries.

Any of the factors set forth above may have an adverse impact on our operating results, financial condition or the expansion of our business.

Provisions of Israeli law and our amended and restated articles of association may delay, prevent or otherwise impede a merger with, or an acquisition of, our company, or an acquisition of a significant portion of our shares, which could prevent a change of control, and negatively affect the price of our ordinary shares.

Israeli corporate law regulates mergers, requires tender offers for acquisitions of shares above specified thresholds, requires special approvals for certain transactions involving directors, officers or significant shareholders and regulates other matters that may be relevant to these types of transactions. These provisions of Israeli law may delay, prevent or make difficult an acquisition of us, which could prevent a change of control and therefore depress the price of our shares, See "Item 10. Additional Information – B. Memorandum and Articles of Association – Provisions restricting change in control of our company" for more information.

Furthermore, Israeli tax considerations may make potential transactions unappealing to us or to our shareholders, especially for those shareholders whose country of residence does not have a tax treaty with Israel which exempts such shareholders from Israeli tax. For example, Israeli tax law does not recognize tax-free share exchanges to the same extent as 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.

Our amended and restated articles of association also contain provisions that could delay or prevent changes in control or changes in our management. These provisions include matters in connection with the election and removal of directors, the size of the our board of directors, the terms of office of our directors and the special majority of our voting rights required to amend such provision in our amended and restated articles of association. , See “Item 6. Directors, Senior Management and Employees – C. Board Practices - Board of Directors and Officers” and "Item 10. Additional Information – B. Memorandum and Articles of Association – Provisions restricting change in control of our company" for additional information.

These and other similar provisions could delay, prevent or impede an acquisition of us or our merger with another company, or an acquisition of a significant portion of our shares, even if such an acquisition or merger would be beneficial to us or to our shareholders. See "Item 10. Additional Information – B . Memorandum and Articles of Association – Provisions Restricting Change in Control of Our Company" and "Item 10. Additional Information – E. Taxation—Israeli Tax Considerations and Government Programs" for additional information.

Because a certain portion of our expenses is incurred in currencies other than the U.S. dollar, our results of operations may be harmed by currency fluctuations and inflation.

Our reporting and functional currency is the U.S. dollar. Most of the royalty payments from potential development and commercialization partners are expected to be payable in U.S. dollars, and we expect our revenues from future licensing agreements to be denominated mainly in U.S. dollars or in Euros. We pay a portion of our expenses in U.S. dollars; however, a portion of our expenses, related to salaries of the employees in Israel and payment to part of the service providers in Israel, are paid in NIS and in other currencies. In addition, a portion of our financial assets is held in NIS. As a result, we are exposed to currency fluctuation risks. For example, if the NIS strengthens against the U.S. dollar, our reported expenses in U.S. dollars may be higher than anticipated. In addition, if the NIS weakens against the U.S. dollar, the U.S. dollar value of our financial assets held in NIS will decline.

It may be difficult to enforce a U.S. judgment against us and our officers and directors in Israel or the U.S., or to serve process on our officers and directors.

We are incorporated in Israel. Most of our executive officers and directors reside outside of the U.S., and all of our assets and most of the assets of our executive officers and directors are located outside of the U.S. Therefore, a judgment obtained against us or such executive officers and our directors in the U.S., including one based on the civil liability provisions of the U.S. federal securities laws, may not be collectible in the U.S. and may not be enforced by an Israeli court. It may also be difficult for you to affect service of process on these persons in the U.S. or to assert U.S. securities law claims in original actions instituted in Israel. In addition, even if an Israeli court agrees to hear a claim, it may determine that Israeli law and not United States law is applicable to the claim. If United States law is found to be applicable, the content of applicable United States 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, it may be impossible to collect any damages awarded by either a U.S. or foreign court.

Your obligations and responsibilities as a shareholder will be governed by Israeli law which may differ in some respects from the obligations and responsibilities of shareholders of U.S. companies. Israeli law may impose obligations and responsibilities on a shareholder of an Israeli company that are not imposed upon shareholders of corporations in the U.S.

We are incorporated under Israeli law. The obligations and responsibilities of the holders of our ordinary shares are governed by our amended and restated articles of association and Israeli law. These obligations and responsibilities differ in some respects from the obligations and responsibilities of shareholders in typical U.S.-based corporations. In particular, a shareholder of an Israeli company has a duty to act in good faith toward the company and other shareholders and to refrain from abusing its power in the company, including, among other things, in voting at the 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 knows 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 implications of these provisions that govern shareholders' actions. These provisions may be interpreted to impose additional obligations and responsibilities on holders of our ordinary shares and/or ADSs that are not typically imposed on shareholders of U.S. corporations.

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

The Companies Law and our amended and restated articles of association permit us to indemnify our directors and officers for acts performed by them in their capacity as directors and officers. The Companies Law and our amended and restated articles of association provide that a company may not exempt or indemnify a director or an office holder nor enter into an insurance contract, which would provide coverage for any monetary liability incurred as a result of (a) a breach by the director or officer of his duty of loyalty, except for insurance and indemnification where the director or officer acted in good faith and had a reasonable basis to believe that the act would not prejudice the company; (b) a breach by the director or officer of his duty of care if the breach was done intentionally or recklessly, except if the breach was solely as a result of negligence; (c) any act or omission done with the intent to derive an illegal personal benefit; or (d) any fine, civil fine, monetary sanctions, or forfeit imposed on the officer or director. See Item 6. Directors, Senior Management and Employees - C. Board Practices - Exculpation, Insurance and Indemnification of Directors and Officers.

We have issued letters of indemnification to our directors and officers, pursuant to which we have agreed to indemnify them in advance for any liability or expense imposed on or incurred by them in connection with acts they perform in their capacity as a director or officer, subject to applicable law. The amount of the advance indemnity will not exceed 25% of our then consolidated shareholders' equity, per our most recent consolidated annual financial statements.

Our indemnification obligations limit the personal liability of our directors and officers for monetary damages for breach of their duties as directors by shifting the burden of such losses and expenses to us. Although we have obtained directors and officers liability insurance, certain liabilities or expenses covered by our indemnification obligations may not be covered by such insurance or the coverage limitation amounts may be exceeded.

As a result of the Motion or other claims which may be filed against our directors and officers, we may need to use a significant amount of our funds to satisfy our indemnification obligations, which could severely harm our business and financial condition and limit the funds available to shareholders who may choose to bring a claim against our company. See "Risks Related to Intellectual Property or Legal Proceedings - Legal proceedings or third-party claims of intellectual property infringement and other legal challenges may require us to spend substantial time and money and could prevent us from developing or commercializing our therapeutic candidates. An adverse result in these infringements and other legal challenges could have a material adverse effect on our business, results of operations and financial conditions".

These provisions and resultant costs may also discourage us from bringing a lawsuit against directors and officers for breaches of their duties, and may similarly discourage the filing of derivative litigation by our shareholders against the directors and officers even though such actions, if successful, might otherwise benefit our shareholders.

Risks primarily related to our ADSs and ordinary shares and other listed securities

We may be classified as a Passive Foreign Investment Company, or PFIC, for U.S. federal income tax purposes in 2015 or in any subsequent year, which may have negative tax consequences for U.S. investors.

We 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 our gross income is "passive income" or (ii) on average at least 50% of our assets by value produce passive income or are held for the production of passive income. Based on our estimated gross income, the average value of our gross assets, and the nature of our business, we believe that we may be classified as a PFIC in the current taxable year and in future years. In addition, because we have valued our goodwill based on the market value of our equity, a decrease in the price of our ordinary shares may result in our becoming a PFIC. If we are treated as a PFIC for any taxable year during which a U.S. investor held our ordinary shares or ADSs, certain adverse U.S. federal income tax consequences could apply to the U.S. investor. See "Item 10. Additional Information – E. Taxation– Passive Foreign Investment Company Consequences."

The market price of our ordinary shares, ADSs and public warrants is subject to fluctuation, which could result in substantial losses by our investors.

The stock market in general, and the market price of our ordinary shares on the TASE, and our ADSs and public warrants on NASDAQ in particular, are subject to fluctuation, and changes in the price of our listed securities may be unrelated to our operating performance. The market price of our ordinary shares on the TASE, and our ADSs and public warrants on NASDAQ have fluctuated in the past, and we expect it will continue to do so. The market price of our ordinary shares and ADSs and public warrants are and will be subject to a number of factors, including:

- announcements of technological innovations or new therapeutic candidates by us or others;
- announcements by us of significant acquisitions, strategic partnerships, in-licensing, out-licensing, joint ventures or capital commitments;
- expiration or terminations of licenses, research contracts or other development or commercialization agreements;
- public concern as to the safety of drugs that we, our current or potential development and commercialization partners or others develop;
- the volatility of market prices for shares of biotechnology companies generally;
- success or failure of research and development projects;
- departure of key personnel;
- developments concerning intellectual property rights or regulatory approvals;
- variations in our and our competitors' results of operations;
- changes in earnings estimates or recommendations by securities analysts, if our ordinary shares or ADSs or public warrants are covered by analysts;
- changes in government regulations or patent decisions;
- developments by our current or potential development and commercialization partners; and
- general market conditions and other factors, including factors unrelated to our operating performance.

These factors and any corresponding price fluctuations may materially and adversely affect the market price of our ordinary shares and ADSs and public warrants and result in substantial losses by our investors.

Additionally, market prices for listed securities of biotechnology and pharmaceutical companies historically have been very volatile. The market for these listed securities has from time to time experienced significant price and volume fluctuations for reasons unrelated to the operating performance of any one company. In the past, following periods of market volatility, shareholders have often instituted securities class action litigation. If we were involved in securities litigation, it could have a substantial cost and divert resources and attention of management from our business, even if we are successful.

Future sales of our ordinary shares or ADSs or other warrants could reduce the market price of our ordinary shares and ADSs and warrants.

As of March 15, 2016, we had an aggregate of 78,075,620 issued and outstanding ordinary shares (not including 21 shares held in treasury), public warrants to purchase 3,366,974 of our ADSs (each ADS representing 20 ordinary shares), non-tradable warrants to purchase 157,945 of our ADSs, which warrants were granted to the underwriters as part of our initial U.S. offering in November 2015, warrants to purchase 1,720,000 ordinary shares issued to lenders of our August Loans, and 2,233,753 non-tradable options to purchase 213,657 ordinary shares. Substantial sales of our ordinary shares or ADSs or other warrants, or the perception that such sales may occur in the future, including sales of shares issuable upon the exercise of options, may cause the market price of our ordinary shares or ADSs or public warrants to decline. Moreover, the issuance of shares underlying our options will also have a dilutive effect on our shareholders, which could further reduce the price of our ordinary shares and ADSs and public warrants on their respective exchanges.

As a foreign private issuer, we are permitted to follow certain home country corporate governance practices instead of applicable Securities and Exchange Commission and NASDAQ Capital Market requirements, which may result in less protection than is accorded to investors under rules applicable to U.S domestic issuers.

As a foreign private issuer, we are permitted to follow certain home country corporate governance practices instead of those otherwise required under the NASDAQ Listing Rules for U.S domestic issuers. We will follow home country practice in Israel with regard to (1) the composition of the board of directors, which does not require that a majority of a company's board of directors be independent, but rather that there are at least two independent directors, (2) director nomination procedures, as permitted by the Companies Law, under which either our board of directors, a group of directors, or shareholder(s) holding sufficient portion of our share capital selects director nominees, subject to the terms of our amended and restated articles of association. Directors are not selected, or recommended for board of director selection, as required by the NASDAQ Listing Rules, by independent directors constituting a majority of the board's independent directors or by a nominations committee comprised solely of independent directors, and (3) quorum requirement at shareholders' meetings, as permitted under the Companies Law, under which and pursuant to our amended and restated articles of association, the quorum required for an ordinary meeting of shareholders consists of at least two shareholders present in person or by proxy who hold or represent at least 25% of the voting rights of our shares (and in an adjourned meeting, with some exceptions, any number of shareholders), instead of 33 1/3% of the issued share capital required under the NASDAQ Listing Rules. In addition, we will follow our home country law, instead of the NASDAQ Listing Rules, which require that we obtain shareholder approval for certain dilutive events, such as for the establishment or amendment of certain equity based compensation plans, an issuance that will result in a change of control of the company, certain transactions other than a public offering involving issuances of a 20% or more interest in the company and certain acquisitions of the stock or assets of another company. Following our home country governance practices as opposed to the requirements that would otherwise apply to a U.S. company listed on The NASDAQ may provide less protection than is accorded to investors under the NASDAQ Listing Rules applicable to domestic issuers.

In addition, as a foreign private issuer, we will be exempt from the rules and regulations under the U.S. Securities Exchange Act of 1934, as amended or 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 will not be required under the Exchange Act, to file annual, quarterly and current reports and financial statements with the SEC as frequently or as promptly as domestic companies whose securities are registered under the Exchange Act.

The depositary for our ADSs will give us a discretionary proxy to vote our ordinary shares underlying ADSs if a holder of our ADSs does not vote at shareholders' meetings, except in limited circumstances, which could adversely affect their interests.

Under the deposit agreement for the ADSs, the depositary will give us a discretionary proxy to vote our ordinary shares underlying ADSs at shareholders' meetings if a holder of our ADSs does not vote, unless:

- we have instructed the depositary that we do not wish a discretionary proxy to be given;
- we have informed the depositary that there is substantial opposition as to a matter to be voted on at the meeting; or
- a matter to be voted on at the meeting would have a material adverse impact on shareholders.

The effect of this discretionary proxy is that a holder of our ADSs cannot prevent our ordinary shares underlying such ADSs from being voted, absent the situations described above, and it may make it more difficult for shareholders to influence the management of our company. Holders of our ordinary shares listed for trading on the TASE are not subject to this discretionary proxy.

We currently do not anticipate paying cash dividends, and accordingly, shareholders must rely on the appreciation in our ADSs for any return on their investment.

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Therefore, the success of an investment in our ADSs will depend upon any future appreciation in their value. There is no guarantee that our ADSs will appreciate in value or even maintain the price at which our holders have purchased their ADSs.

The ability of any Israeli company to pay dividends or repurchase its shares is subject to Israeli law, and the amount of cash dividends payable may be subject to devaluation in the Israeli currency.

The ability of an Israeli company to pay dividends or repurchase its shares is governed by Israeli law, which provides that distributions, including cash dividends and share repurchases, may be made only out of retained earnings as determined for statutory purposes. Since we do not have earnings, we currently do not have any ability to pay dividends or repurchase our shares.

Investors in our ADSs may not receive the same distributions or dividends as those we make to the holders of our ordinary shares, and, in some limited circumstances, investors in our ADSs may not receive any value for them, if it is illegal or impractical to make them available to investors in our ADSs.

The depositary for the ADSs has agreed to pay investors in our ADSs the cash dividends or other distributions it or the custodian receives on ordinary shares or other deposited securities underlying the ADSs, after deducting its fees and expenses. Investors in our ADSs will receive these distributions in proportion to the number of ordinary shares their ADSs represent. However, the depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any holders of ADSs. For example, it would be unlawful to make a distribution to a holder of ADSs if it consists of securities that require registration under the Securities Act of 1933, as amended or the Securities Act, but that are not properly registered or distributed under an applicable exemption from registration. In addition, conversion into U.S. dollars from foreign currency that was part of a dividend which was distributed in foreign currency made in respect of deposited ordinary shares may require the approval or license of, or a filing with, any government or agency thereof, which may be unobtainable. In these cases, the depositary may determine not to distribute such property and hold it as "deposited securities" or may seek to affect a substitute dividend or distribution, including net cash proceeds from the sale of the dividends that the depositary deems an equitable and practicable substitute. We have no obligation to register under U.S. securities laws any ADSs, ordinary shares, rights or other securities received through such distributions. We also have no obligation to take any other action to permit the distribution of ADSs, ordinary shares, rights or anything else to holders of ADSs. In addition, the depositary may withhold from such dividends or distributions its fees and an amount on account of taxes or other governmental charges to the extent the depositary believes it is required to make such withholding. This means that investors in our ADSs may not receive the same distributions or dividends as those we make to the holders of our ordinary shares, and, in some limited circumstances, investors in our ADSs may not receive any value for such distributions or dividends if it is illegal or impractical for us to make them available to investors in our ADSs. These restrictions may cause a material decline in the value of the ADSs.

Holders of ADSs must act through the depositary to exercise rights of shareholders of our company.

Holders of our ADSs do not have the same rights as our shareholders and may only exercise the voting rights with respect to the underlying ordinary shares in accordance with the provisions of the deposit agreement for the ADSs. Under Israeli law, the minimum notice period required to convene a shareholders' meeting is no less than 35 or 21 calendar days, depending on the proposals on the agenda for the shareholders' meeting. When a shareholder meeting is convened, holders of our ADSs may not receive sufficient notice of the meeting to permit them to withdraw their ordinary shares to allow them to cast their vote with respect to any specific matter. In addition, the depositary and its agents may not be able to send voting instructions to holders of our ADSs or carry out their voting instructions in a timely manner. We will make all reasonable efforts to cause the depositary to extend voting rights to holders of our ADSs in a timely manner, but we cannot assure holders that they will receive the voting materials in time to ensure that they can instruct the depositary to vote the ordinary shares underlying their ADSs. Furthermore, the depositary and its agents will not be responsible for any failure to carry out any instructions to vote, for the manner in which any vote is cast or for the effect of any such vote. As a result, holders of our ADSs may not be able to exercise their right to vote and they may lack recourse if the ordinary shares underlying their ADSs are not voted as they requested. In addition, ADS holders will not be able to call a shareholders' meeting unless they first withdraw their ordinary shares from the ADS program and convert them into the underlying ordinary shares held in the Israeli market in order to allow them to submit to us a request to call a meeting with respect to any specific matter, in accordance with the applicable provisions of the Companies Law and our amended and restated articles of association.

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

Our ordinary shares trade on the TASE, and our ADSs and public warrants trade on NASDAQ. Trading on these markets take place in different currencies (U.S. dollars on NASDAQ and New Israeli Shekels, or NIS, on the TASE), and at different times (resulting from different time zones, different trading days and different public holidays in the U.S. and Israel). The trading prices of our securities on these two markets may differ due to these and other factors. Any decrease in the price of our securities on one of these markets could cause a decrease in the trading price of our securities on the other market.

Our ADSs and warrants have little prior trading history in the U.S., and an active market may not develop or be sustained, which may limit the ability of our investors to sell our ADSs and warrants in the U.S.

Although our ADSs and public warrants have been traded on NASDAQ since November 20, 2015, an active trading market for our ADSs or warrants may never develop or may not be sustained if one develops. If an active market for our ADSs or warrants does not develop, it may be difficult for an investor to sell its ADSs or warrants.

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

The trading market for our ADSs and public warrants will rely in part on the research and reports that equity research analysts publish about us and our business. The price of our ADSs or public warrants could decline if such research or reports are not published or if one or more securities analysts downgrade our ADSs or public warrants or if those analysts issue other unfavorable commentary or cease publishing reports about us or our business.

We have broad discretion as to the use of the net proceeds from our November 2015 initial public offering in the U.S. and may not use them effectively.

We currently intend to use the net proceeds from our November 2015 initial public offering on NASDAQ (Offering) to expand our clinical development program, specifically with respect to our Phase III clinical trial for our leading therapeutic candidate, KIT-302, finance the CMC activities required for submitting a New Drug Application to the FDA, perform the final PK (pharmacokinetic) trial for the selected formulation of KIT-302, finance our business development activities to enable out-licensing of our leading therapeutic candidate, KIT-302, repay outstanding August Loans; expand our clinical development pipeline for additional drug products; and for general corporate purposes, including working capital requirements. For more information, see "Item 14 Material Modifications to the Rights of Security Holders and Use of Proceeds – E. Use of Proceeds." However, our management will have broad discretion in the application of the net proceeds from the Offering. Our shareholders may not agree with the manner in which our management chooses to allocate the net proceeds from the Offering. The failure by our management to apply these funds effectively could have a material adverse effect on our business, financial condition and results of operation. Pending their use, we may invest the net proceeds from the Offering in a manner that does not produce income.

We will incur increased costs as a result of operating as a public company in the U.S, and our management will be required to devote substantial time to new compliance initiatives.

Our ADSs and public warrants have been traded on NASDAQ since November 20, 2015. As a public company whose securities are listed in the United States, we incur accounting, legal and other expenses that we did not incur as a public company listed on the TASE, including costs associated with our reporting requirements under the Exchange Act. We also anticipate that we will incur costs associated with corporate governance requirements, including requirements under Section 404 and other provisions of the Sarbanes-Oxley Act, as well as rules implemented by the SEC and NASDAQ, and provisions of Israeli corporate law applicable to public companies. We expect that these rules and regulations will increase our legal and financial compliance costs, introduce new costs such as investor relations and stock exchange listing fees, and will make some activities more time-consuming and costly. We are currently evaluating and monitoring developments with respect to these rules, and we cannot predict or estimate the amount of additional costs we may incur or the timing of such costs.

As an "emerging growth company," as defined in the Jumpstart Our Business Startups Act, or JOBS Act, we may take advantage of certain temporary exemptions from various reporting requirements, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes Oxley Act (and the rules and regulations of the SEC thereunder). When these exemptions cease to apply, we expect to incur additional expenses and devote increased management effort toward ensuring compliance with them. We cannot predict or estimate the amount of additional costs we may incur as a result of becoming a public company or the timing of such costs.

Pursuant to Section 404 of the Sarbanes-Oxley Act and the related rules adopted by the SEC and the Public Company Accounting Oversight Board, starting with the second annual report that we file with the SEC after the closing of our initial U.S. offering in November 2015, our management will be required to report on the effectiveness of our internal control over financial reporting. In addition, once we no longer qualify as an "emerging growth company" under the JOBS Act and lose the ability to rely on the exemptions related thereto discussed above and depending on our status as per Rule 12b-2 of the Exchange Act, our independent registered public accounting firm may also need to attest to the effectiveness of our internal control over financial reporting under Section 404. We have only very recently commenced the process of determining whether our existing internal controls over financial reporting systems are compliant with Section 404 and whether there are any material weaknesses or significant deficiencies in our existing internal controls. This process will require the investment of substantial time and resources, including by our chief financial officer and other members of our senior management. As a result, this process may divert internal resources and take a significant amount of time and effort to complete. In addition, we cannot predict the outcome of this determination and whether we will need to implement remedial actions in order to implement effective controls over financial reporting. The determination and any remedial actions required could result in us incurring additional costs that we did not anticipate, including the hiring of outside consultants. Irrespective of compliance with Section 404, any failure of our internal controls could have a material adverse effect on our stated results of operations and harm our reputation. As a result, we may experience higher than anticipated operating expenses, as well as higher independent auditor fees during and after the implementation of these changes. If we are unable to implement any of the required changes to our internal control over financial reporting effectively or efficiently or are required to do so earlier than anticipated, it could adversely affect our operations, financial reporting and/or results of operations and could result in an adverse opinion on internal controls from our independent auditors and cause the market price of our ordinary shares ADSs and warrants to decline.

Changes in the laws and regulations affecting public companies will result in increased costs to us as we respond to their requirements. These laws and regulations could make it more difficult or more costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers. We cannot predict or estimate the amount or timing of additional costs we may incur in order to comply with such requirements.

We are an "emerging growth company" and the reduced disclosure requirements applicable to emerging growth companies may make our ordinary shares less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act, and we may take advantage of certain exemptions from various requirements that are applicable to other public companies that are not "emerging growth companies." Most of such requirements relate to disclosures that we would only be required to make if we also ceased to be a foreign private issuer in the future, for example, the requirement to hold stockholder advisory votes on executive and severance compensation and executive compensation disclosure requirements for U.S. companies. However, as a foreign private issuer, we would still be required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act. We are exempt from such requirement for as long as we remain an emerging growth company, which may be up to five fiscal years after the date of this offering. We will remain an emerging growth company until the earliest of: (a) the last day of our fiscal year during which we have total annual gross revenues of at least $1.0 billion; (b) the last day of our fiscal year following the fifth anniversary of the closing of our initial U.S. offering; (c) the date on which we have, during the previous three-year period, issued more than $1.0 billion in non-convertible debt; or (d) the date on which we are deemed to be a "large accelerated filer" under the Exchange Act. When we are no longer deemed to be an emerging growth company, we will not be entitled to the exemptions provided in the JOBS Act discussed above. We cannot predict if investors will find our ordinary shares, ADSs, or warrants less attractive as a result of our reliance on exemptions under the JOBS Act. If some investors find our ordinary shares, ADS, or warrants less attractive as a result, there may be a less active trading market for our ordinary shares, ADS, and warrants and our share price may be more volatile.

ITEM 4. INFORMATION ON THE COMPANY

A. History and Development of the Company

Kitov Holdings was incorporated under the laws of the State of Israel (under a previous name) on August 12, 1968 and its ordinary shares were originally listed for trading on the TASE in 1978. Our ordinary shares are currently traded on the TASE under the symbol “KTOV”, and our ADSs and our public warrants are traded on NASDAQ under the symbols "KTOV" and "KTOVW", respectively.

In October 2012, the District Court in Lod approved the creditors arrangement in accordance with Section 350 of the Companies Law in order to effectuate the sale by Kitov Holdings (then known as Mainrom Line Logistics Ltd.) of all its activities, assets, rights, obligations and liabilities to a private company held by its then controlling shareholders, and all rights of Kitov Holdings’ creditors against it were extinguished. The sale was made pursuant to an arrangement between Kitov Holdings and its creditors. Following such sale and a related cash distribution to Kitov Holdings’ shareholders, Kitov Holdings remained without any assets, debt and/or liabilities. As described in the District Court approval, in connection with the sale, on October 31, 2012, the former controlling shareholders sold control of Kitov Holdings (then a shell company) to Mr. Sheer Roichman. From the completion of these transactions until the completion of the acquisition of Kitov Pharmaceuticals described below, Kitov Holdings did not conduct any business activities and was a public shell company listed on the TASE with no assets, debt and/or liabilities.

We operate through our wholly owned Israeli subsidiary, Kitov Pharmaceuticals Ltd., in the research and development of combinations of existing drugs in advanced stages of development. Kitov Pharmaceuticals Ltd. was founded in June 2010, and pursuant to an Asset Purchase Agreement, dated October 13, 2010, between Kitov Pharmaceuticals and JPW PCH LLC, or JPW, JPW sold to Kitov Pharmaceuticals JPW’s rights and interests in and to U.S. and international patent applications relating to KIT-301 and KIT-302. Kitov Pharmaceuticals assumed all liabilities arising from ownership, use or exercise, of rights under, the patent applications.

On July 11, 2013, we acquired Kitov Pharmaceuticals Ltd. As part of the acquisition, Mainrom Line Logistics Ltd. changed its name to Kitov Pharmaceuticals Holdings Ltd. For more information regarding this transaction, see "Item 7. Major Shareholders and Related Party Transactions – B. Related Party Transactions – Share Transfer Agreement with Kitov Pharmaceuticals".

We had no material capital expenditures for the years ended December 31, 2015, 2014, and 2013.

Recent Developments

On November 25, 2015 we completed the closing of an underwritten public offering of 3,158,900 American Depository Shares (ADSs), each representing 20 of our ordinary shares, and warrants to purchase up to 3,158,900 ADSs. The ADSs and warrants were issued in a fixed combination of one ADS and one warrant to purchase one ADS for a combined price to the public of $4.13. In addition, the underwriters partially exercised their option to purchase an additional 220,074 warrants to purchase 220,074 ADSs. The warrants have a per ADS exercise price of $4.13, are exercisable immediately, and will have a term of five years from the date of issuance. The gross proceeds to us from this offering were approximately $13 million, prior to deducting underwriting discounts, commissions and other offering expenses. Since November 20, 2015, our ADSs and warrants have been traded on NASDAQ under the symbols “KTOV” and "KTOVW", respectively.

On December 15, 2015, we announced that the Phase III, double-blind, placebo-controlled clinical trial for our leading drug candidate, KIT-302, successfully met the primary efficacy endpoint of the trial protocol as approved by the FDA. Data from the trial further revealed that KIT-302 tended to reduce blood pressure more than the widely used hypertension drug amlodipine besylate when administered alone. We plan to file our NDA for marketing approval of KIT-302 with the FDA in the second half of 2016.

A combination drug, KIT-302, simultaneously treats pain caused by osteoarthritis and treats hypertension, which is a common side effect of stand-alone drugs that treat osteoarthritis pain. KIT-302 is comprised of two FDA approved drugs, celecoxib (Celebrex®) for the treatment of pain caused by osteoarthritis and amlodipine besylate, a drug designed to treat hypertension.

The trial protocol, approved by the FDA through the SPA process, was designed to quantify the decrease of hypertension in patients receiving KIT-302. The trial was performed in the U.K. in four groups of twenty-six (26) to forty-nine (49) patients, with a total of 152 patients. Each patient was treated over a total period of two weeks. Group One was treated with KIT-302, comprised of celecoxib and amlodipine besylate. Group Two was treated with amlodipine besylate only, one of the components of KIT-302. Group Three was treated with celecoxib only, the other component of KIT-302. Group Four was treated with a double placebo. The trial began in June 2014 and was completed in November 2015.

The primary efficacy end-point of the trial was to show that a combination of the two components of KIT-302, as demonstrated in Group One, lowers daytime systolic blood pressure by at least 50% of the reduction in blood pressure achieved in patients in Group Two, who were treated with amlodipine besylate only.

The trial results demonstrated that the number of 152 patients treated was found to be adequate to provide statistical validity and therefore, the results were final. These final results showed that in patients treated with amlodipine besylate only, there was a mean reduction in daytime systolic blood pressure of 8.8 mm Hg. In patients treated with KIT-302, there was a mean reduction in daytime systolic blood pressure of 10.6 mm Hg. Therefore, the primary efficacy endpoint of the study has been successfully achieved with a p value of 0.001.

B. Business Overview

We are a biopharmaceutical company focused on the development of therapeutic candidates for the simultaneous treatment of two clinical conditions:

- pain caused by osteoarthritis; and
- hypertension (high blood pressure), which can be pre-existing or caused by the treatment for osteoarthritis.

In particular, we focus on developing combinations of existing drugs in advanced stages of development. We currently have two combinations in our pipeline, KIT-301, based on the generic drugs naproxen and isradipine, and KIT-302, based on the generic drugs celecoxib and amlodipine besylate. Both naproxen and celecoxib are active ingredients of known and approved-for-use drugs designed primarily to relieve pain caused by osteoarthritis. Celecoxib is the active ingredient in the branded drug “Celebrex®”. These combinations are designed to simultaneously relieve pain caused by osteoarthritis and treat hypertension, which is one of the side effects of using non-steroidal anti-inflammatory drugs, or NSAIDs, for treating pain caused by osteoarthritis.

We are currently focusing on our development efforts for KIT-302, which has recently completed its Phase III clinical study. We are currently not developing KIT-301, for which we have an active IND, due to our need to allocate resources for advancing the development of KIT-302. Depending on market acceptance of KIT-302 if approved, we will consider whether to continue the further development of KIT-301.

Where applicable, we intend to seek FDA approval for the commercialization of our therapeutic candidates through the Section 505(b)(2) regulatory path under the Federal Food, Drug, and Cosmetic Act of 1938, as amended, and in corresponding regulatory paths in other foreign jurisdictions. Our current pipeline consists of two clinical development therapeutic candidates, KIT-301, which has been cleared for Phase III clinical trials and KIT-302, which has recently completed its Phase III clinical trial, both of which will be subject to review and approval by the FDA. Upon and subject to receipt of the requisite approvals, we intend to commercialize our therapeutic candidates through licensing and other commercialization arrangements with pharmaceutical companies on a global and/or territorial basis. We may also evaluate, on a case by case basis, co-development and similar arrangements, as well as independent commercialization of our therapeutic candidates.

Our competitive strengths

We believe there are several advantages to the therapeutic candidates we are developing, such as:

- providing a solution to the concerns of physicians who avoid prescribing an NSAID treatment for pain caused by osteoarthritis due to its cardiovascular side effects;
- reassuring physicians who are concerned that their patients who are treated for osteoarthritis will also be treated for hypertension, which is a known side effect of NSAID treatments for pain caused by osteoarthritis. This is a particular concern, as hypertension is usually not accompanied by tangible symptoms, and therefore patients may not be aware of their condition or the need to treat it;
- using one drug that also includes an active ingredient that treats hypertension either as an existing condition or as a side effect of using other drugs, ensures that the patient receives the suitable treatment for their disease and for its side effect;
- purchasing one drug as opposed to purchasing two separate drugs may lead to financial savings for patients in the U.S. by requiring payment of just one co-payment and prescription fee as opposed to a double co-payment and prescription fee. In addition, the use of one combination drug reduces the patient's discretion with respect to whether to purchase and use only one of the drugs and provides a comprehensive dual medical treatment in one combined drug; and
- using calcium channel blockers in our therapeutic candidates as an antihypertensive. Calcium channel blockers are not included in the FDA Safety Information Release for NSAIDs co-administered with angiotensin converting enzyme, inhibitors, or ACE inhibitors, or with angiotensin II receptor antagonists.

In addition to the aforementioned medical and economic advantages, we believe the combination drugs that we have developed have several commercial advantages, such as reduced development time compared to the development time of new chemical entities (NCEs) and decreased risk factors in the development process. These commercial advantages derive from the fact that combination drugs are based on known materials already approved for use by the FDA. The FDA offers a shortened regulatory procedure referred to as a "505(b)(2) NDA" to approve combination drugs. This procedure may be used to file a request to approve a product that relies on the results of the safety and effectiveness trials performed for the components of the combination in the past by others and not by the filers of the request for approval. Accordingly, the approval process in a 505(b)(2) NDA is shorter and less expensive compared to the approval process for NCEs. In addition, the use of known, proven and safe components recognized by physicians and medical organizations, and the enhanced medical effect of concurrently treating and preventing hypertension, may shorten the time and decrease the costs usually required for the acceptance of the new product in the drug marketplace.

Our strategy

Our goal is to become a significant player in the development of innovative chemical drugs with a clinical and commercial added value.

Key elements of our strategy are to:

- develop our therapeutic candidates with clinical and commercial advantages in the treatment of hypertension and pain caused by osteoarthritis, based on a combination of existing drugs and obtain approval thereof from the FDA and other foreign regulatory authorities;
- expand our line of therapeutic candidates through the acquisition or in-licensing of technologies, products and drugs intended to meet clinical needs, thereby utilizing the skills, knowledge and experience of our personnel to develop and enhance the value of additional products, and bring them to market efficiently;

- capitalize on the FDA's 505(b)(2) regulatory pathway to obtain more timely and efficient approval of our formulations of previously approved products, when applicable;

- cooperate with third parties to both develop and commercialize therapeutic candidates in order to share costs and leverage the expertise of others; and

- enter into sub-license agreements with international companies for potential or future therapeutic candidates based on potential upfront and milestone payments, royalties and/or other marketing arrangements, depending on product and market conditions.

Our two current clinical stage therapeutic candidates, "KIT-301" and "KIT-302," are described below.

Background on Osteoarthritis and Hypertension

Numerous factors influence the drug market, including the aging of the general population. As life expectancy increases, we expect that demand will increase for innovative drugs that treat diseases related to the elderly, such as osteoarthritis and hypertension.

Osteoarthritis

Arthritis means joint inflammation. The term is used to describe the pain, stiffness and/or swelling in the joints of the body where one or more bones are joined by ligaments. A normal joint provides a smooth surface enabling adjacent bones to move and glide on each other during normal motion. In contrast, an arthritic joint is one that may have varying degrees of inflammation and possibly destruction of the joint cartilage. These destructive changes preclude normal motion and cause pain.

The most common type of arthritis is called osteoarthritis and is more common with advancing age. People with osteoarthritis usually have joint pain and a decreased range of joint movement. Unlike some other forms of arthritis, osteoarthritis affects only the joints. This condition is also sometimes called degenerative joint disease. Osteoarthritis primarily affects the joint cartilage. Healthy cartilage allows bones to glide over one another and absorbs energy from the shock of physical movement. However, with osteoarthritis, the surface layer of cartilage breaks down and wears away. This allows the bony surface of the different bones under the cartilage to rub together, causing, pain, swelling, and loss of motion of the joint. Over time, affected joints may lose their normal shape. Also, bone spurs, small growths called osteophytes, may grow on the edges of the joint further impairing joint function. Thus, bits of bone or cartilage can break off and float inside the joint space, causing more pain and possible damage.

Osteoarthritis in the younger population is usually caused by traumatic injuries to the joints. In contrast, in the older population it is a more of a chronic degenerative disease process. The main symptom of osteoarthritis is pain that appears gradually, worsens with exertion, and is transiently relieved by rest.

The pain caused by osteoarthritis is described by patients as a deep pain or a burning sensation related to the joint tissues of the affected area. Osteoarthritis mainly affects the cartilage and disrupts the structural balance in the cartilage of the joint, causing the cartilage cells to increase production of new raw materials required to create cartilage, but concurrently produce enzymes that digest the cartilage.

Osteoarthritis is one of the most common diseases worldwide causing physical disability in adults. According to data published in the Center for Disease Control (CDC) website, an estimated 26.9 million U.S. adults in 2005 were diagnosed with osteoarthritis, of which approximately 50% suffer from hypertension. Among individuals in the U.S., it is estimated that over 40% will eventually suffer from osteoarthritis in at least one joint (Zhang Y., 2010 Clinics in Geriatric Medicine).

The pharmaceuticals used for treating osteoarthritis include a range of drugs. The particular choice of treatment is made according to the disease severity. These can range from acetaminophen for cases of milder severity, to Voltaren®, naproxen, and Celebrex® for moderate severity, up to treatment with narcotics for the most severe cases.

Various non pharmacological treatments are intended to relieve the pain caused by the disease and to preserve and improve joint function. Among these treatments are changes in the patient's life style, namely diet, physiotherapy and exercise. The objectives of these treatments are to strengthen the muscles adjacent to the joints and increase their ranges, thereby reducing body weight, and decreasing the loads on the weight carrying joints to subsequently reduce the intensity of the pain.

In some cases, the conservative non pharmacological treatments are not sufficiently helpful. In such cases, patients typically request medical treatment. According to data published on the website of the Mayo Clinic in April 2013, the most common medical treatments are the use of analgesics, such as NSAIDs, which include enzyme inhibitors, such as COX-2. NSAIDs treat inflammation by inhibiting enzymes responsible for the development of inflammation and subsequent pain. COX-2 enzyme inhibitors are non-steroidal drugs that treat inflammation by directly inhibiting COX-2, an enzyme responsible for the development of inflammation and subsequent pain but do not target the COX-1 enzyme. Targeting selectivity for COX-2 reduces the risk of peptic ulceration, and is the main advantage of celecoxib, rofecoxib and other members of this drug class over non COX-2 selective NSAIDs.

After several COX-2 inhibiting drugs were approved for marketing, data from clinical trials revealed that COX-2 inhibitors caused a significant increase in heart attacks and strokes, with some drugs in the class possibly having worse risks than others. See "Business - Our Therapeutic Candidates – Competitive Treatments for Pain Caused by Osteoarthritis".

A typical osteoarthritis treatment plan with these analgesics is as follows: (i) initial treatment of minor osteoarthritis will begin with use of drugs such as acetaminophen; (ii) in the event that acetaminophen treatment is not effective, the physician will proceed to treatments using NSAIDs, which will begin using drugs such as Ibuprofen followed by naproxen and/or other NSAIDs (more than 20 types of drugs, including COX-2 enzyme inhibitors); (iii) in cases where treatment with these drugs is ineffective, the treatment will be direct injection of steroids into the affected joint; (iv) in cases where steroid injection is ineffective, treatment by injecting hyaluronic acid (HA) into the affected joint will be considered; and (v) in the event that all the aforementioned treatments fail, the patient may consider surgical replacement of the affected joint.

As noted above, NSAIDs, both over-the-counter and prescription, are commonly taken to manage the pain of backache, osteoarthritis, rheumatoid arthritis, headache and other painful conditions. In 2012, approximately 100 million prescriptions were dispensed for oral anti-arthritis NSAIDs for the management of pain.

NICOX, a pharmaceutical company, has attempted to develop NAPROXCINOD ®, an NCE, naproxen-based drug intended to treat pain and to act as an anti-hypertensive. From 2005 to 2010, NICOX completed three Phase III clinical trials following a significant investment. However, the results of the trials did not meet the FDA's requirements. Therefore, in May 2010, an outside advisory committee to the FDA recommended against approving the drug. As a result of this recommendation, and its own internal review, the FDA rejected the request for NDA approval. According to an announcement by NICOX in April 2012, pursuant to an appeal filed by NICOX in July 2011, a meeting was held in April 2012 between representatives of NICOX and the FDA, in which NICOX was informed that in order to gain approval of its drug, it must file a new NDA, that would include results from additional clinical trials, for the purpose of approving a specific dosage of the drug.

On July 9, 2015 the FDA published a safety announcement requiring labels for prescription NSAIDs to indicate that the risk of heart attack or stroke can occur as early as the first weeks of using an NSAID and that the risk may increase with longer use of the NSAID. In effect, the current labeling, in effect since 2005, will be strengthened as a result of a review by the FDA of a variety of new safety information on prescription and over-the-counter NSAIDs, including observational studies, a large combined analysis of clinical trials, and other scientific publications. These studies were discussed at a joint meeting of the Arthritis Advisory Committee and Drug Safety and Risk Management Advisory Committee held in February 2014.

Hypertension (High Blood Pressure)

Hypertension is the most common chronic disease in the western world, affecting approximately thirty percent (30%) of the U.S. adult population, according to an article in Morbidity and Mortality Weekly Report (Gillespie CD et al 2013). Untreated, hypertension can cause significant morbidity and mortality.

According to its physiological definition, "hypertension" is an excessive pressure applied by the blood on the walls of the blood vessels. The term hypertension refers to excessive arterial blood pressure, which is the pressure in the arteries that propels blood to body organs.

The blood pressure is created as a result of the contraction of the cardiac muscle propelling blood into the arteries, which possess a limited capacity to store the blood. Blood pressure is measured in units of mercury (Hg) millimeters (mm Hg). Diagnosing hypertension in adults requires at least two measures on two different occasions. There are two blood pressure values:

- Systolic pressure is the peak pressure in the arteries measured in the cardiac cycle, during the contraction of the heart (systole); and
- Diastolic pressure is the lowest pressure point in the arteries measured when the heart's left ventricle is relaxing and there is no contraction of the heart (diastole).

In the past, hypertension was generally defined as a systolic blood pressure of greater than 140 mm Hg or a diastolic blood pressure of greater than 90 mm Hg. However, as discussed below, a recently halted NIH study may result in these designated values being set lower.

The cause of hypertension in 95% of patients is unknown, and in these cases hypertension is defined as "essential hypertension". However, some studies postulate that genetic factors and environmental factors are involved in the initial development of hypertension. These factors include high salt consumption, obesity, excessive alcohol consumption, and probably mental and behavioral factors, which may be caused by various circumstances, including working in certain professions. Extreme hypertension may lead to functional disorders, and worsening health, while the affected person does not necessarily feel it and/or is aware of it. Therefore, hypertension is often referred to as the "silent killer".

The danger of hypertension is continuing damage to blood vessels in critical areas of the body, such as blood vessels in the heart, kidneys, eyes, and to the nerve tissue in the brain where any damage may cause a stroke. Moreover, damage to the blood vessels may cause blockage due to arteriosclerosis and lead to the tearing of the vessels. These complications may cause various diseases and even death.

Hypertension treatment methods focus on reducing the patient's blood pressure to normal values, thereby preventing the occurrence of complications in the long term. Even a small increase in blood pressure may cause significant cardiovascular problems. For example, it has been shown that any increase in blood pressure above a systolic value of 115 mm Hg is associated with an increased risk of suffering a cardiovascular death (Prospective Studies Collaboration, The Lancet 2002). This finding has been repeatedly replicated and it is now established that there is no safe level of blood pressure increase above of the "normotensive baseline value" of approximately 120 systolic and 70 diastolic. The documentation of a danger of any increase in blood pressure above a value of 120/70 was recently documented in September of 2015 in a large NIH sponsored clinical trial (http://www.nhlbi.nih.gov/news/press-releases/2015/landmark-nih-study-shows-intensive-blood-pressuremanagement-may-save-lives.) which enrolled over 9000 patients age 50 and older. This study also documented that patients age 50 and older with systolic blood pressures greater than 120 had a greater rate of adverse cardiovascular events than did those whose systolic blood pressure was treated to levels below 120.

It has been recognized for many decades that hypertension requires treatment. This fact has been recently re-emphasized by a paper that reviewed 147 prior randomized studies of antihypertensive treatments. This meta-analysis study (Law MR et al, BMJ 2009), concluded that the majority of the adult population with hypertension can be expected to benefit considerably from using anti-hypertension drugs.

Hypertension can be treated with many different classes of medications. These include diuretics, beta blockers, alpha blockers, calcium channel blockers, ACE inhibitors, angiotensin receptor antagonists and vasodilators. In general, these medications work by either relaxing blood vessels and thereby lowering the pressure in arteries, or by assisting the body in removing fluid and thereby decreasing the pressure inside of arteries.

Although drugs from each of the various classes of antihypertension medications are able to reduce blood pressure, there are marked differences in their side effects profiles. For example, the diuretics can result in kidney problems, while the beta blockers can slow the heart rate. It is therefore important for physicians carefully to select which antihypertension medications to prescribe for patients based upon the patient's other medical problems, including what concomitant medications they are receiving.

Blood pressure can undergo significant alterations when subjects are placed on various medications. For example, according to a May 2010 FDA Joint Meeting of the Arthritis Advisory Committee and the Drug Safety and Risk Management Advisory Committee report published by the FDA, an increase of about 3.5 mm Hg was diagnosed following the use of naproxen, while the use of Celebrex causes an increase of about 2.5 mm Hg. In addition, in August 2011 the FDA issued a Safety Information release stating that co-administration of NSAIDs, including selective COX-2 inhibitors, with ACE inhibitors or with angiotensin II receptor antagonists, may result in deterioration of renal function, including possible acute renal failure, and that the antihypertensive effect of ACE inhibitors may be attenuated by NSAIDs. No such Safety Information release was issued with regard to calcium channel blockers, which is the anti-hypertensive used in our therapeutic candidates.

Background on Combination Products

Numerous companies worldwide have developed in recent years successful combination products comprised of a combination of two or more drugs to treat various medical conditions, where the safety and effectiveness of each of the drugs was proven separately.

Combination products manufactured and sold which are similar to our therapeutic candidates, include:

- Vimovo®, which was developed by Pozen Inc. and was approved by the FDA in May 2010. Vimovo® is a combination of naproxen and esomeprazole magnesium, marketed by AstraZeneca PLC worldwide (except in the U.S.) and by Horizon Pharma in the U.S., and is designed for treating both pain and preventing gastric ulcer. Vimovo's® net sales in the U.S. reached $163 million in 2014, compared to net sales of $20 million in 2013.

- Caduet®, a combination of Lipitor® and amlodipine, was originally developed and manufactured by Pfizer and is designated for treating both cholesterol and hypertension, with approximate sales of $180 million in 2014.

- Janumet®, a combination of metformin and sitagliptin, manufactured by Merck & Co. Inc. and designated to treat diabetes, with approximate sales of $2,071 million in 2014.

Combination drugs may provide improved medical treatment of patients diagnosed as suffering from two or more different diseases and also may provide convenience to patients by using a single drug instead of multiple drugs. In addition, combination drugs have significant commercial advantages deriving from maintaining and even increasing the market share of the active ingredients after their patents expire by extending the life span of the patents for the active ingredients through the use of combination drugs.

Our Therapeutic Candidates

Studies estimate that approximately 13.5 million patients in the U.S. alone may suffer concurrently from hypertension and chronic osteoarthritis pain in the joints, according to data published by the CDC. We are developing two combinations, KIT-301 based on the generic drugs naproxen and isradipine, and KIT-302 based on the generic drugs celecoxib and amlodipine besylate. Both naproxen and celecoxib are active ingredients of known and approved-for-use drugs designed primarily to relieve pain caused by osteoarthritis. Celecoxib is the active ingredient in the branded drug "Celebrex®". Our combinations are designed to simultaneously relieve pain caused by osteoarthritis and treat hypertension, which is one of the side effects of using NSAIDs for treating pain caused by osteoarthritis. Our strategy in developing our therapeutic candidates is based on our belief that the added anti-hypertensive drug will decrease the side effect of increased hypertension typically caused by the use of NSAIDs alone.

To date, no combination drug exists that offers the combined treatment of pain caused by osteoarthritis and hypertension. We therefore believe that KIT-301 and KIT-302 potentially hold significant advantages over the currently available drugs in the market, due to the fact that the drug treatment of osteoarthritis together with hypertension eases the burden of the treatment process for patients by providing the ability to use one drug instead of multiple drugs concurrently, thereby increasing the patients' ease of compliance with the required treatment. KIT-301 does not include a treatment for gastrointestinal problems caused by the use of naproxen, the generic drug that is one of the components of KIT-301. In contrast, KIT-302 uses celecoxib, an NSAID that does not produce the extent of gastrointestinal side effects seen with other NSAIDs. For professional considerations and in order to manage our financial and human resources, we intend to advance the development of KIT-302 first, and only then consider the further development of KIT-301.

KIT-301

KIT-301 is a fixed dosage combination product based on two known and approved-for-use active ingredients (naproxen and isradipine), the combination of which we believe enables effective concurrent treatment of hypertension and pain caused by osteoarthritis. We are currently not developing KIT-301, for which we have an active IND, due to our need to allocate resources for advancing the development of KIT-302. Depending on market acceptance of KIT-302 if approved, we will consider whether to continue the further development of KIT-301.

KIT-302

Similar to KIT-301, KIT-302 is a fixed dosage combination product based on two known active ingredients (celecoxib and amlodipine besylate), the effectiveness and safety of which has been separately proven for each, and which is intended to enable the concurrent treatment of pain caused by osteoarthritis and hypertension.

On November 7, 2013, we filed with the FDA the final statistical plan for the Phase III clinical trial protocol for KIT-302 as part of the SPA procedures. On February 20, 2014, the FDA replied and indicated that the proposed data analysis of the trial's results that we submitted to the FDA provides a suitable solution to achieve the primary endpoint of the Phase III clinical trial and to support the final request for approval, which will be submitted. As a result of the SPA process, the FDA approved the Phase III trial design for our clinical trial, and cleared our clinical trial to begin, and on June 18, 2014, we commenced the clinical trial, as described below. The clinical trial was performed using the Adaptive Trial Design method, or ATD, in accordance with the SPA. Based on the ATD format, in the first stage of the trial 150 patients were to be recruited. Then, the results of the trial were to be disclosed to an independent external data monitoring committee, which was then to analyze the results and determine the number of additional patients that we might have needed to recruit in order to demonstrate statistical validity and to meet the primary end point of the trial.

The interim analysis has been completed and documented such that no further patients needed to be enrolled. The final analysis of the data was then undertaken and it determined that KIT-302 had met its FDA approved primary efficacy endpoint.

Below is a summary of our projected timeline for the development of KIT-302:

Current Status	2016	2017
FDA Approved SPA. Phase III clinical trial completed	Final conclusive PK study, completion of CMC including stability testing. Submission of NDA to the FDA. Continuation of our business development activity with regard to KIT-302.	Anticipated FDA approval for marketing

KIT-302 is based on two generic drugs (amlodipine besylate and celecoxib). Until December 2015 celecoxib was protected by patents held by Pfizer Inc. (Celebrex®). The YSPTO granted Pfizer a "reissue patent" covering methods of treating osteoarthritis and other approved conditions with celecoxib, the active ingredient in Celebrex®. The reissued patent extended U.S. patent protection for Celebrex® from May 30, 2014 to Dec. 2, 2015.

We currently expect to receive approval from the FDA to market KIT-302 in 2017. As a result of this timing and because KIT-302 combines the treatment of osteoarthritis by celecoxib with amlodipine besylate, which treats the side effect of hypertension, we believe that KIT-302 may be an attractive alternative to the newly marketed generic versions of Celebrex®.

Research and Development

Our strategy is to develop two drug combinations that are intended to treat hypertension and pain caused by osteoarthritis. These combinations are comprised of known and approved-for-use components, the combination of which is intended to simultaneously treat the pain caused by osteoarthritis and reduce blood pressure, thereby offsetting a side effect caused by the use of NSAIDs for osteoarthritis. Following discussions with the FDA, the FDA approved a development design in accordance with the 505(b)(2) NDA track. The FDA did not require us to perform pre-clinical trials (*i.e.*, animal studies), and therefore we are required only to conduct a single Phase III clinical trial and a single standard pharmacokinetic trial, or PK Trial, for each of our therapeutic candidates.

For the development of KIT-302, we performed a double blind, placebo controlled, Phase III clinical trial for testing the decrease of hypertension in patients receiving our KIT-302 therapeutic candidate. This trial was performed in the U.K. in four groups of twenty-six (26) to forty-nine (49) patients (a total of 152 patients), with each patient treated over a total period of two weeks. Group One was treated with the two components of KIT-302 (celecoxib and amlodipine besylate)., Group Two was treated with a standard drug available in the market for treating hypertension (amlodipine besylate, one of the components of KIT-302), Group Three was treated with celecoxib only, and Group Four received a double placebo The trial began in June 2014, and the final patient completed the study in November 2015.

The purpose of the trial was to show that a combination of the two components of KIT-302, as demonstrated in Group One, lowered blood pressure by at least 50% as compared to the reduction in blood pressure in patients in Group Two (treatment with amlodipine besylate only); however, we were not required to demonstrate or measure efficacy in treatment of pain caused by osteoarthritis. Group Three and Group Four were for control purposes and will not be considered in evaluating the primary endpoint. The trial was conducted with off-the-shelf drugs, while the combination drug was being developed in parallel by Dexcel Ltd., or Dexcel. The trial was being conducted with only one dosage of amlodipine besylate (10 mg), although we expect to seek marketing approval from the FDA for three dosages (10mg, 5 mg, and 2.5 mg), each combined with 200 mg of celecoxib. We announced the top line trial results in December 2015, showing that we successfully met the primary efficacy endpoint of the trial protocol as approved by the FDA. Data from the trial further revealed that KIT-302 tended to reduce blood pressure more than the widely used hypertension drug amlodipine besylate alone.

The trial results demonstrated that the number of 152 patients treated was adequate to provide statistical validity and therefore, the results were final. These final results showed that in patients treated with amlodipine besylate only, there was a mean reduction in daytime systolic blood pressure of 8.8 mm Hg. In patients treated with KIT-302, there was a mean reduction in daytime systolic blood pressure of 10.6 mm Hg. Therefore, the primary efficacy endpoint of the study has been successfully achieved with a p value of 0.001.

Additional data from the trial results showed the favorable blood pressure effects of KIT-302 were present in all blood pressure variables measured in the study. The data indicated that the blood pressure reduction synergy seen with combining celecoxib and amlodipine, is seen not only in the study's primary efficacy endpoint of daytime systolic blood pressure, but was also seen for daytime diastolic blood pressure measurements, and in all other blood pressure variables. After two weeks of treatment the reduction for daytime diastolic blood pressure measurements with amlodipine alone was 5.5 mm Hg, while for patients treated with KIT-302's components the reduction was 7.6 mm Hg. For nighttime systolic blood pressure after two weeks of treatment the reduction with amlodipine therapy alone was 6.3 mm Hg, while for patients treated with KIT-302's components the reduction was 10.7 mm Hg. For nighttime diastolic blood pressure after two weeks of treatment the reduction with amlodipine besylate alone was 3.1 mm Hg, while for patients treated with KIT-302's components the reduction was 7.2 mm Hg. Thus, the synergy in blood pressure reduction demonstrated with KIT-302's two components was present at all times of day and with both blood pressure measures. Although celecoxib when combined with amlodipine appears to have a synergistic effect and lowers blood pressure, it has the opposite effect when administered by itself. While not conclusive, we believe the medical community may take great interest in this study's findings and its implications for pain management and hypertension.

The final and complete analyses, including the clinical study report, are expected to be completed in May 2016. We plan to file our NDA for marketing approval of KIT-302 with the FDA in the second half of 2016.

In addition, in connection with our Development Services Agreement with Dexcel, pursuant to which Dexcel developed the formulation for KIT-302 and is performing the subsequent stability testing and manufacturing scale-up in quantities adequate for submission of an NDA to the FDA, Dexcel has performed a pilot clinical bioequivalence trial, or the Pilot PK Study. This Pilot PK Study was performed during April and May 2015, after completion of the formulation of two prototypes of KIT-302 to check the pharmacokinetics of the combination drug in order to show that the blood levels achieved with our combination are the same as those obtained with the individual components. On June 9, 2015, we obtained the successful results of the Pilot PK Study. "Item 4. Information on the Company – B. Business Overview – Development Services Agreement with Dexcel" below for more information.

The Phase III clinical trial for KIT-302 was conducted in medical centers in the United Kingdom on the basis of approvals received from the British Regulatory Authority (MHRA) and the U.K. ethics committees. It is not currently known whether the European regulatory authorities will require additional studies in order to grant their approval to market KIT-302 in Europe.

Given the results of the Phase III clinical trial for KIT-302, we are considering employing a similar development strategy for our second therapeutic candidate, KIT-301; however, we have not yet made a determination as to when we will start the development of KIT-301, if at all.

Competition and Market

The pharmaceutical market is characterized by large international pharmaceutical companies that develop a wide range of products, both generic and NCEs, which operate alongside smaller companies, such as ours, that develop a specific drug or a combination of drugs. Therefore, many small companies enter into agreements with such global companies during the drug development stage in order to continue the development or marketing of the drug, taking advantage of the financial, marketing and/or other resources available to such global companies. At the same time, the global companies tend to enter into agreements with smaller companies in order to save development time and resources. The global drug sector is a highly developed market with a turnover of hundreds of billions of U.S. dollars and intense competition. Most of the drugs we intend to develop have competing drugs, developed at the same time by other companies and organizations. We are therefore exposed to competition in our field of operation. Although we believe our therapeutic candidates have advantages which our competitors' products lack, there is a constant risk in the drug development field that a competing party will complete the development stages before we are able to develop our therapeutic candidates intended for the same disease. Moreover, a constant threat in our market is presented by new drugs that have already completed all the development stages and have already entered the market and are competing with the treatments and drugs previously available on the market. All of the therapeutic candidates that we are currently developing are intended for oral use.

Competitive Treatments for Pain Caused by Osteoarthritis

The competition for KIT-302 and KIT-301 is expected to come from the oral anti-arthritic market, or more specifically the traditional non-selective NSAIDs (such as naproxen and diclofenac), traditional NSAID/gastroprotective agent combination products or combination product packages (such as Vimovo®, Arthrotec®, Prevacid® and NapraPAC™) and the only COX-2 inhibitor in the U.S. market, Celebrex® (including generic versions of Celebrex® that we expect to be sold following expiration of the patent). Sales of Celebrex in the U.S alone amounted to $1.7 billion in 2014.

Due to the voluntary withdrawal of Vioxx® by Merck & Co. in September 2004, the FDA ordered the withdrawal of Bextra® by Pfizer and issued a Public Health Advisory in April 2005, requiring manufacturers of all prescription products containing NSAIDs to provide warnings regarding potential adverse cardiovascular events as well as life-threatening gastrointestinal events associated with the use of NSAIDs. Moreover, subsequent to an FDA advisory committee meeting in February 2005 that addressed the safety of NSAIDs, and, in particular, the cardiovascular risks of COX-2 selective NSAIDs, the FDA has indicated that long-term studies evaluating cardiovascular risk will be required to approve new NSAID products that may be used on an intermittent or chronic basis. We believe that KIT-302 has a competitive advantage over other drugs in the market because, as a COX-2 inhibitor, it has limited gastrointestinal side effects, and due to the addition of amlodipine besylate it is designed to address existing hypertension and the cardiovascular side effects of NSAIDs.

Intellectual Property

Patents, trademarks and licenses and market exclusivity

Our policy is to seek to protect our proprietary position by, among other methods, filing U.S. and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business. We also rely on our trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary position. We vigorously defend our intellectual property to preserve our rights and gain the benefit of our technological investments. Our business is not dependent, however, upon any single patent, trademark or contract. See “Item 3. Key Information – D. Risk Factors – Risks Related to Intellectual Property”.

We own two patent applications. If granted, the two patent applications would have a maximum term extending until 2029, in all jurisdictions where the cases are pending. The claimed subject matter in the two patent applications would include claims to new treatment methods using known compounds and new formulations and dosage types including unique combinations of known compounds. The following is a brief description of our patent applications:

- An application for a patent relating to a drug which addresses the users of anti-inflammatory drugs, pain relief drugs or fever reducing drugs of the NSAID type, in combination with anti-hypertension treatment, aiming to prevent or reduce the side effects related to the cardiovascular system. Patent applications related to this application were filed in the U.S., Australia, Japan, Canada and Europe in May 2009. Two provisional applications for the patent were filed with priority dates in 2008; and

- An application to approve a patent relating to a drug for treating hypertension or rapid pulse caused by a stimulating medical treatment (e.g., drugs against obesity or ADHD). The request for the patent includes a combination of a recognized and proven drug for treating hypertension caused by using drugs for treating ADHD, including stimulants (e.g., CNS stimulants), or from using the two drugs separately, to prevent increased hypertension or rapid pulse caused by using a stimulant. The patent application includes additional claims which are based on NSAID, which causes increased hypertension or rapid pulse. The patent application was filed in the U.S. in February 2011 as a continuation in part application of the first application with the same priority date.

In the branded pharmaceutical industry, the majority of a branded drug's commercial value is usually realized during the period in which the product has market exclusivity. In the U.S. and some other countries, when market exclusivity expires and generic versions of a product are approved and marketed, there can often be very substantial and rapid declines in the branded product's sales. The rate of this decline varies by country and by therapeutic category, and the number of generic competitor entrants to the market, among other factors; however, following patent expiration, branded products often continue to have market viability based upon the goodwill of the product name, which typically benefits from trademark protection.

A brand product's market exclusivity is generally determined by two forms of intellectual property: patent rights held by the brand company and any regulatory forms of exclusivity to which the NDA-holder is entitled.

Patents are a key determinant of market exclusivity for most branded pharmaceuticals. Patents provide the brand company with the right to exclude others from practicing an invention related to the medicine. Patents may cover, among other things, the active ingredient(s), various uses of a drug product, pharmaceutical formulations, drug delivery mechanisms and processes for (or intermediates useful in) the manufacture of products, and polymorphs. Protection for individual products extends for varying periods in accordance with the expiration dates of patents in the various countries. The protection afforded, which may also vary from country to country, depends upon the type of patent, its scope of coverage and the availability of meaningful legal remedies in the country.

Market exclusivity is also sometimes influenced by regulatory exclusivity rights. Many developed countries provide certain non-patent incentives for the development of medicines. For example, the U.S., the European Union and Japan each provide for a minimum period of time after the approval of a new drug during which the regulatory agency may not rely upon the data of the original party who developed the drug to approve a competitor's generic copy. Regulatory exclusivity rights are also available in certain markets as incentives for research on new indications, on orphan drugs and on medicines useful in treating pediatric patients. Regulatory exclusivity rights are independent of any patent rights and can be particularly important when a drug lacks broad patent protection. Most regulatory forms of exclusivity, however, do not prevent a competitor from gaining regulatory approval prior to the expiration of regulatory data exclusivity on the basis of the competitor's own safety and efficacy data on its drug, even when that drug is identical to that marketed by the innovator.

We estimate the likely market exclusivity period for each of our 505(b)(2) products on a case-by-case basis. It is not possible to predict the length of market exclusivity for any of our branded products with certainty because of the complex interaction between patent and regulatory forms of exclusivity, and inherent uncertainties concerning patent litigation. There can be no assurance that a particular product will enjoy market exclusivity for the full period of time that we currently estimate or that the exclusivity will be limited to the estimate.

Government Regulations and Funding

Pharmaceutical companies are subject to extensive regulation by foreign, federal, state and local agencies, such as the FDA in the U.S., the Ministry of Health in Israel, or the various European regulatory authorities. The manufacture, distribution, marketing and sale of pharmaceutical products are subject to government regulation in the U.S. and various foreign countries. Additionally, in the U.S., we must follow rules and regulations established by the FDA requiring the presentation of data indicating that our products are safe and efficacious and are manufactured in accordance with current good manufacturing practices (cGMP) regulations. If we do not comply with applicable requirements, we may be fined, the government may refuse to approve our marketing applications or allow us to manufacture or market our products, and we may be criminally prosecuted. We and our manufacturers and clinical research organizations may also be subject to regulations under other foreign, federal, state and local laws, including, but not limited to, the U.S. Occupational Safety and Health Act, the Resource Conservation and Recovery Act, the Clean Air Act and import, export and customs regulations as well as the laws and regulations of other countries. As a result, pharmaceutical companies must ensure their compliance with the Foreign Corrupt Practices Act and federal healthcare fraud and abuse laws, including the False Claims Act.

These regulatory requirements impact our operations and differ from one country to another, so that securing the applicable regulatory approvals of one country does not imply the approval of another country. The approval procedures involve high costs and are manpower intensive, usually extend over many years and require highly skilled and professional resources.

U.S. Food and Drug Administration Approval Process

The steps usually required to be taken before a new drug may be marketed in the U.S. generally include:

- completion of pre-clinical laboratory and animal testing;
- completion of required chemistry, manufacturing and controls testing;
- the submission to the FDA of an IND, the application for which must be evaluated and found acceptable by the FDA before human clinical trials may commence;
- performance of adequate and well-controlled human clinical trials to establish the safety, pharmacokinetics and efficacy of the proposed drug for its intended use;
- submission and approval of an NDA; and
- agreement with FDA of the language on the package insert.

Clinical studies are conducted under protocols detailing, among other things, the objectives of the study, what types of patients may enter the study, schedules of tests and procedures, drugs, dosages, and length of study, as well as the parameters to be used in monitoring safety, and the efficacy criteria to be evaluated. A protocol for each clinical study and any subsequent protocol amendments must be submitted to the FDA as part of the IND process.

In all the countries that are signatories of the Helsinki Declaration (including Israel), the prerequisite for conducting clinical trials (on human subjects) is securing the preliminary approval of the competent authorities of that country to conduct medical experiments on human subjects in compliance with the other principles established by the Helsinki Declaration.

The clinical testing of a drug product candidate generally is conducted in three sequential phases prior to approval, but the phases may overlap or be combined. A fourth, or post approval, phase may include additional clinical studies. The phases are generally as follows:

Phase I clinical trials are normally conducted in small groups of healthy volunteers to assess safety of various dosing regimens and pharmacokinetics. After a safe dose has been established, in Phase II clinical trials the drug is administered to small populations of sick patients to look for initial signs of efficacy in treating the targeted disease or condition and to continue to assess safety. In the case of vaccines, the participants are healthy and the signs of efficacy can be obtained in early Phase I, therefore this Phase is defined as Phase I/II. Phase III clinical trials are usually multi-center, double-blind controlled trials in hundreds or even thousands of subjects at various sites to assess as fully as possible both the safety and effectiveness of the drug.

Clinical trials must be conducted in accordance with the FDA's good clinical practices, or GCP, requirements. The FDA may order the temporary or permanent discontinuation of a clinical study at any time or impose other sanctions if it believes that the clinical study is not being conducted in accordance with FDA requirements or that the participants are being exposed to an unacceptable health risk. An institutional review board, or IRB, generally must approve the clinical trial design and patient informed consent at study sites that the IRB oversees and also may halt a study, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions. Additionally, some clinical studies are overseen by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board or committee. This group recommends whether or not a trial may move forward at designated check points based on access to certain data from the study. The clinical study sponsor may also suspend or terminate a clinical trial based on evolving business objectives and/or competitive climate.

As a drug product candidate moves through the clinical testing phases, manufacturing processes are further defined, refined, controlled and validated. The level of control and validation required by the FDA increases as clinical studies progress. We and the third-party manufacturers on which we rely for the manufacture of our therapeutic candidates and their respective components (including the API) are subject to requirements that drugs be manufactured, packaged and labeled in conformity with cGMP. To comply with cGMP requirements, manufacturers must continue to spend time, money and effort to meet requirements relating to personnel, facilities, equipment, production and process, labeling and packaging, quality control, recordkeeping and other requirements.

Assuming completion of all required testing in accordance with all applicable regulatory requirements, detailed information on the product candidate is submitted to the FDA in the form of an NDA, requesting approval to market the product for one or more indications, together with payment of a user fee, unless waived. An NDA includes all relevant data available from pertinent nonclinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information on the chemistry, manufacture, controls and proposed labeling, among other things. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the product candidate for its intended use to the satisfaction of the FDA.

If an NDA submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the Prescription Drug User Fee Act, or PDUFA, the FDA's goal is to complete its initial review and respond to the applicant within ten months of submission, unless the application relates to an unmet medical need, or is for a serious or life-threatening indication, in which case the goal may be within six months of NDA submission. However, PDUFA goal dates are not legal mandates and the FDA response often occurs several months beyond the original PDUFA goal date. Further, the review process and the target response date under PDUFA may be extended if the FDA requests or the NDA sponsor otherwise provides additional information or clarification regarding information already provided in the NDA. The NDA review process can, accordingly, be very lengthy. During its review of an NDA, the FDA may refer the application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it typically follows such recommendations. Data from clinical studies are not always conclusive and the FDA and/or any advisory committee it appoints may interpret data differently than the applicant.

After the FDA evaluates the NDA and inspects manufacturing facilities where the drug product and/or its API will be produced, it will either approve commercial marketing of the drug product candidate with prescribing information for specific indications or issue a complete response letter indicating that the application is not ready for approval and stating the conditions that must be met in order to secure approval of the NDA. If the complete response letter requires additional data and the applicant subsequently submits that data, the FDA nevertheless may ultimately decide that the NDA does not satisfy its criteria for approval. The FDA could also approve the NDA with a Risk Evaluation and Mitigation Strategies, or REMS, plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling, development of adequate controls and specifications, or a commitment to conduct post-marketing testing. Such post-marketing testing may include Phase IV clinical trials and surveillance to further assess and monitor the product's safety and efficacy after approval. Regulatory approval of drug product candidates for serious or life-threatening indications may require that participants in clinical studies be followed for long periods to determine the overall survival benefit of the drug product candidate.

If the FDA approves one of our therapeutic candidates, we will be required to comply with a number of post-approval regulatory requirements. We would be required to report, among other things, certain adverse reactions and production problems to the FDA, provide updated safety and efficacy information and comply with requirements concerning advertising and promotional labeling for any of our therapeutic candidates. Also, quality control and manufacturing procedures must continue to conform to cGMP after approval, and the FDA periodically inspects manufacturing facilities to assess compliance with cGMP, which imposes extensive procedural, substantive and record keeping requirements. If we seek to make certain changes to an approved product, such as certain manufacturing changes, we will need FDA review and approval before the change can be implemented. For example, if we change the manufacturer of a product or our API, the FDA may require stability or other data from the new manufacturer, and such data will take time and are costly to generate, and the delay associated with generating these data may cause interruptions in our ability to meet commercial demand, if any. While physicians may use products for indications that have not been approved by the FDA, we may not label or promote the product for an indication that has not been approved. Securing FDA approval for new indications is similar to the process for approval of the original indication and requires, among other things, submitting data from adequate and well-controlled studies that demonstrate the product's safety and efficacy in the new indication. Even if such studies are conducted, the FDA may not approve any change in a timely fashion, or at all.

Section 505(b)(2) New Drug Applications

We intend to submit applications for our initial therapeutic candidates via the 505(b)(2) regulatory pathway. As an alternate path for FDA approval of new indications or new formulations of previously-approved products, a company may file a Section 505(b)(2) NDA, instead of a "stand-alone" or "full" NDA. Section 505(b)(2) of the Food, Drug, and Cosmetic Act, or FDC, was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the Hatch-Waxman Amendments. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Some examples of products that may be allowed to follow a 505(b)(2) path to approval are drugs that have a new dosage form, strength, route of administration, formulation or indication.

The Hatch-Waxman Amendments permit the applicant to rely upon certain published nonclinical or clinical studies conducted for an approved product or the FDA's conclusions from prior review of such studies. The FDA may require companies to perform additional studies or measurements to support any changes from the approved product. The FDA may then approve the new product for all or some of the labeled indications for which the reference product has been approved, as well as for any new indication supported by the Section 505(b)(2) application. While references to nonclinical and clinical data not generated by the applicant or for which the applicant does not have a right of reference are allowed, all development, process, stability, qualification and validation data related to the manufacturing and quality of the new product must be included in an NDA submitted under Section 505(b)(2).

To the extent that the Section 505(b)(2) applicant is relying on the FDA's conclusions regarding studies conducted for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations*, or Orange Book. Specifically, the applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. The Section 505(b)(2) application also will not be approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the reference product has expired. Thus, the Section 505(b)(2) applicant may invest a significant amount of time and expense in the development of its products only to be subject to significant delay and patent litigation before its products may be commercialized.

Special Protocol Assessment

The special protocol assessment, or SPA, process is designed to facilitate the FDA's review and approval of drugs by allowing the FDA to evaluate the proposed design and size of Phase III clinical trials that are intended to form the primary basis for determining a drug product's efficacy. Upon specific request by a clinical trial sponsor, the FDA will evaluate the protocol and respond to a sponsor's questions regarding, among other things, primary efficacy endpoints, trial design and data analysis plans, within 45 days of receipt of the request.

The FDA ultimately assesses whether the protocol design and planned analysis of the trial are acceptable to support regulatory approval of the drug candidate with respect to effectiveness of the indication studied. All agreements and disagreements between the FDA and the sponsor regarding an SPA must be clearly documented in an SPA letter or the minutes of a meeting between the sponsor and the FDA.

Even if the FDA agrees to the design, execution and analyses proposed in protocols reviewed under the SPA process, the FDA may revoke or alter its agreement, such as under the following circumstances:

- public health concerns emerge that were unrecognized at the time of the protocol assessment, or the director of the review division determines that a substantial scientific issue essential to determining safety or efficacy has been identified after testing has begun;

- a sponsor fails to follow a protocol that was agreed upon with the FDA; or

- the relevant data, assumptions or information provided by the sponsor in a request for SPA change, are found to be false statements or misstatements, or are found to omit relevant facts.

In addition, a documented SPA may be modified, and such modification will be deemed binding on the FDA review division, except under the circumstances described above, if the FDA and the sponsor agree in writing to modify the protocol and such modification is intended to improve the study. We have obtained an SPA with the FDA for our Phase III clinical trial protocol for KIT-302. Agreement by the FDA to an SPA does not guarantee that the results of a study conducted in accordance with the agreement will be successful.

FDA Guidelines on Anti-Hypertensive Drugs

In March 2011, the FDA published a new draft guideline stating that drugs designed to be anti-hypertensive may include in the usage indication section of the package insert a statement that "Reduced blood pressure decreases the risk of suffering fatal and non-fatal cardiovascular events, mainly stroke and myocardial infarction". We do not intend to prove through our clinical trials that our therapeutic candidates reduce the risk of suffering from the aforesaid diseases. Nevertheless, we expect that the said draft guideline will have a positive effect on the combination drugs we are developing because the combination drugs we are developing are intended to prevent hypertension. The FDA has informed us in writing that the package insert of our combination drug product may contain the statement provided in the draft guideline.

European Regulatory Authorities

In the event that we wish to perform trials in Europe or market or sell our therapeutic candidates in Europe, we must apply to an applicable country's regulatory authorities with a request to approve our therapeutic candidates according to the Mutual Recognition Procedure (MRP), which is a procedure applied by European Directive No. 2001/83/EC that enables access to medicinal products (drugs) in 27 countries of the European Union. The MRP approval process requires the applicant to receive approval in one of the EU countries and then apply for recognition of the other member countries to acknowledge the approval within their territory. It is not currently known whether the European regulatory authorities will require additional studies in order to grant their approval to market KIT-302 in Europe.

The Israeli Ministry of Health

Our operations are subject to permits from the Israeli Ministry of Health on two levels:

First, pertaining to the import of drugs and/or raw materials, we are required to apply to the Ministry of Health for approval from its medical accessories and devices unit (AMR).

Second, pertaining to research and development, when we conduct trials in human, the trials will be subject to the approval of the Helsinki Committee, which acts by force of the Public Health Regulations (Trials in Human Beings), 1980 (Trials in Human Subjects Regulations) and according to the guidelines of the Helsinki declaration, or any other approval required by the Ministry of Health. According to the Trials in Human Beings Regulations, the Helsinki Committee must plan and approve every experimental process that involves human beings. The Helsinki Committee is an institutional committee that acts in the medical institution where the trial is performed and is the party that approves and supervises the entire trial process. In practice, the physician, who is the chief researcher, submits a trial protocol to the committee on behalf of the requesting party. The committee forwards its decisions regarding the requests for medical trials that were approved by the committee to the manager of the medical institute and the manager has the authority to approve the requests without additional approval of the Ministry of Health. According to the procedure for medical trials in human beings of the Ministry of Health, the Helsinki Committee will not approve performance of a medical trial, unless it is absolutely convinced that the following conditions, among others, are fulfilled: (a) the expected benefits for the participant in the medical trial and to the requesting party to justify the risk and the inconvenience involved in the medical trial to its participant; (b) the available medical and scientific information justifies the performance to the requested medical trial; (c) the medical trial is planned in a scientific manner that enables a solution to the tested question and is described in a clear, detailed and precise manner in the protocol of the medical trial, conforming with the Helsinki principles declaration; (d) the risk to the participant in the medical trial is as minimal as possible; (e) optimal monitoring and follow-up of the participant in the medical trial; (f) the initiator, the chief researcher and the medical institute are capable and undertake to allocate the resources required for adequate execution of the medical trial, including qualified personnel and required equipment; and (g) the nature of the commercial agreement with the chief researcher and the medical institute does not impair the adequate performance of the medical trial.

All phases of clinical studies conducted in Israel must be conducted in accordance with the Trials in Human Subjects Regulations, including amendments and addenda thereto, the Guidelines for Clinical Trials in Human Subjects issued by the Israel Ministry of Health (the Guidelines) and the International Conference for Harmonized Tripartite Guideline for Good Clinical Practice. The regulations and the Guidelines stipulate that a medical study on humans will only be approved after the Helsinki Committee at the hospital intending to perform the study has approved the medical study and notified the relevant hospital director in writing. In addition, certain clinical studies require the approval of the Ministry of Health. The Helsinki Committee will not approve the performance of the medical study unless it is satisfied that it has advantages to the study participants and society at large that justify the risk and inconvenience for the participants and that the medical and scientific information justifies the performance of the requested medical study. The relevant hospital director, and the Ministry of Health, if applicable, also must be satisfied that the study is not contrary to the Helsinki Declaration or to other regulations. The Ministry of Health also licenses and regulates the marketing of pharmaceuticals in Israel, requiring the relevant pharmaceutical to meet internationally recognized cGMP standards.

Pervasive and continuing regulation in the U.S.

After a drug is approved for marketing and enters the marketplace, numerous regulatory requirements continue to apply. These include, but are not limited to:

- the FDA's cGMP regulations require manufacturers, including third party manufacturers, to follow stringent requirements for the methods, facilities and controls used in manufacturing, processing and packing of a drug product;

- labeling regulations and the FDA prohibitions against the promotion of drugs for unapproved uses (known as off-label uses), as well as requirements to provide adequate information on both risks and benefits during promotion of the drug;

- approval of product modifications or use of a drug for an indication other than approved in an NDA;

- adverse drug experience regulations, which require us to report information on adverse events during pre-market testing;

- post-market testing and surveillance requirements, including Phase IV trials, when necessary to protect the public health or to provide additional safety and effectiveness data for the drug; and

- the FDA's recall authority, whereby it can ask, or under certain conditions order, drug manufacturers to recall from the market a product that is in violation of governing laws and regulation. After a drug receives approval, any modification in conditions of use, active ingredient(s), route of administration, dosage form, strength or bioavailability, will require a new approval, for which it may be possible to submit a 505(b)(2), accompanied by additional clinical data necessary to demonstrate the safety and effectiveness of the product with the proposed changes. Additional clinical studies may be required for proposed changes.

Other U.S. Healthcare Laws and Compliance Requirements

For products distributed in the United States, we will also be subject to additional healthcare regulation and enforcement by the federal government and the states in which we conduct our business. Applicable federal and state healthcare laws and regulations include the following:

- The federal healthcare anti-kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving, or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order, or recommendation of, any good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid;

- The Ethics in Patient Referrals Act, commonly referred to as the Stark Law, and its corresponding regulations, prohibit physicians from referring patients for designated health services (including outpatient drugs) reimbursed under the Medicare or Medicaid programs to entities with which the physicians or their immediate family members have a financial relationship or an ownership interest, subject to narrow regulatory exceptions, and prohibits those entities from submitting claims to Medicare or Medicaid for payment of items or services provided to a referred beneficiary;

- The federal False Claims Act imposes criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government claims for payment that are false or fraudulent or making a false statement to avoid, decrease, or conceal an obligation to pay money to the federal government; and

- Health Insurance Portability and Accountability Act of 1996, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. This statute also prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items, or services.

- Analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government.

Reimbursement

Sales of our therapeutic candidates in the United States may depend, in part, on the extent to which the costs of the therapeutic candidates will be covered by third-party payers, such as government health programs, commercial insurance and managed health care organizations. These third-party payers are increasingly challenging the prices charged for medical products and services. Additionally, the containment of health care costs has become a priority of federal and state governments, and the prices of drugs have been a focus in this effort. The United States government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. If these third-party payers do not consider our therapeutic candidates to be cost-effective compared to other available therapies, they may not cover our therapeutic candidates after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our therapeutic candidates on a profitable basis.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, (the MMA), imposed new requirements for the distribution and pricing of prescription drugs for Medicare beneficiaries and included a major expansion of the prescription drug benefit under Medicare Part D. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities which will provide coverage of outpatient prescription drugs. Part D plans include both stand-alone prescription drug benefit plans and prescription drug coverage as a supplement to Medicare Advantage plans. Unlike Medicare Parts A and B, Part D coverage is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for therapeutic candidates for which we receive marketing approval. However, any negotiated prices for our therapeutic candidates covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payers often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payers.

On February 17, 2009, President Obama signed into law the American Recovery and Reinvestment Act of 2009. This law provides funding for the federal government to compare the effectiveness of different treatments for the same illness. A plan for the research will be developed by the Department of Health and Human Services, the Agency for Healthcare Research and Quality and the National Institutes of Health, and periodic reports on the status of the research and related expenditures will be made to Congress. Although the results of the comparative effectiveness studies are not intended to mandate coverage policies for public or private payers, it is not clear how such a result could be avoided and what if any effect the research will have on the sales of our therapeutic candidates, if any such therapeutic candidates or the condition that it is intended to treat is the subject of a study. It is also possible that comparative effectiveness research demonstrating benefits in a competitor's product could adversely affect the sales of our therapeutic candidates. Decreases in third-party reimbursement for our therapeutic candidates or a decision by a third-party payer to not cover our therapeutic candidates could reduce physician usage of the therapeutic candidates and have a material adverse effect on our sales, results of operations and financial condition.

The Patient Protection and Affordable Care Act

On March 23, 2010, President Obama signed into legislation the Patient Protection and Affordable Care Act, which was subsequently amended by the Healthcare and Education Reconciliation Act (as amended, the Affordable Care Act). The Affordable Care Act will result in sweeping changes across the health care industry. The primary goal of this comprehensive legislation is to extend health insurance coverage to currently uninsured legal U.S. residents through a combination of public program expansion and private sector health insurance reforms. To fund the expansion of insurance coverage, the Affordable Care Act contains measures designed to promote quality and cost efficiency in health care delivery and to generate budgetary savings in the Medicare and Medicaid programs. The Affordable Care Act's provisions are designed to encourage providers to find cost savings in their clinical operations. Pharmaceuticals represent a significant portion of the cost of providing care. Through modified reimbursement rates and other incentives, the U.S. government is requiring that providers identify the most cost-effective services, supplies and pharmaceuticals. This environment has caused changes in the purchasing habits of providers and resulted in specific attention to the pricing negotiation, product selection and utilization review surrounding pharmaceuticals. This attention may result in our therapeutic candidates being chosen less frequently or the pricing being substantially lowered. Additionally, the Affordable Care Act is expected to expand and increase industry rebates for drugs covered under Medicaid programs and make changes to the coverage requirements under the Medicare Part D program. We cannot predict the impact of the Affordable Care Act on pharmaceutical companies as many of the Affordable Care Act reforms require the promulgation of detailed regulations implementing the statutory provisions which has not yet occurred. The legislation also includes significant provisions that encourage state and federal law enforcement agencies to increase activities related to preventing, detecting and prosecuting those who commit fraud, waste and abuse in federal healthcare programs, including Medicare, Medicaid and Tricare. Since the enactment of the Affordable Care Act, numerous regulations have been issued providing further guidance on its requirements. The Affordable Care Act continues to be implemented through regulation and government activity but is subject to possible amendment, additional implementing regulations and interpretive guidelines. Several states have decided not to expand their Medicaid programs and are seeking alternative reimbursement models to provide care to the uninsured. The manner in which these issues are resolved could materially affect the extent to which and the amount at which pharmaceuticals are reimbursed by government programs such as Medicare, Medicaid and Tricare.

C. Organizational Structure

Our corporate structure consists of Kitov Pharmaceuticals Holdings Ltd., incorporated in the State of Israel, and our wholly owned operating subsidiary, Kitov Pharmaceuticals Ltd., an Israeli limited corporation which was founded in June 2010.

D. Property, Plant and Equipment

All of our facilities are leased, and we do not own any real property. Our principal executive offices are located in the Round Tower in the Azrieli Center, Tel-Aviv, Israel. The space is in a commercial office building and has approximately 100 square meters pursuant to a 60-month lease which commenced on January 1, 2015. In addition, we sub-lease a 20 square meter office space at 11 Beit Hadfus Street, Jerusalem, Israel pursuant to a sub-lease agreement entered into on July 16, 2014 with a third party which terminates on July 31, 2016. We have no material tangible fixed assets apart from the properties described above. We believe our facilities are adequate and suitable for our current needs.

ITEM 4A. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

You should read the following discussion of our financial condition and results of operations in conjunction with the financial statements and the notes thereto included elsewhere in this Annual Report on Form 20-F. The following discussion contains forward-looking statements that reflect our plans, estimates and beliefs. Our actual results could differ materially from those discussed in the forward-looking statements. Factors that could cause or contribute to these differences include those discussed below and elsewhere in this Annual Report on Form 20-F, particularly those in "Item 3. Key Information – D. Risk Factors." See "*Special Note Regarding Forward-Looking Statements."*

Introduction

We are a biopharmaceutical company focused on the development of therapeutic candidates for the simultaneous treatment of two clinical conditions:

- pain caused by osteoarthritis, and
- hypertension (high blood pressure), which can be pre-existing or caused by the treatment for osteoarthritis.

In particular, we focus on developing combinations of existing drugs in advanced stages of development. We currently have two combinations in our pipeline, KIT-301, based on the generic drugs naproxen and isradipine, and KIT-302, based on the generic drugs amlodipine besylate and celecoxib.. Both naproxen and celecoxib are active ingredients of known and approved-for-use drugs designed primarily to relieve pain caused by osteoarthritis. Celecoxib is the active ingredient in the branded drug "Celebrex®". These combinations are designed to simultaneously relieve pain caused by osteoarthritis and treat hypertension, which is one of the side effects of using NSAIDs for treating pain caused by osteoarthritis. Since the commencement of our pharmaceutical research and development activities, we have not generated any revenues.

We are currently focusing our development efforts on KIT-302, which recently completed its Phase III clinical study. We are currently not developing KIT-301, for which we have an active IND, due to our need to allocate resources for advancing the development of KIT-302. Depending on market acceptance of KIT-302 if approved, we will consider whether to continue the further development of KIT-301.

Where applicable, we intend to seek FDA approval for the commercialization of our therapeutic candidates through the Section 505(b)(2) regulatory path under the Federal Food, Drug, and Cosmetic Act of 1938, as amended, and in corresponding regulatory paths in other foreign jurisdictions. Our current pipeline consists of two clinical development therapeutic candidates, KIT-301 and KIT-302, which have been cleared for Phase III clinical trials, which will then be subject to review and approval by the FDA. Upon and subject to receipt of the requisite approvals, we intend to commercialize our therapeutic candidates through licensing and other commercialization arrangements with pharmaceutical companies on a global and/or territorial basis. We may also evaluate, on a case by case basis, co-development and similar arrangements, as well as the independent commercialization of our therapeutic candidates.

On July 11, 2013, Kitov Holdings (then known as Mainrom Line Logistics Ltd.) acquired issued and outstanding shares of Kitov Pharmaceuticals, in exchange for the issuance by Kitov Holdings to Kitov Pharmaceuticals' shareholders of ordinary shares constituting, immediately following such issuance, approximately 63.75% of the fully diluted share capital of Kitov Holdings (subject to an issuance of additional ordinary shares of Kitov Holdings to Kitov Pharmaceuticals' shareholders following the attainment of a milestone in connection with our Phase III clinical trial for KIT-302, which issuance of additional shares was completed on December 24, 2015). See "Item 7. Major Shareholders and Related Party Transactions – B. Related Party Transactions – Share Transfer Agreement with Kitov Pharmaceuticals". The acquisition was accounted for under IFRS as issued by the IASB, as a reverse merger, and therefore the consolidated financial statements of Kitov Holdings presented in this Annual Report on Form 20-F include the financial results of Kitov Pharmaceuticals for the three years ended December 31, 2015, 2014 and 2013 and of Kitov Holdings for the period from July 11, 2013 to December 31, 2015.

History of Losses

Since commencement of our pharmaceutical research and development operations, we have generated significant losses mainly in connection with the research and development of our therapeutic candidates. Such research and development activities are expected to expand over time and will require further resources if we are to be successful. As a result, we expect to continue incurring operating losses, which may be substantial over the next several years, and will need to obtain additional funds to further develop our research and development programs. As of December 31, 2015, we had an accumulated deficit of approximately $14.1 million.

We plan to fund our future operations through commercialization and out-licensing of our therapeutic candidates and to raise additional capital in the future through either debt or equity financing. We believe our existing working capital will be sufficient to meet our present requirements through at least the next twelve months.

Components of Statement of Operations

Research and Development Expenses

See "C. Research and Development, Patents and Licenses" below.

General and Administrative Expenses

General and administrative expenses consist primarily of compensation for directors, employees and consultants in executive and operational functions. Other significant general and administrative expenses include professional fees for outside accounting and legal services, travel costs and insurance premiums.

Expenses Related to Stock Exchange Listing

Expenses related to stock exchange listing represents the effective cost of the acquisition of Kitov Holdings, at that time a public shell company, from an accounting perspective, by Kitov Pharmaceuticals. The cost was determined based on the market value of the outstanding shares of Kitov Holdings that were held by the former shareholders of Kitov Holdings immediately following the acquisition.

Other Expenses

Other expenses represent payments made to Mr. Sheer Roichman as required by the Share Transfer Agreement. See “Item 7. Major Shareholders and Related Party Transactions – B. Related Party Transactions – Share Transfer Agreement with Kitov Pharmaceuticals”.

Finance Income and Finance Expense

Finance Income comprises changes in the fair value of financial liabilities and Finance Expense consists primarily of interest and fees in connection with loans granted to Kitov Holdings from third parties and related parties.

Critical Accounting Policies and Estimates

The preparation of financial statements in conformity with IFRS as issued by the IASB, requires companies to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. These estimates and judgments are subject to an inherent degree of uncertainty and actual results may differ. Our significant accounting policies are more fully described in Note 3 to our annual financial statements included elsewhere in this Annual Report on Form 20-F. Critical accounting estimates and judgments are evaluated and are based on historical experience and other factors, including expectations of future events that are believed to be reasonable under the circumstances, and are particularly important to the portrayal of our financial position and results of operations.

Share-based compensation

In accordance with IFRS 2 Share – based Payment, the grant of stock options to our employees for services rendered represents a supplementary benefit. Under IFRS 2 Share – based Payment, we estimate the fair value of these stock options at the grant date and record the value within shareholders’ equity. Fair value is determined using a standard option pricing model that takes into account the specific features of the stock option plan (net price, period of exercise, etc.), market data at the grant date (such as price, volatility, etc.) and behavioral assumptions relating to option holders. Different assumptions could result in material changes to the expense amounts recorded for these options.

A. Operating Results

Comparison of the Year Ended December 31, 2015 to the Year Ended December 31, 2014

Research and Development Expenses

Research and development expenses decreased to $2.560 million during the year ended December 31, 2015 from $3.192 million during the year ended December 31, 2014. This decrease was primarily due to the offset of amounts to be paid to us under the terms of our agreement with Dexcel. See "Item 10. Additional Information – C. Material Contracts – Development Services Agreement with Dexcel".

General and Administrative Expenses

General and administrative expenses increased to $1.509 million during the year ended December 31, 2015 from $1.269 million during the year ended December 31, 2014. This increase was primarily due to rent expense incurred upon our move into new offices in January 2015 and additional travel expenses.

Other Expenses

During the year ended December 31, 2014, other expenses were NIS 2.5 million (approximately $720,000 based on the representative rate of exchange on the date of payment, March 12, 2014) due to the payment to Mr. Sheer Roichman as required by the Share Transfer Agreement. See “Item 7. Major Shareholders and Related Party Transactions – B. Related Party Transactions – Share Transfer Agreement with Kitov Pharmaceuticals". During the year ended December 31, 2015 there were no other expenses.

Operating Loss

Operating loss decreased to $4.069 million during the year ended December 31, 2015 from $5.181 million during the year ended December 31, 2014 primarily due to the decrease in research and development expenses and the lack of other expenses described above.

Finance Expense

Net finance expense increased to $133,000 during the year ended December 31, 2015 from $71,000 during the year ended December 31, 2014 primarily resulting from a greater change in the fair value of financial liabilities associated with our series 2 warrants.

Loss for the Period

Loss for the period decreased to $4.202 million during the year ended December 31, 2015 from $5.252 million during the year ended December 31, 2014 primarily due to the decrease in research and development expenses and the lack of other expenses described above.

Comparison of the Year Ended December 31, 2014 to the Year Ended December 31, 2013

Research and Development Expenses

Research and development expenses increased to $3.192 million during the year ended December 31, 2014 from $109,000 during the year ended December 31, 2013. This increase was primarily due to costs associated with preparation for and conduct of the Phase III clinical trial for KIT-302 and the formulation of the combination drug by Dexcel.

General and Administrative Expenses

General and administrative expenses increased to $1.269 million during the year ended December 31, 2014 from $1.061 million during the year ended December 31, 2013. This increase was primarily due to additional professional fees as a public company, following the acquisition of Kitov Pharmaceuticals by Kitov Holdings on July 11, 2013, as well as increased salary costs and consulting fees.

Expenses Related to Stock Exchange Listing

Expenses related to stock exchange listing was $1.383 million during the year ended December 31, 2013 and represents the effective cost of the acquisition of Kitov Holdings, at that time a public shell company, from an accounting perspective, by Kitov Pharmaceuticals. There were no such expenses during the year ended December 31, 2014.

Other Expenses

During the year ended December 31, 2014, other expenses were NIS 2.5 million (approximately $720,000 based on the representative rate of exchange on the date of payment, March 12, 2014) due to the payment to Mr. Sheer Roichman as required by the Share Transfer Agreement. See “Item 7. Major Shareholders and Related Party Transactions – B. Related Party Transactions – Share Transfer Agreement with Kitov Pharmaceuticals". During the year ended December 31, 2013 there were no other expenses.

Operating Loss

Operating loss increased to $5.181 million during the year ended December 31, 2014 from $2.553 million during the year ended December 31, 2013 due to the increases in research and development expenses, general and administrative expenses and other expenses described above.

Finance Expense

Finance expense increased to $345,000 during the year ended December 31, 2014 from $75,000 during the year ended December 31, 2013 primarily resulting from the weaker rate of exchange of NIS to U.S. dollars in 2014. Finance income was $274,000 during the year ended December 31, 2014 as a result of changes in the fair value of financial liabilities. There was no finance income during the year ended December 31, 2013.

Loss for the Year

Loss for the year increased to $5.252 million during the year ended December 31, 2014 from $2.628 million during the year ended December 31, 2013 due to the increase in operating loss and finance expense described above.

JOBS Act

On April 5, 2012, the Jumpstart Our Business Startups Act, or the JOBS Act, was signed into law. Section 107 of the JOBS Act 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 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 have elected to utilize this exemption and, therefore, we will not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. In addition, as a result of this election, our future financial statements may not be comparable to those of public companies that are not emerging growth companies and are required to comply with public company effective dates for new or revised accounting standards.

Subject to certain conditions set forth in the JOBS Act, as an "emerging growth company," we also elected or may elect to rely on other exemptions, including without limitation, not (i) providing an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404 and (ii) complying with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements (auditor discussion and analysis). These exemptions will apply until the earliest of (a) the last day of our fiscal year during which we have total annual gross revenues of at least $1.0 billion; (b) the last day of our fiscal year following the fifth anniversary of the closing of our initial public offering on NASDAQ on November 25, 2015; (c) the date on which we have, during the previous three-year period, issued more than $1.0 billion in non-convertible debt; or (d) the date on which we are deemed to be a "large accelerated filer" under the Exchange Act.

B. Liquidity and Capital Resources

Our therapeutic candidates are in the research and development stage and therefore do not generate revenues. Since commencement of our operations as a pharmaceutical research and development company, our activities have been financed by equity offerings and private loans. We have raised an aggregate of approximately NIS 4.1 million (approximately $1.137 million) from private loans (all of which have been repaid) and gross proceeds of approximately NIS 33.5 million (approximately $9.2 million based on the representative rates of exchange on the dates of the closings, March 3, 2014, September 3, 2014, and March 30, 2015) from our public offerings on the TASE and approximately $13.0 million from our initial public offering on NASDAQ in November 2015 (described below). The proceeds from the public offerings were used to repay the private loans and to fund our ongoing operations. As of December 31, 2015, we had on hand approximately $10.6 million in cash and cash equivalents.

We believe that our current cash and cash equivalents are sufficient to complete the research and development of KIT-302 until its anticipated approval for marketing by the FDA in 2017. Since we do not know when we will begin to generate significant revenues from our therapeutic candidates, if ever, should we decide to develop KIT-301 and any additional therapeutic candidates, we may need substantial additional funds to acquire, develop, and/or commercialize such therapeutic candidates. However, additional financing may not be available on acceptable terms, if at all. Our long term capital requirements will depend on many factors, including:

- the regulatory path of our therapeutic candidates;
- our ability to successfully commercialize our therapeutic candidates, including securing commercialization agreements with third parties and favorable pricing and market share;
- the progress, success and cost of our clinical trials and research and development programs;
- the costs, timing and outcome of regulatory review and obtaining regulatory approval of our therapeutic candidates and addressing regulatory and other issues that may arise post-approval;
- the costs of obtaining and enforcing our issued patents and defending intellectual property-related claims;
- the costs of developing sales, marketing and distribution channels; and
- our consumption of available resources more rapidly than currently anticipated, resulting in the need for additional funding sooner than anticipated.

If we are unable to commercialize or out-license our therapeutic candidates or obtain future financing, we may be forced to delay, reduce the scope of, or eliminate one or more of our research and development programs related to the therapeutic candidates, which may have a material adverse effect on our business, financial condition and results of operations.

Cash Flow

Operating activities

For the year ended December 31, 2015, net cash flow used in operating activities was approximately $3.308 million compared to approximately $4.526 million for the year ended December 31, 2014. The decrease in net cash flow used in operating activities was due to a reduction in costs associated with the formulation of the combination drug, KIT-302, by Dexcel and by the absence of other expenses described above. The operating activities consisted of regulatory, strategy, planning and the conduct of the Phase III clinical trial for KIT-302 and the formulation and testing of prototypes of KIT-302, including increased payments to consultants and other service providers.

Investment activities

We had no investment activities during the years ended December 31, 2015, 2014 and 2013.

Financing activities

For the year ended December 31, 2015, financing activities consisted of net proceeds from issuance of ADSs and public warrants on NASDAQ of $10.6 million and the issuance of shares and TASE listed warrants on the TASE of $2.0 million, the repayment of loans received from related parties of $294,000, and the payment of interest of $145,000, compared to the issuance of shares and TASE listed warrants on the TASE of $6.6 million, repayment of loans received from related parties of $622,000, net repayment of loans received from third parties of $114,000, proceeds from conversion of options to shares of $57,000, and interest payments of $100,000 for the year ended December 31, 2014. The proceeds from the share issuances in 2014 and 2015 were used to finance the activities related to the Phase III clinical trial for KIT-302 and the formulation of prototypes of KIT-302.

As of December 31, 2015 we had no borrowings.

As of December 31, 2015, and as of the date of this Annual Report on Form 20-F, we had no commitments for capital expenditures.

C. Research and Development, Patents and Licenses

Our research and development expenses consist primarily of costs of clinical trials, salaries, and consulting fees (including share-based payments), and fees paid to external service providers. We primarily use external service providers to manufacture our therapeutic candidates and to perform clinical trials with our therapeutic candidates. We charge all research and development expenses to operations as they are incurred. We expect our research and development expense to remain our primary expense in the near future as we continue to develop our therapeutic candidates.

From the commencement of the pharmaceutical research and development activities of Kitov Pharmaceuticals through December 31, 2015, we incurred research and development expenses of approximately $6.217 million. Set forth below is a summary of the research and development costs for the years ended December 31, 2015, 2014 and 2013. Virtually all of the costs were incurred in connection with the development of KIT-302.

	Year Ended December 31			
	2015	**2014**	**2013**	**Total**
	(U.S. dollars in thousands)			
Total direct project costs	2,560	3,192	109	5,861

In addition to the major cost of clinical trials and CMC development, research and development expenses include consulting expenses for regulatory and project management work required for development of our therapeutic candidate portfolio. Set forth below is a summary of our research and development expenses based on the type of expenditure.

	Year Ended December 31		
	2015	**2014**	**2013**
	(U.S. dollars in thousands)		
Payroll expenses - related party	**321**	**128**	**47**
Sub-contractors	**2,239**	**3,064**	**62**
	2,560	**3,192**	**109**

In April 2014, we entered into an agreement with Dexcel for the development of the drug formulation for KIT-302 and its manufacture in quantities sufficient to support the filing of an NDA with the FDA (see "Item 10. Additional Information– C. Material Contracts – Development Services Agreement with Dexcel"). We therefore began incurring costs in 2014 for the development of the drug formulation for KIT-302.

Due to the inherently unpredictable nature of clinical development processes, we are unable to estimate with any certainty the costs we will incur in the continued development of our therapeutic candidates for potential commercialization. We estimate a total cost of approximately $500,000 of research and development expenses related to the Phase III clinical trial for KIT-302, $750,000 in order to complete the CMC work for KIT-302, and $500,000 for the final formulation PK trial for KIT-302. In addition, we will incur cost of approximately $150,000 to prepare for the Phase III clinical trial for KIT-301.

While we are currently focused on advancing our therapeutic candidates, our future research and development expenses will depend on the clinical success of each therapeutic candidate, as well as available resources and the ongoing assessments of each therapeutic candidate's commercial potential. In addition, we cannot forecast with any degree of certainty which therapeutic candidates may be subject to future commercialization arrangements, when such commercialization arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements. See "Item 3. Key Information – D. Risk Factors – If we and/or our potential commercialization partners are unable to obtain FDA or other foreign regulatory authority approval for our therapeutic candidates, we and/or our potential commercialization partners will be unable to commercialize our therapeutic candidates."

As we obtain results from clinical trials, we may elect to discontinue or delay development and clinical trials for certain therapeutic candidates in order to focus our resources on more promising therapeutic candidates or projects. Completion of clinical trials by us or our licensees may take several years or more, but the length of time generally varies according to the type, complexity, novelty and intended use of a therapeutic candidate. See "Item 3. Key Information – D. Risk Factors – Risks Related to Our Business and Regulatory Matters."

We expect our research and development expenses to increase from current levels as we continue the advancement of our clinical trials and therapeutic candidates' development. The lengthy process of completing clinical trials and seeking regulatory approvals for our therapeutic candidates requires substantial expenditures. Any failure or delay in completing clinical trials, or in obtaining regulatory approvals, could cause a delay in generating product revenue and cause our research and development expenses to increase and, in turn, have a material adverse effect on our operations. Due to the factors set forth above, we are not able to estimate with any certainty if and when we would recognize any net revenues from our therapeutic candidates.

D. ***Trend Information***

We are a biopharmaceutical company which focuses its activities on the development of our therapeutic candidates. It is not possible for us to predict with any degree of accuracy the outcome of our research and development or commercialization efforts with regard to any of our therapeutic candidates. Our research and development expenditure is our primary expenditure. Increases or decreases in research and development expenditure are primarily attributable to the level and results of our clinical trial activities and the amount of expenditure on those trials.

E. Off-Balance Sheet Arrangements

We are not party to any transactions, agreements or other contractual arrangements with unconsolidated entities whereby we have financial guarantees, subordinated retained interests, derivative instruments or other contingent arrangements that expose us to material continuing risks, contingent liabilities, or any other obligations under a variable interest in an unconsolidated entity that provides us with financing, liquidity, market risk or credit risk support.

F. Tabular Disclosure of Contractual Obligations

The following table summarizes our significant contractual obligations as of December 31, 2015.

	Total	**Less than 1 year**	**1-3 years**	**3-5 years**	**More than 5 years**
			(U.S. dollars in thousands) (unaudited)		
Office lease obligations	250	65	123	62	-
Obligations to R&D service providers (1)	1,800	1,800			-
Total	2,050	1,865	123	62	-

(1) Reflects payments payable to Java Clinical Research and its sub-contractors, DABL Limited and Dexcel Ltd. upon achievement of various performance milestones in accordance with current time estimates, pursuant to our service agreements with them. See "Item 10. Additional Information– C. Material Agreements – Development Services Agreement with Dexcel".

Kitov Pharmaceuticals had no material capital expenditures for the years ended December 31, 2015, 2014 and 2013.

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

A. Directors and Senior Management

The following table sets forth the name, age and position of each of our executive officers, directors (and director nominees), as well as our senior employees, as of the date of this Annual Report on Form 20-F. Unless otherwise stated, the address for any of the individuals listed below is c/o Kitov Pharmaceuticals Holdings Ltd., One Azrieli Center, Round Building, 23rd Floor, Tel Aviv, 6701101, Israel.

Name	Age	Position
John Paul Waymack, M.D., Sc.D.	62	Chairman of the Board of Directors and Chief Medical Officer
Isaac Israel	37	Chief Executive Officer and Director
Simcha Rock, CPA, MBA	66	Chief Financial Officer and Director
Moran Sherf-Blau, CPA, M.A. (1)(2)	35	Independent and External Director
Alain Zeitoun, M.D., M.A. (1)	54	Independent and External Director
Yair Katzir (1)	38	Independent Director
Gil Ben-Menachem, Ph.D., MBA	49	Vice President of Business Development
Avraham Ben-Tzvi, Adv.	45	General Counsel and Company Secretary

(1) Member of our audit committee

John Paul Waymack, M.D., Sc.D. was one of the founders of Kitov Pharmaceuticals and has served as the chairman of our board of directors and who fulfills duties and responsibilities of chief medical officer since July 2013. Dr. Waymack has over 20 years of experience in the biopharma field. Dr. Waymack is a former academic transplant surgeon and a former FDA medical officer, with over fifteen years of experience in drug development as a consultant to major pharmaceutical companies, including Pfizer, Roche, Pharmacia, Warner Lambert and Searle. During his 10 years of academic career, Dr. Waymack published over 100 scientific essays, mainly in the fields of prostaglandins and immunology. In addition, Dr. Waymack volunteered to the U.S. Army, where he was commissioned and served as a Major in the Medical Corp. in the position of chief of surgical studies in the U.S. Army's Institute for Surgical Research. Dr. Waymack was also an associate professor of surgery at the University of Texas Medical Branch and at the University of Medicine and Dentistry of New Jersey.

Isaac Israel has served as our chief executive officer and a member of the board since October 2012. Mr. Israel was the founding chief executive officer of BeeContact Ltd. (formerly TASE:BCNT), from 2001 until 2007. Since 2008 Mr. Israel has served as founding chief executive officer of Uneri Capital Ltd., a consulting firm in the capital markets field, owned by Mr. Israel, that specializes in the healthcare sector. In providing such consulting services, Mr. Israel also serves as a member of the board of directors of various healthcare corporations, both private and public, including as chairman of the board of NextGen Biomed Ltd., which is traded on the TASE. Since 2011 Mr. Israel has also provided business development services to Capital Point Ltd. (TASE:CPTP).

Simcha Rock, CPA, MBA, has served as our chief financial officer and a member of the board since July 2013. Mr. Rock was a private equity manager at Edmond de Rothschild Private Equity Management, a firm specializing in the management of venture capital and other private equity investments funds, from February 2000 until January 2011, with responsibility for all financial, legal and administrative matters for several investment funds. Prior to 2000, Mr. Rock held financial management positions at Intel Electronics Ltd., The Jerusalem College of Technology, and JC Technologies Ltd. Mr. Rock holds a BA from Yeshiva University and an MBA from Cleveland State University.

Moran Sherf-Blau, CPA, M.A., has served as a member of our board since December 2013. Ms. Sherf-Blau is the founder and owner of Total Finance Ltd., a company that provides accounting and financial management services to public, government, and private companies and acts as the chief financial officer of Bio-cell Ltd., a company traded on the TASE. Ms. Sherf-Blau also served as an executive certified public accountant in PricewaterhouseCoopers Israel.

Alain Zeitoun, M.D., M.A., has served as a member of our board since December 2013. Dr. Zeitoun's experience includes serving as chief executive officer of Chi2Gel, an Israeli medical device company, business unit director and European marketing leader at Merck Sharp and Dohme Israel (Merck & Co) as well as medical and marketing positions at Procter & Gamble and Boehringer Ingelheim pharmaceutical companies in France. In these positions, Dr. Zeitoun was in charge of several therapeutic fields, such as cardiology, rheumatology, orthopedics and gastroenterology. Dr. Zeitoun holds an M.D. degree from Paris Medical School and a Master's degree from ESCP Europe Business School, Paris, France.

Yair Katzir, CPA has served as a member of our board since March 2, 2016. Mr. Katzir is presently the chief financial officer of Derech Eretz Highways (1997) Ltd., an Israeli company owned by many of the leading institutional investors in Israel including major insurance companies, banks, pension funds and other money management firms, which is the concessionaire for the Cross Israel Highway (Road 6), where he has served since 2011. Derech Eretz Highways (1997) Ltd., is responsible for the finance, design, construction, operation and maintenance of the Cross Israel Highway which is one of the largest [BOT][NTD: not defined] infrastructure projects undertaken in Israel in recent years. From May 2007 until October 2011 Mr. Katzir served as the chief financial controller of Adama Holding Public Ltd., a TASE listed residential real estate company. Previously he worked as an auditor at Ernst & Young (Israel) Ltd. Mr. Katzir holds a Bachelor's Degree in Business Administration and Accounting from the College of Management in Rishon LeTzion, Israel.

Gil Ben-Menachem, Ph.D., MBA has served as our vice president business development since January 2016. He has over 15 years of experience in the pharmaceutical, biotechnology, and venture capital industries. He was most recently head of innovative products at Dexcel Pharma, the second largest Israeli pharmaceutical company. Dr. Ben-Menachem previously served as director of business development at Teva Pharmaceutical Industries, where he was responsible for business development efforts in connection with partnering and acquisition deals for late stage innovative drug candidates. Prior positions held by Dr. Ben-Menachem include serving as chief executive officer of OphthaliX, a company that developed drugs in the ophthalmology space, and serving as director of business development at Paramount Biosciences, a New York based merchant bank and biotechnology venture capital firm. Dr. Ben-Menachem received his Ph.D. from the Hebrew University, and MBA from the University of Maryland. He concluded his postdoctoral training in immunology and microbiology at the NIH.

Avraham Ben-Tzvi, Adv. has served as our general counsel since November 2015 and was appointed as our secretary in December 2015. Mr. Ben-Tzvi previously served as general counsel and company secretary at Medigus Ltd., a minimally invasive endosurgical tools medical device and miniaturized imaging equipment company which is listed on NASDAQ and the TASE, from April 2014 until November 2015. Prior to that he served as an attorney at Yigal Arnon & Co. from 2009 to 2014 where, among other corporate and commercial work, he advised companies and underwriters on various offerings by Israeli companies listing in the U.S. and/or Israel and on various SEC and Israeli related securities law filings. Prior to 2009, Mr. Ben-Tzvi worked in a number of business development, corporate finance and banking roles at companies in the financial services, manufacturing and software development industries. Mr. Ben-Tzvi holds a BA in Economics from Yeshiva University in New York and an LLB from Sha'arei Mishpat College of Law in Hod Hasharon, Israel.

The spouses of Simcha Rock, our chief financial officer, and Philip Serlin, who served as an independent and unaffiliated director from July 2013 until March 2016, are first cousins. Other than this relationship, there are no family relationships among any of our office holders (including directors).

B. Compensation

Director Compensation

Under the Companies Law, 5754-1999, and related regulations, external directors are entitled to a fixed annual compensation and an additional payment for each meeting attended. We currently pay our external directors, Dr. Zeitoun and Ms. Sherf-Blau, an annual fee of NIS 24,786 (approximately $6,352) and a fee of NIS 1,435 (approximately $368) per meeting (or a smaller amount in case they do not physically attend the meeting). Mr. Yair Katzir an independent director is compensated at the same rate as the external directors. During the year ended December 31, 2015, we paid our external and independent directors NIS 194,988 (approximately $41,135) in the aggregate.

Directors' Service Contracts

There are no arrangements or understandings between us and any of our subsidiaries, on the one hand, and any of our directors, on the other hand, providing for benefits upon termination of their employment or service as directors of our company or any of our subsidiaries, except as provided in certain employment or service agreements with our executive officers who also serve as directors.

Executive Compensation

The aggregate compensation paid, and benefits in-kind granted to or accrued on behalf of all of our directors and senior management for their services, in all capacities, to us during the year ended December 31, 2015, was approximately $1.399 million. As of December 31, 2015, the total amount set aside as an actuarial estimate by us to provide post-employment benefits for certain office holders was in the aggregate amount of approximately $185 thousand. We have not set aside amounts to provide post-employment benefits for the remaining office holders.

We have entered into engagement agreements with each of our 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 laws.

Our directors and executive officers hold exemption and indemnification letters and a valid D&O insurance policy. For information on exemption and indemnification letters granted to our officers and directors, please see "Item 6. Directors, Senior Management and Employees - C. Board Practices - Exculpation, Insurance and Indemnification of Directors and Officers".

Below is a breakdown of the annual compensation of each of our executive officers for the year ended December 31, 2015, with respect to whom, as of the date of this Annual Report on Form 20-F, disclosure is either required in our home country, or whose compensation by us has otherwise previously been disclosed publicly on an individual basis:

Name	Position	Salary or other payments[1] in (in $ thousands)	Bonus payments or accruals (in $ thousands)	Share-based payment (in $ thousands)	Total (in $ thousands)
Dr. J. Paul Waymack	Chairman of the Board	169	168		448
Isaac Israel	Chief Executive Officer and Director	190	267		492
Simcha Rock	Chief Financial Officer and Director	182	164	7	392

[1] Includes social benefits, such as payments to the National Insurance Institute, advanced education funds, managers' insurance and pension funds; vacation pay; and recuperation pay as mandated by Israeli law, and car lease or vehicle use reimbursement related benefits.

Consulting Agreement with Waymack Inc. (wholly owned by Dr. John Paul Waymack)

In July 2013, we entered into a consulting agreement with Waymack Inc. for the services of Dr. John Paul Waymack, one of our founders, pursuant to which Dr. Waymack provides services to us as chief medical officer and as the chairman of our board of directors. In return for Dr. Waymack's services, as of March 2014 we paid Waymack Inc. a monthly fee of NIS 29,880 (approximately $8,690 per month based on the representative rate of exchange on June 30, 2014). As of September 2014, we are paying Waymack Inc. a monthly fee of $14,000. The service agreement may be terminated by either party upon 180 days' advance notice to the other party. In addition to the above monthly fee Waymack Inc. is entitled to the following additional compensation:

Retirement Grant. A retirement grant upon termination of Dr. Waymack's engagement with us, provided that the termination is not due to circumstances that do not entitle an employee to severance payments under any applicable law and/or under any judicial decision of a competent tribunal. The retirement grant is (i) three (3) times the monthly fee if the services provided by Dr. Waymack have been provided for a consecutive period of at least 18 months; or (ii) six (6) times the monthly fee if the services provided by Dr. Waymack have been provided for a consecutive period of at least three years.

Annual Bonus. Annual bonus, which shall not exceed twelve (12) times the monthly fee, of which at least 80% is based on measurable criteria and either (i) up to 20% or (ii) up to three (3) times the monthly fee is based on non-measurable criteria under our compensation policy. Below is a description of the annual bonus based on measurable criteria:

(i) a bonus in the amount of one (1) time the monthly fee for each NIS 5 million (gross) increase during the calendar year compared to the previous calendar year-end of our equity and/or asset value, taking into consideration and offsetting any relevant decrease in our equity and/or asset value which occurred in the 12 months previous to such increase; (ii) a bonus in the amount of one (1) time the monthly fee for each NIS 5 million (gross) increase in income from sales of our products in the calendar year compared to the previous calendar year; (iii) a bonus in the amount of three (3) times the monthly fee for completion of in-licensing transaction for a new product, *provided however* that in any event the bonus will not be paid prior to the clinical trial phase and IND approval with respect to the new product; (iv) a bonus in the amount of one (1) time the monthly fee for each NIS 10 million increase in our market value during the calendar year compared to the previous calendar year-end; (v) a bonus in the amount of six (6) times the monthly fee for each target successfully achieved in a clinical trial as of Phase II of the trial and a bonus in the amount of one (1) time the monthly fee for each target successfully achieved in a clinical trial as of Phase I; (vi) a bonus in the amount of six (6) times the monthly fee upon approval by the FDA (NDA approval) or any comparable regulatory authority in connection with our products provided however that such bonus shall not be paid for each product more than once; and (vii) a bonus in the amount of two (2) times the monthly fee after completion of registration of our securities on a U.S. stock exchange.

Special bonus based on either a Merger Transaction or a Commercialization Transaction. A special bonus equal to*:*

(i) 4% of our valuation determined in a Merger Transaction; provided that: (a) in the event that a commission is paid to third parties, the total bonus paid to Waymack Inc., any other office holders, and any third parties with respect thereto will not exceed 8% of the valuation, and the bonus paid to each such office holder shall be calculated pro rata; (b) in any event Waymack Inc. will not be entitled to a bonus based on a Merger Transaction in an amount exceeding $500,000; A "Merger Transaction" means one or more related transactions of either: (A) sale, lease, license or any transfer of all or most of our assets or securities; (B) merger so that the shareholders holding at least 50% of our issued and outstanding share capital prior to the consummation of such transaction hold less than 50% of our issued and outstanding share capital or the share capital of the surviving company following the consummation of such transaction, provided however that our valuation in such Merger Transaction is at least $25 million;

(ii) 4% of the cumulative revenues actually received from a Commercialization Transaction, less any payments made to third parties. The initial bonus is payable upon the receipt of at least $5 million as a result of the commercialization of our products. In the event we receive additional revenues as a result of a Commercialization Transaction exceeding such amount, Waymack Inc. will be entitled to an additional monthly bonus against revenues received by us as a result of the Commercialization Transaction in the prior month; provided that: (a) in the event that a commission is paid to third parties, the total bonus paid to Waymack Inc. and any other office holders, and any third parties with respect thereto will not exceed 10% of the total revenues, and the bonus paid to each such office holder shall be calculated pro rata; (b) in any event Waymack Inc. will not be entitled to a bonus based on a Commercialization Transaction in an amount exceeding $500,000. A "Commercialization Transaction" means the execution of a licensing and/or distribution agreement of our products with revenues of at least $5 million. Waymack Inc. will be entitled to the bonus as a result of a Commercialization Transaction only upon our receipt of at least $5 million as a result of the commercialization of our products.

In the event our cash balance decreases below NIS 2 million, we may, by a resolution of the compensation committee (or the audit committee acting in lieu of a compensation committee pursuant to the Companies Law) and the board of directors, decrease and/or choose not to grant the annual bonus and/or the special bonus, provided that such resolution was made with respect to all of our office holders. Upon the increase of our cash balance above such amount, we shall grant the foregone annual bonus and/or the special bonus, as applicable.

In the event of the reference of our auditors in the auditors' opinion on our financial statements with respect to significant doubt as to our ability to continue as a "going concern," we may, by a resolution of the compensation committee (or the audit committee acting in lieu of a compensation committee pursuant to the Companies Law) and the board of directors, decrease and/or choose not to grant the special bonus, provided that such resolution was made with respect to all of our office holders. However, upon the removal of the auditors' "going concern" reference, we may grant the special bonus with respect to a past merger transaction.

Employment Agreement with Mr. Isaac Israel (previously Service Agreement with Uneri Capital Ltd.)

In July 2013, we entered into a services agreement with Uneri Capital Ltd., a private company wholly owned by Mr. Isaac Israel, for the provision of part-time management services according to our needs. For such services we paid as of such date monthly payments of NIS 25,000 (approximately $7,300 per month based on the representative rate of exchange on June 30, 2014). As of September 2014 we terminated the engagement with Uneri Capital and entered into an employment agreement with Mr. Isaac Israel as our chief executive officer pursuant to which we pay Mr. Israel a base salary of NIS 40,000 (approximately $10,593) per month.

In addition to the above we provide Mr. Israel a leased company car at a monthly cost of up to NIS 4,000 (approximately $1,059), management insurance policy and advanced study fund. The employment agreement may be terminated upon 90 days' prior notice to the other party. In addition, Mr. Israel is entitled to the following additional compensation:

Retirement Grant. A retirement grant upon termination of Mr. Israel's employment with us, provided that the termination is not due to circumstances that do not entitle an employee to severance payments under any applicable law and/or under any judicial decision of a competent tribunal. The retirement grant is (i) one (1) time the monthly salary if the services provided by Mr. Israel have been provided for a consecutive period of at least 18 months; or (ii) three (3) times the monthly salary if the services provided by Mr. Israel have been provided for a consecutive period of at least three years;

Annual Bonus. Annual bonus, which shall not exceed twelve (12) times the monthly salary of which at least 80% is based on measurable criteria and either (i) up to 20% or (ii) up to three (3) times the monthly salary is based on non-measurable criteria under our compensation policy. The annual bonus based on measurable criteria is payable for the same events and in the same amounts as the agreement with Waymack Inc. described above, except that the bonus to Mr. Israel for each target successfully achieved in a clinical trial as of Phase I is two (2) times his monthly salary.

Special bonus based on either a Merger Transaction, Fund Raise or a Commercialization Transaction. A special bonus equal to: (i) 4% of our valuation determined in a Merger Transaction payable in the same manner as the agreement with Waymack Inc. described above; (ii) NIS 200,000 for each Fund Raise, provided however, in the event that a commission is paid to third parties, the total bonus paid to Mr. Israel, any other office holders and any third parties with respect thereto will not exceed 10% of the Fund Raise amount (gross); and (iii) 4% of the cumulative revenues actually received from a Commercialization Transaction, less any payments made to third parties, payable in the same manner as the agreement with Waymack Inc. described above. A "Fund Raise" means a raise by us of each NIS 10 Million (cumulative), in any calendar year, commencing as of October 1, 2014.

We may, by a resolution of the compensation committee (or the audit committee acting in lieu of a compensation committee pursuant to the Companies Law) and the board of directors, decrease and/or choose not to grant the annual bonus and/or the special bonus, in the manner described above regarding the Service Agreement with Waymack Inc.

Consulting Agreement with Mr. Simcha Rock

In July 2013, we entered into a consulting agreement with Mr. Rock pursuant to which Mr. Rock provides services to us as our chief financial officer. In return for Mr. Rock's services, as of March 2014, we paid Mr. Rock a monthly fee of NIS 35,000 (approximately $10,200 per month based on the representative rate of exchange on June 30, 2014). As of September 2014, we are paying Mr. Rock NIS 50,000 (approximately $13,242) per month. The agreement may be terminated by either party upon 90 days' prior notice to the other party.

In addition to the above monthly fee Mr. Rock is, as of September 1, 2014, entitled to a leased company car at a monthly cost of up to NIS 3,000 (approximately $795) and to the following additional compensation:

Retirement Grant. A retirement grant upon termination of Mr. Rock's employment with us, provided that the termination is not due to circumstances that do not entitle an employee to severance payments under any applicable law and/or under any judicial decision of a competent tribunal. The retirement grant is (i) one (1) time the monthly fee if the services provided by Mr. Rock have been provided for a consecutive period of at least 18 months; or (ii) three (3) times the monthly fee if the services provided by Mr. Rock have been provided for a consecutive period of at least three years;

Annual Bonus. Annual bonus, which shall not exceed twelve (12) times the monthly fee of which at least 80% is based on measurable criteria and either (i) up to 20% or (ii) up to three (3) times the monthly fee is based on non-measurable criteria under our compensation policy. The annual bonus based on measurable criteria is payable for the same events and in the same amounts as the agreement with Waymack Inc. described above, except that the bonus to Mr. Rock for meeting the targets of our clinical trials in a clinical trial as of Phase II is four (4) times his monthly fee and after completion of registration of our securities on a U.S. stock exchange the bonus to Mr. Rock shall be four (4) times the monthly fee and the measurable criteria for Mr. Rock includes a bonus in the amount of three (3) times the monthly fee for meeting our budget objectives.

Special bonus based on either a Merger Transaction, Fund Raise or a Commercialization Transaction. A special bonus equal to: (i) 4% of our valuation determined in a Merger Transaction payable in the same manner as the agreement with Waymack Inc. described above, provided that the bonus payable to Mr. Rock based on a Merger Transaction will not exceed $350,000; (ii) NIS 100,000 for each Fund Raise, provided however, in the event that a commission is paid to third parties, the total bonus paid to Mr. Rock, any other office holders and any third parties with respect thereto will not exceed 10% of the Fund Raise amount (gross); and (iii) 4% of the cumulative revenues actually received from a Commercialization Transaction, less any payments made to third parties, payable in the same manner as the agreement with Waymack Inc. described above, provided that the bonus payable to Mr. Rock based on a Commercialization Transaction will not exceed $350,000.

We may, by a resolution of the compensation committee (or the audit committee acting in lieu of a compensation committee pursuant to the Companies Law) and the board of directors, decrease and/or choose not to grant the annual bonus and/or the special bonus, in the manner described above regarding the Service Agreement with Waymack Inc.

In addition, in July 2014 we granted Mr. Rock 1,188,967 non-tradable options under our 2013 Option Plan to purchase 91,455 ordinary shares. Of these options: (a) 1,011,500 options to purchase 77,805 ordinary shares will vest pro rata on a monthly basis over a period of 18 months from the date of grant and will be exercisable at an exercise price of NIS 10.40 (approximately $2.75) per ordinary share for a period of three years commencing from the date of grant of the options; and (b) 177,467 options to purchase 13,651 ordinary shares vested as of the date of the grant and are exercisable at an exercise price of NIS 10.40 (approximately $2.75) per ordinary share and will have a term of three years from the date of grant. Following the attainment of the Milestone under the Share Transfer Agreement in connection with our Phase III trial for KIT-302, we were required to grant to Mr. Rock an additional 181,089 options to purchase 13,929 ordinary shares. See "Item 7. Major Shareholders and Related Party Transactions – B. Related Party Transactions – Share Transfer Agreement with Kitov Pharmaceuticals". These options will vest as of the date of grant and will be exercisable at an exercise price of NIS 10.40 (approximately $2.75) per ordinary share and will have a term of three years from the date of grant. Mr. Rock has waived the receipt of this option grant.

C. Board Practices

Board of Directors and Officers

Our board of directors consists of six directors, including Dr. Zeitoun and Ms. Sherf-Blau, who qualify as external directors and whose appointment fulfills the requirements of the Companies Law to have two external directors (see "Management − Board of Directors and Officers − External Directors"). These two directors, as well as Mr. Katzir, also qualify as independent directors under the corporate governance standards of the NASDAQ Listing Rules and the independence requirements of Rule 10A-3 of the Exchange Act.

Our directors (excluding external directors, if any are appointed) shall be nominated, and then appointed at our general meeting with a regular majority. The directors elected to serve (who are not external directors) are divided into three classes, with each class comprising one-third of the members of the board of directors (who are not external directors, if any were appointed), (hereinafter the "first class"; the "second class"; and the "third class"). If the number of directors is not equally divisible by three, each of the first class and the second class will be comprised of a different number, the closest and lowest to one-third, while the third class will be comprised of the remaining directors (who are not external directors, if any were appointed). The first division into thirds will be carried out in accordance with the board of director's decision in relation to the classification above, at the discretion of the board of directors. If the number of directors changes, the number of directors in each class will change in accordance with the aforesaid rule.

At our 2016 annual general meeting of shareholders, the term of appointment of the directors included in the first class shall end. At our 2017 annual general meeting of shareholders, the appointment of the directors included in the second class shall end. At our 2018 general meeting of shareholders, the appointment of the directors included in the third class shall end. In the annual general meeting that will take place each year, the annual general meeting shall be entitled to elect directors who shall be elected for a Three-Year Term to replace the class of directors whose term in office has expired as of such annual general meeting, and so on ad infinitum, so that the directors who shall be elected as stated above shall enter office at the end of the general meeting under which they were elected, unless a later date was decided at the time of the appointment, and shall serve for Three-Year Terms (unless their appointment will be terminated in accordance with the provisions of our amended and restated articles of association), and so that each year, the term in office of one of the classes of directors shall expire at the annual general meeting of such year. A "Three-Year Term" means a term of office of a director until the third annual general meeting which shall be held following the date of their election as director, provided that each director shall continue to serve in office until his successor is duly elected and qualified, or until his retirement, death, resignation or removal. Our board of directors has not yet carried out the first division into classes, and as such it is not yet certain which of the directors' terms of office will end by the 2016 annual general meeting.

Under our amended and restated articles of association, the number of directors on our board of directors will be no less than four and no more than 9 (including any external directors to the extent that external directors are required to be appointed under the Companies Law) ("Maximum Number"). The majority of the members of the board of directors shall be residents of Israel, unless our center of management shall have been transferred to another country in accordance with a resolution of the board of directors by a majority of three quarters (75%) of the participating director votes. The number of directors may be changed, at any time and from time to time, by the shareholders with a majority of (a) 75% of the voting rights participating and voting on the matter in the applicable general meeting and (b) more than 47.9% of all of the voting rights in the Company as of the record date established for the applicable general meeting ("Special Majority"). The board members may appoint a director at any time to fill any vacancies until the next annual meeting of the shareholders set to take place at the end of the Three-Year Term for the class of directors to which such director is so appointed by the Board ("Additional Director"), provided that the total number of the members of the board of directors serving at such time will not exceed the Maximum Number.

The shareholders may at all times, by a Special Majority vote of the shareholders, replace or dismiss a director (in the case of replacement, only if the appointed director is not a corporation). A director to be replaced shall be given a reasonable opportunity to address the shareholders at their meeting.

The tenure of a director expires pursuant to the provisions of our amended and restated articles of association and the Companies Law, upon death or if s/he becomes incompetent, unless removed from office as described above. Notwithstanding the foregoing, the term of office for external directors under Israeli law is three years.

In addition, 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 company and initiate debate regarding the manner in which financial information is presented. In determining the number of directors required to have such expertise, the 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 and that Mr. Rock (who also serves as our CFO), Mr. Katzir and Ms. Sherf-Blau are each deemed to have such expertise.

Alternate Directors

Our amended and restated articles of association provide, as allowed by the Companies Law, that any director may, at all times, appoint any person (which is not a corporation) by written notice to us to serve as an alternate director at a meeting of the board of directors. A person who is not qualified to be appointed as a director, a person who is already serving as a director or a person who is already serving as an alternate director for another director, may not be appointed as an alternate director, unless otherwise permitted by applicable law. A director who is already serving as a director may be appointed as an alternate director for a member of a committee of the board of directors so long as he or she is not already serving as a member of such committee, and if the alternate director is to replace an external director, he or she is required to be an external director and to have either "financial and accounting expertise" or "professional expertise," depending on the qualifications of the external director he or she is replacing. So long as the external director's appointment is valid, the alternate director shall be entitled to participate and vote in every meeting of the board of directors from which the appointing director is absent. Subject to the terms of appointment, the alternate director will be regarded as a director and shall have all of the authority of the director he or she is replacing. An appointing director may at any time cancel the appointment of an alternate director. The term of appointment of an alternate director will end if the appointing director notifies us in writing of the termination or cancellation of the appointment or if the appointing director's appointment is terminated.

External Directors

Qualifications of External Directors

Under the Companies Law, companies incorporated under the laws of the State of Israel that are "public companies," including Israeli companies with shares listed on NASDAQ, are required to appoint at least two external directors who meet the qualification requirements set forth in the Companies Law. Dr. Zeitoun and Ms. Sherf-Blau serve as our external directors.

A person may not serve as an external director if the person is a relative of a controlling shareholder or if on the date of the person's appointment or within the preceding two years the person or his or her relatives, partners, employers or anyone to whom that person is subordinate, whether directly or indirectly, or entities under the person's control have or had any affiliation with any of ("Affiliated Party"): (1) us; (2) any person or entity controlling us on the date of such appointment; (3) any relative of a controlling shareholder; or (4) any entity controlled, on the date of such appointment or within the preceding two years, by us or by a controlling shareholder. If there is no controlling shareholder or any shareholder holding 25% or more of voting rights in the company, a person may not serve as an external director if the person has any affiliation to the chairman of the board of directors, the general manager (chief executive officer), any shareholder holding 5% or more of the company's shares or voting rights or the senior financial officer as of the date of the person's appointment.

The term "controlling shareholder" means a shareholder with the ability to direct the activities of the company, other than by virtue of being an office holder. A shareholder is presumed to have "control" of the company and thus to be a controlling shareholder of the company if the shareholder holds 50% or more of the "means of control" of the company. "Means of control" is defined as (1) the right to vote at a general meeting of a company or a corresponding body of another corporation; or (2) the right to appoint directors of the corporation or its general manager. For the purpose of approving transactions with controlling shareholders, the term also includes any shareholder that holds 25% or more of the voting rights of the company if the company has no shareholder that owns more than 50% of its voting rights. 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 affiliation includes:

- an employment relationship;
- a business or professional relationship maintained on a regular basis;
- control; and
- service as an office holder, excluding service as a director in a private company prior to the first offering of its shares to the public 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.

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

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

A person may not serve as an external director if that person or that person's relative, partner, employer, a person to whom such person is subordinate (directly or indirectly) or any entity under the person's control has a business or professional relationship with any entity that has an affiliation with any Affiliated Party, even if such relationship is intermittent (excluding insignificant relationships). Additionally, any person who has received compensation intermittently (excluding insignificant relationships) other than compensation permitted under the Companies Law may not continue to serve as an external director.

No person can serve as an external director if the person's position or other affairs create, or may create, a conflict of interest with the person's responsibilities as a director or may otherwise interfere with the person's ability to serve as a director or if such a person is an employee of the Israeli Securities Authority or of an Israeli stock exchange. If at the time an external director is appointed all current members of the board of directors, who are not controlling shareholders or relatives of controlling shareholders, are of the same gender, then the external director to be appointed must be of the other gender. In addition, a person who is a director of a company may not be elected as an external director of another company if, at that time, a director of the other company is acting as an external director of the first company.

The Companies Law provides that an external director must meet certain professional qualifications or have financial and accounting expertise, and that at least one external director must have financial and accounting expertise. However, if at least one of our other directors (1) meets the independence requirements of the Exchange Act, (2) meets the standards of the NASDAQ Listing Rules for membership on the audit committee and (3) has financial and accounting expertise as defined in the Companies Law and applicable regulations, then neither of our external directors is required to possess financial and accounting expertise as long as both possess other requisite professional qualifications. The determination of whether a director possesses financial and accounting expertise is made by the board of directors. A director with financial and accounting expertise is a director who by virtue 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 so that he or she is able to fully understand our financial statements and initiate debate regarding the manner in which the financial information is presented.

The regulations promulgated under the Companies Law define an external director with requisite professional qualifications as a director who satisfies one of the following requirements: (1) the director holds an academic degree in either economics, business administration, accounting, law or public administration, (2) the director either holds an academic degree in any other field or has completed another form of higher education in the company's primary field of business or in an area which is relevant to his or her office as an external director in the company, or (3) the director has at least five years of experience serving in any one of the following, 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 substantial scope of business, (b) a senior position in the company's primary field of business or (c) a senior position in public administration.

Until the lapse of a two-year period from the date that an external director of a company ceases to act in such capacity, the company in which such external director served, and its controlling shareholder or any entity under control of such controlling shareholder may not, directly or indirectly, grant such former external director, or his or her spouse or child, any benefit, including via (i) the appointment of such former director or his or her spouse or his child as an officer in the company or in an entity controlled by the company's controlling shareholder, (ii) the employment of such former external director and (iii) the engagement, directly or indirectly, of such former external director as a provider of professional services for compensation, including via an entity under his or her control. With respect to a relative who is not a spouse or a child, such limitations shall only apply for one year from the date such external director ceased to be engaged in such capacity.

Election and Dismissal of External Directors

Under Israeli law, external directors are elected by a majority vote at a shareholders' meeting, provided that either:

- the majority of the shares that are voted at the meeting in favor of the election of the external director, excluding abstentions, include at least a majority of the votes of shareholders who are not controlling shareholders and do not have a personal interest in the appointment (excluding a personal interest that did not result from the shareholder's relationship with the controlling shareholder); or
- the total number of shares held by non-controlling shareholders or any one on their behalf that are voted against the election of the external director does not exceed two percent of the aggregate voting rights in the company.

Under Israeli law, the initial term of an external director of an Israeli public company is three years. The Companies Law provides that after an initial term of three years, external directors may be re-elected to serve in that capacity for up to two additional three year terms, provided that either: (i) (1) his or her service for each such additional term is recommended by one or more shareholders holding in aggregate at least 1% of the company's voting rights and is approved at a shareholders meeting by a majority of the shares held by non-controlling 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 for such purpose any abstentions, 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 (2) the external director who has been nominated in such fashion by the shareholders is not a "linked or competing shareholder", and does not have or has not had, on or within the two years preceding the date of such person's appointment to serve as another term as external director, any affiliation with a linked or competing shareholder. The term "linked or competing shareholder" means the shareholder(s) who nominated the external director for reappointment or a substantial shareholder of the company holding more than 5% of the shares in the company, provided that at the time of the reappointment, such shareholder(s) of the company, the controlling shareholder of such shareholder(s) of the company, or a company under such shareholder (s) of the company's control, has a business relationship with the company or are competitors of the company; (ii) 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 disinterested majority required for the initial election of an external director (as described above); or (iii) the external director has proposed himself for reappointment and the reappointment was approved as provided in sub-section (i) above. The term of office for external directors for Israeli companies traded on certain foreign stock exchanges, including NASDAQ, may be further extended, indefinitely, in increments of additional three-year terms, in each case provided that, in addition to re-election in such manner described above: (1) the audit committee and subsequently the board of directors of the company confirm that, in light of the external director's expertise and special contribution to the work of the board of directors and its committees, the re-election for such additional period is beneficial to the company; and (2) prior to the approval of the reelection of the external director, the company's shareholders have been informed of the term previously served by such nominee and of the reasons why the board of directors and audit committee recommended the extension of such nominee's term. An external director may be removed by the same special majority of the shareholders required for his or her election, if he or she ceases to meet the statutory qualifications for appointment or if he or she violates his or her fiduciary duty to the company. An external director may also be removed by order of an Israeli court if the court finds that the external director is permanently unable to exercise his or her office, has ceased to meet the statutory qualifications for his or her appointment, has violated his or her fiduciary duty to the company, or has been convicted by a court outside Israel of certain offenses detailed in the Companies Law.

If the vacancy of an external directorship causes a company to have fewer than two external directors, the company's board of directors is required under the Companies Law to call a special general meeting of the company's shareholders as soon as possible to appoint such number of new external directors so that the company thereafter has two external directors.

Additional Provisions Relating to External Directors

Under the Companies Law, each committee authorized to exercise any of the powers of the board of directors is required to include at least one external director and its audit and compensation committees are required to each include all of the external directors.

An external director is entitled to compensation and reimbursement of expenses in accordance with regulations promulgated under the Companies Law and is prohibited from receiving any other compensation, directly or indirectly, in connection with serving as a director except for certain exculpation, indemnification and insurance provided by the company, as specifically allowed by the Companies Law.

Audit Committee

Companies Law Requirements

Under the Companies Law, the board of directors of any public company must also appoint an audit committee comprised of at least three directors, including all of the external directors. The chairman of the audit committee must be an external director. The audit committee may not include:

- the chairman of the board of directors;
- a controlling shareholder or a relative of a controlling shareholder;
- any director employed by us or by one of our controlling shareholders or by an entity controlled by our controlling shareholders (other than as a member of the board of directors); or
- any director who regularly provides services to us, to one of our controlling shareholders or to an entity controlled by our controlling shareholders.

According to the Companies Law, the majority of the members of the audit committee, as well as the majority of members present at audit committee meetings, will be required to be "unaffiliated" under the Companies Law (as defined below) and the chairman of the audit committee will be required to be an external director. Any persons disqualified from serving as a member of the audit committee may not be present at the audit committee meetings, unless the chairman of the audit committee has determined that such person is required to be present at the meeting or if such person qualifies under one of the exemptions of the Companies Law.

The term "unaffiliated director" is defined under the Companies Law as either an external director or an "unaffiliated director" who meets the following conditions and who is appointed or classified as such according to the Companies Law: (1) the conditions for his or her appointment as an external director (as described above) are satisfied and the audit committee approves the director having met such conditions and (2) he or she has not served as a director of the company for over nine consecutive years with any interruption of up to two years of his or her service not being deemed a disruption to the continuity of his or her service.

Under the NASDAQ Listing Rules, we are required to maintain an audit committee consisting of at least three independent directors, all of whom are financially literate and one of whom has accounting or related financial management expertise.

Each of the members of the audit committee is required to be "independent" as such term is defined in Rule 5605(a)(2) of the NASDAQ Listing Rules and in Rule 10A-3(b)(1) under the Exchange Act, which is different from the general test for independence of board and committee members. The independence requirements of the Exchange Act implement two basic criteria for determining independence: (1) audit committee members are barred from accepting directly or indirectly any consulting, advisory or other compensatory fee from the issuer or an affiliate of the issuer, other than in the member's capacity as a member of the board of directors and any board committee, and (2) audit committee members may not be an "affiliated person" of the issuer or any subsidiary of the issuer apart from her or his capacity as a member of the board of directors and any board committee. The SEC has defined "affiliate" for non-investment companies as "a person that directly, or indirectly through one or more intermediaries, controls, or is controlled by, or is under common control with, the person specified." The term "control" is intended to be consistent with the other definitions of this term under the Exchange Act as "the possession, direct or indirect, of the power to direct or cause the direction of the management and policies of a person, whether through the ownership of voting securities, by contract, or otherwise."

Audit Committee Role

Under the Companies Law, our audit committee:

- recommends to the board of directors to recommend to our shareholders to appoint and approve the compensation of the independent registered public accounting firm engaged to audit our financial statements;
- monitors deficiencies in the management of the Company, inter alia, in consultation with the independent registered public accounting firm and internal auditor, and advises the board of directors on how to correct such deficiencies;
- decides whether to approve and recommend to the board of directors to approve engagements or transactions that require the audit committee's approval under the Companies Law relating generally to certain related party transactions. The audit committee must pre-determine procedures for a competitive process, or other procedures, before approving related party transactions with controlling shareholders, even if such transactions are deemed by the audit committee not to be extraordinary transactions. This process is to be supervised by the audit committee, or any person authorized for such supervision, or via any other method approved by the audit committee;
- decides as to what transactions shall be considered as "extraordinary transactions" as such term is defined under the Companies Law in connection with related party transaction;
- determines the approval process for transactions that are not negligible, as well as determine which types of transactions would require the approval of the audit committee. Non-negligible transactions are defined as related party transactions with a controlling shareholder, or in which the controlling shareholder has a personal interest, even if they are deemed by the audit committee not to be extraordinary transactions but which have also been classified by the audit committee as non-negligible transactions;
- meets and receives reports from both the internal auditors and the independent registered public accounting firm dealing with matters that arise in connection with their audits; and
- regulates the company's rules on employee complaints, and implementing a whistleblower protection plan with respect to employee complaints of business irregularities.

In accordance with the Sarbanes-Oxley Act of 2002 and the NASDAQ Listing Rules, the audit committee is also directly responsible for the appointment, compensation and performance of our independent auditors, and pre-approves audit and non-audit services to be provided by the independent auditors. In addition, the audit committee is responsible for assisting the board of directors in reviewing our annual financial statements, the adequacy of our internal controls and our compliance with legal and regulatory requirements. The audit committee also oversees our major financial risk exposures and policies for managing such potential risks, discusses with management and our independent auditor significant risks or exposure and assesses the steps management has taken to minimize such risk.

Our board of directors has adopted an audit committee charter setting forth the responsibilities of the audit committee, which are consistent with the provisions of the Companies Law, rules and regulations of the SEC and the NASDAQ Listing Rules.

Approval of Transactions with Related Parties

The approval of the audit committee (or under certain circumstances the compensation committee) is required to effect specified actions and transactions with office holders and controlling shareholders and their relatives, or in which they have a personal interest. The audit committee may not approve an action or a transaction with a controlling shareholder or with an office holder unless at the time of approval the audit committee meets the composition requirements under the Companies Law.

Our audit committee consists of Mr. Katzir, Dr. Zeitoun and Ms. Sherf-Blau. Ms. Sherf-Blau serves as the chairman of the audit committee. All members of our audit committee meet the requirements for financial literacy under the applicable rules and regulations of the SEC and the NASDAQ Listing Rules. Our board of directors has determined that Ms. Sherf-Blau and Mr. Katzir are audit committee financial experts as defined by the SEC rules and have the requisite financial experience as defined by the NASDAQ Listing Rules.

Compensation Committee

Amendment No. 20 to the Companies Law, which became effective as of December 2012 ("Amendment No. 20"), established new regulations relating to the terms of office and employment of directors and officers in Israeli public companies and companies that have publicly issued debentures. Such companies are required to appoint a compensation committee in accordance with the guidelines set forth in the Companies Law.

The compensation committee must comply with the following requirements (the "Israeli Compensation Committee Composition Requirements"):

i. The compensation committee must consist of at least three members;
ii. All of the external directors must serve on the committee and constitute a majority of its members;
iii. The chairman of the compensation committee must be an external director;
iv. The remaining members need not be external directors but must be directors who qualify to serve as members of the audit committee (as described above); and
v. The provisions of the Companies Law and Regulations that govern the compensation and reimbursement terms of external directors must also apply to members of the compensation committee who are not external directors.

In accordance with the Companies Law, the roles of the compensation committee are, among others, as follows:

- to recommend to the board of directors the compensation policy for directors and officers, and to recommend to the board of directors once every three years whether the compensation policy that had been approved should be extended for a period of more than three years;

- to recommend to the board of directors updates to the compensation policy, from time to time, and examine its implementation;

- to decide whether to approve the terms of office and employment of directors and officers that require approval of the compensation committee; and

- to decide whether the compensation terms of the chief executive officer of the company which were determined pursuant to the compensation policy need not be brought for approval of the shareholders because it will harm the ability to engagement with the chief executive officer.

Under Amendment 27 to the Companies Law, which became effective as of February 17, 2016, the audit committee of an Israeli public company which meets the Israeli Compensation Committee Composition Requirements is permitted to act as the compensation committee of the company in lieu of having a separate committee. Our audit committee presently meets this requirement and on March 16, 2016 our board of directors resolved to have the audit committee assume the responsibilities of the compensation committee pursuant to this new provision in the Companies Law. Henceforth, and for so long as our audit committee also meets the Israeli Compensation Committee Composition Requirements or until our board of directors determines otherwise, our audit committee will act in lieu of a compensation committee with respect to all of the roles and responsibilities of a compensation committee. The members of the compensation committee until it was disbanded were Dr. Zeitoun, Ms. Sherf-Blau and Mr. Serlin (until the end of his term as a director).

In addition to the roles mentioned above our audit committee will also make recommendations to our board of directors regarding the awarding of employee equity grants.

Compensation Policy

In accordance with the provisions of Amendment No. 20, public companies must adopt a compensation policy with respect to the terms of service and employment of their directors and officers. The compensation policy must be approved by the compensation committee (or the audit committee acting in lieu of a compensation committee pursuant to the Companies Law) and board of directors, and subject to limited exceptions, by the shareholders. Shareholder approval requires one of the following: (i) the majority of shareholder votes counted at general meeting including the majority of all of the votes of those shareholders who are non-controlling shareholders and do not have a personal interest in the approval of the compensation policy, who participate at the meeting (excluding abstentions) or (ii) the total number of votes against the proposal among the shareholders mentioned in paragraph (i) does exceed two percent (2%) of the voting rights in the company. Under special circumstances, the board of directors may approve the compensation policy despite the objection of the shareholders on the condition that the compensation committee (or the audit committee acting in lieu of a compensation committee pursuant to the Companies Law) and then the board of directors decide, on the basis of detailed arguments and after discussing again the compensation policy, that approval of the compensation policy, despite the objection of the meeting of shareholders, is for the benefit of the company.

On January 12, 2014, our shareholders approved our compensation policy (as amended by our shareholders on November 20, 2014, the "Compensation Policy") which will be in effect for a period of three years from the date of approval. The Compensation Policy does not, on its own, grant any rights to our directors or officers. The Compensation Policy includes both long term and short term compensation elements and is to be reviewed from time to time by our compensation committee (or the audit committee acting in lieu of a compensation committee pursuant to the Companies Law) and board, according to the requirements of the Companies Law.

In general, compensation for officers will be examined while taking into consideration the following parameters, including, among others (i) education, qualifications, expertise, seniority (with us in particular, and in the officer's profession in general), professional experience and achievements of the officer; (ii) meeting by the officer of the targets set for him, if relevant; (iii) the officer's position, the scope of his responsibility and previous wage agreements that were signed with him; and (iv) the ratio between the total cost of the proposed engagement terms of an officer and the total cost of the wages for all of our other employees, officers and contractors, and in particular compared to the average or median wage of such employees, officers and contractors and the effect of this ratio and difference, if any, on labor relations.

Under the Compensation Policy, we are entitled to provide a compensation package to officers which may include fixed salary (a base salary and ancillary benefits), annual cash bonus and share-based compensation, or any combination thereof, and additional standard benefits ("Compensation Package"). An unofficial English translation of the full text of our Compensation Policy is attached to this Annual Report on Form 20-F as Exhibit 4.9.

Financial Statement Examination Committee

Under the Companies Law and the Companies Regulations (Conditions for Approval of Financial Statements), 5770 - 2010, the board of directors of a public company traded on the TASE 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. The function of a financial statements examination committee is to discuss and provide recommendations to the board of directors (including the report of any deficiency found) with respect to the following issues: (i) estimations and assessments made in connection with the preparation of financial statements; (ii) internal controls related to the financial statements; (iii) completeness and propriety of the disclosure in the financial statements; (iv) the accounting policies adopted and the accounting treatments implemented in material matters of the company; and (v) valuations, including assumptions and estimates, on which information provided in the financial reporting is based. The committee may also examine the independent registered public accounting firm's scope of work and compensation. Following our initial offering in the U.S. and listing of our securities on NASDAQ, and consistent with the provision in such regulation that the Companies Regulations (Conditions for Approval of Financial Statements), 5770 - 2010 do not apply to a company whose securities are traded on certain foreign exchanges such as NASDAQ, and in light of the fact that in accordance with the Sarbanes-Oxley Act of 2002 and the NASDAQ Listing Rules, the audit committee is directly responsible for the appointment, compensation and performance of our independent auditors, and for assisting the board of directors in reviewing our annual financial statements, the adequacy of our internal controls and our compliance with legal and regulatory requirements, our board of directors resolved in February 2016 to disband the financial statement examination committee, and directed that the activities performed previously by such committee will going forward be performed by our Audit Committee. The members of the financial statement examination committee until the date it was disbanded were Dr. Zeitoun, Ms. Sherf-Blau and Mr. Serlin.

Investment Committee

Our board of directors has established an investment committee in order to oversee the management and investment of the Company's cash and cash equivalents. This committee meets on an ad hoc basis as required and is empowered to establish guidelines and policies, as well as to make decisions, with respect to managing our financial assets. Since its establishment and to date, Mr. Simcha Rock coordinates the management of the committee. The present members of the committee are Mr. Rock, Mr. Katzir and Ms. Sherf-Blau. The investment committee provides periodic updates to the Board of Directors as required under the Companies Law.

Internal Auditor

Under the Companies Law, the board of directors of a public company must appoint an internal auditor based on the recommendation of the audit committee. The role of the internal auditor is, among other things, to examine whether a company's actions comply with applicable law and orderly business procedure. Under the Companies Law, the internal auditor may not be a related party or an office holder or a relative of a related party or of an office holder, nor may the internal auditor be the company's independent auditor or the representative of the same.

A "related party" is defined in the Companies Law as (i) a holder of 5% or more of the issued share capital or voting power in a company, (ii) any person or entity who has the right to designate one or more directors or to designate the chief executive officer of the company, or (iii) any person who serves as a director or as a chief executive officer of the company. Our internal auditor is Pinhas Bar-Shmuel, certified public accountant (Isr.).

Fiduciary Duties and Approval of Specified Related Party Transactions and Compensation under Israeli Law

Fiduciary Duties of Office Holders

The Companies Law imposes a duty of care and a fiduciary duty on all office holders of a company. The duty of care of an office holder is based on definition of negligence under the Israeli Torts Ordinance (New Version) 5728-1968. This duty of care requires an office holder to act with the degree of proficiency with which a reasonable office holder in the same position would have acted under the same circumstances. The duty of care includes, among other things, a duty to use reasonable means, in light of the circumstances, to obtain:

- information on the business 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 such action.

The fiduciary duty incumbent on an office holder requires him or her to act in good faith and for the benefit of the company, and includes, among other things, the duty to:

- refrain from any act involving a conflict of interest between the performance of his or her duties in the company and his or her other duties or personal affairs;
- refrain from any activity that is competitive with the business of the company;
- refrain from exploiting any business opportunity of the company for the purpose of gaining a personal advantage 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 fiduciary duty, 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 time before the approval of such act. Any such approval is subject to the terms of the Companies Law, setting forth, among other things, the appropriate corporate bodies of the company entitled to provide such approval, and the methods of obtaining such approval.

Disclosure of Personal Interests of an Office Holder and Approval of Transactions

The Companies Law requires that an office holder promptly disclose to the company any personal interest that he or she may have and all related material information or documents relating to any existing or proposed transaction by the company. An interested office holder's disclosure must be made promptly and in any event no later than the first meeting of the board of directors at which the transaction is considered. An office holder is not obliged to disclose such information if the personal interest of the office holder 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, once an office holder has complied with the above disclosure requirement, a company may approve a transaction between the company and the office holder or a third party in which the office holder has a personal interest. However, a company may not approve a transaction or action that is not to the company's benefit.

Under the Companies Law, unless the articles of association of a company provide otherwise, a transaction with an office holder or with a third party in which the office holder has a personal interest, which is not an extraordinary transaction, requires approval by the board of directors. The Companies Law provides that such a transaction, which is not an extraordinary transaction, may be approved by the board of directors or a committee of the board of directors or any other entity (which has no personal interest in the transaction) authorized by the board of directors. Our amended and restated articles of association provide that transactions in which officers have a personal interest but not extraordinary transactions can be approved by our chief executive officer and chief financial officer (unless they have the personal interest; in which case it will be one of our directors instead of such interested officer). If the transaction considered is an extraordinary transaction with an office holder or third party in which the office holder has a personal interest, then audit committee approval is required prior to approval by the board of directors. For the approval of compensation arrangements with directors and executive officers, see "Item 6. Directors, Senior Management and Employees – B. Compensation ."

Any persons who have a personal interest in the approval of a transaction that is brought before a meeting of the board of directors or the audit committee may not be present at the meeting or vote on the matter. However, if the chairman of the board of directors or the chairman of the audit committee has determined that the presence of an office holder with a personal interest is required, such office holder may be present at the meeting for the purpose of presenting the matter. Notwithstanding the foregoing, a director who has a personal interest may be present at the meeting and vote on the matter if a majority of the directors or members of the audit committee have a personal interest in the approval of such transaction. If a majority of the directors at a board of directors meeting have a personal interest in the transaction, such transaction also requires approval of the shareholders of the company.

A "personal interest" is defined under the Companies Law as the personal interest of a person in an action or in a transaction of the company, including the personal interest of such person's relative or the interest of any other corporate body in which the person or such person's relative is a director or general manager, a 5% shareholder or holds 5% or more of the voting rights, or has the right to appoint at least one director or the general manager, but excluding a personal interest stemming solely from the fact of holding shares in the company. A personal interest also includes (1) a personal interest of a person who votes according to a proxy of another person, including in the event that the other person has no personal interest, and (2) a personal interest of a person who gave a proxy to another person to vote on his or her behalf regardless of whether the discretion of how to vote lies with the person voting or not.

An "extraordinary transaction" is defined under the Companies Law 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 the company's profitability, assets or liabilities.

Disclosure of Personal Interests of a Controlling Shareholder and Approval of Transactions

The Companies Law also requires that a controlling shareholder promptly disclose to the company any personal interest that he or she may have and all related material information or documents relating to any existing or proposed transaction by the company. A controlling shareholder's disclosure must be made promptly and in any event no later than the first meeting of the board of directors at which the transaction is considered. 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 of the company, directly or indirectly, with a controlling shareholder or a controlling shareholder's relative (including through a corporation controlled by a controlling shareholder), regarding the company's receipt of services from the controlling shareholder, and if such controlling shareholder is also an office holder of the company, regarding his or her terms of employment, require the approval of each of (i) the audit committee or the compensation committee with respect to the terms of the engagement of the company, (ii) the board of directors and (iii) the shareholders, in that order. In addition, the shareholder approval must fulfill one of the following requirements:

- a majority of the shares held by shareholders who have no personal interest in the transaction and are voting at the meeting must be voted in favor of approving the transaction, excluding abstentions; or
- the shares voted by shareholders who have no personal interest in the transaction who vote against the transaction represent no more than 2% of the voting rights in the company.

In addition, any extraordinary transaction with a controlling shareholder or in which a controlling shareholder has a personal interest with a term of more than three years requires the abovementioned approval every three years, however, such transactions not involving the receipt of services or compensation can be approved for a longer term, provided that the audit committee determines that such longer term is reasonable under the circumstances.

The Companies Law requires that every shareholder that participates, in person, by proxy or by voting instrument, in a vote regarding a transaction with a controlling shareholder or in which such has a personal interest, must indicate in advance or in the ballot whether or not that shareholder has a personal interest in the vote in question. Failure to so indicate will result in the invalidation of that shareholder's vote.

Compensation of Directors and Executive Officers

Directors. Under Amendment No. 20, the compensation of our directors requires the approval of our compensation committee (or the audit committee acting in lieu of a compensation committee pursuant to the Companies Law), the subsequent approval of the board of directors and, unless exempted under the regulations promulgated under the Companies Law, the approval of the shareholders at a general meeting. If the compensation of our directors is inconsistent with our stated compensation policy, then, provided that those provisions that must be included in the compensation policy according to the Companies Law have been considered by the compensation committee (or the audit committee acting in lieu of a compensation committee pursuant to the Companies Law) and board of directors, shareholder approval will also be required, as follows:

- at least a majority of the shares held by all shareholders who are not controlling shareholders and do not have a personal interest in such matter, present and voting at such meeting, are voted in favor of the compensation package, excluding abstentions; or
- the total number of shares of non-controlling shareholders and shareholders who do not have a personal interest in such matter voting against the compensation package does not exceed 2% of the aggregate voting rights in the company.

Executive Officers Other Than the Chief Executive Officer. The Companies Law requires the compensation of a public company's executive officers (other than the chief executive officer) to be approved by, first, the compensation committee (or the audit committee acting in lieu of a compensation committee pursuant to the Companies Law), second, by the company's board of directors and third, if such compensation arrangement is inconsistent with the company's stated compensation policy, the company's shareholders (by a special majority vote as discussed above with respect to the approval of director compensation). However, if the shareholders of the company do not approve a compensation arrangement with an executive officer that is inconsistent with the company's stated compensation policy, the compensation committee (or the audit committee acting in lieu of a compensation committee pursuant to the Companies Law) and board of directors may override the shareholders' decision if each of the compensation committee (or the audit committee acting in lieu of a compensation committee pursuant to the Companies Law) and the board of directors provide detailed reasons for their decision.

Chief Executive Officer. The compensation paid to a public company's chief executive officer is required to be approved by, first, the company's compensation committee (or the audit committee acting in lieu of a compensation committee pursuant to the Companies Law); second, the company's board of directors, and third, the company's shareholders (by a special majority vote as discussed above with respect to the approval of director compensation). However, if the shareholders of the company do not approve the compensation arrangement with the chief executive officer, the compensation committee (or the audit committee acting in lieu of a compensation committee pursuant to the Companies Law) and board of directors may override the shareholders' decision if each of the compensation committee (or the audit committee acting in lieu of a compensation committee pursuant to the Companies Law) and the board of directors provide a detailed report for their decision.

The compensation committee (or the audit committee acting in lieu of a compensation committee pursuant to the Companies Law) and board of directors approval should be in accordance with the company's stated compensation policy; however, in special circumstances, they may approve compensation terms of a chief executive officer that are inconsistent with such policy provided that they have considered those provisions that must be included in the compensation policy according to the Companies Law and that shareholder approval was obtained (by a special majority vote as discussed above with respect to the approval of director compensation). The compensation committee (or the audit committee acting in lieu of a compensation committee pursuant to the Companies Law) may waive the shareholder approval requirement with regards to the approval of the initial engagement terms of a candidate for the chief executive officer position, if they determine that the compensation arrangement is consistent with the company's stated compensation policy, and that the chief executive officer did not have a prior business relationship with the company or a controlling shareholder of the company and that subjecting the approval of the engagement to a shareholder vote would impede the company's ability to employ the chief executive officer candidate.

Duties of Shareholders

Under the Companies Law, a shareholder has a duty to refrain from abusing its power in the company and to act in good faith and in an acceptable manner in exercising its rights and performing its obligations to the company and other shareholders, including, among other things, when voting at meetings of shareholders on the following matters:

- an amendment to the articles of association;
- an increase in the company's authorized share capital;
- a merger; and
- the approval of related party transactions and acts of office holders that require shareholder approval.

A shareholder also has a general duty to refrain from discriminating against other shareholders.

The remedies generally available upon a breach of contract will also apply to a breach of the shareholder duties mentioned above, and in the event of discrimination against other shareholders, additional remedies are available to the injured shareholder.

In addition, any controlling shareholder, any shareholder that knows that its vote can determine the outcome of a shareholder vote and any shareholder that, under a company's articles of association, has the power to appoint or prevent the appointment of an office holder, or any other power with respect to a company, is under a duty to act with fairness towards the company. The Companies Law does not describe the substance of this duty 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, taking the shareholder's position in the company into account.

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 a fiduciary duty. 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 and restated articles of association include such a provision. The company may not exculpate in advance a director from liability arising out of a prohibited dividend or distribution to shareholders.

Under the Companies Law and the Securities Law, 5738 – 1968 ("Securities Law") a company may indemnify an office holder in respect of the following liabilities, payments and expenses incurred for acts performed by him or her as an office holder, either in advance of an event or following an event, provided its articles of association include a provision authorizing such indemnification:

- a monetary liability incurred by or 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 reasonable attorneys' fees, incurred by the office holder 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 or in connection with a monetary sanction;
- a monetary liability imposed on him or her in favor of a payment for a breach offended at an Administrative Procedure (as defined below) as set forth in Section 52(54)(a)(1)(a) to the Securities Law;

- expenses associated with an Administrative Procedure conducted regarding an office holder, including reasonable litigation expenses and reasonable attorneys' fees; and
- 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.

An "Administrative Procedure" is defined as a procedure pursuant to chapters H3 (Monetary Sanction by the Israeli Securities Authority), H4 (Administrative Enforcement Procedures of the Administrative Enforcement Committee) or I1 (Arrangement to prevent Procedures or Interruption of procedures subject to conditions) to the Securities Law.

Under the Companies Law and the 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 a fiduciary duty 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 duty of care to the company or to a third party, to the extent such a breach arises out of the negligent conduct of the office holder;
- a monetary liability imposed on the office holder in favor of a third party;
- a monetary liability imposed on the office holder in favor of an injured party at an Administrative Procedure pursuant to Section 52(54)(a)(1)(a) of the Securities Law; and
- expenses incurred by an office holder in connection with an Administrative Procedure, including reasonable litigation expenses and reasonable attorneys' fees.

Under the Companies Law, a company may not indemnify, exculpate or insure an office holder against any of the following:

- a breach of fiduciary duty, except for indemnification and insurance for a breach of the fiduciary duty 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 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 or forfeit levied against the office holder.

Under the Companies Law, exculpation, indemnification and insurance of office holders must be approved by the compensation committee (or the audit committee acting in lieu of a compensation committee pursuant to the Companies Law) and the board of directors and, with respect to directors or controlling shareholders, their relatives and third parties in which such controlling shareholders have a personal interest, also by the shareholders.

Our amended and restated articles of association permit us to exculpate, indemnify and insure our office holders to the fullest extent permitted or to be permitted by law. Our office holders are currently covered by a directors' and officers' liability insurance policy.

We have entered into agreements with each of our current office holders exculpating them from a breach of their duty of care to us to the fullest extent permitted by law, subject to limited exceptions, and undertaking to indemnify them to the fullest extent permitted by law, subject to limited exceptions, including with respect to liabilities resulting from our Registration Statement on Form F-1 filed in connection with our initial public offering in the U.S. during November 2015, to the extent that these liabilities are not covered by insurance. This indemnification is limited to events determined as foreseeable by the board of directors based on our activities, and to an amount or according to criteria determined by the board of directors as reasonable under the circumstances. The maximum aggregate amount of indemnification that we may pay to our office holders based on such indemnification agreement is with respect to all permitted indemnification, including in connection with a public offering of our securities, an amount equal to 25% of our shareholders' equity on a consolidated basis, based on our most recent financial statements made publicly available before the date on which the indemnification payment was made. Such indemnification amounts are in addition to any insurance amounts. Each office holder who agrees to receive this letter of indemnification also gives his approval to the termination of all previous letters of indemnification that we have provided to him or her in the past, if any.

Insofar as indemnifications for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling the registrant pursuant to the foregoing provisions, the registrant has been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

To our knowledge, other than with respect to the Motion described further in "Item 8. Financial Information – A. Financial Statements and Other Financial Information – Legal Proceedings", there is no pending litigation or proceeding against any of our office holders as to which indemnification is being sought, nor are we aware of any pending or threatened litigation that may result in claims for indemnification by any office holder.

D. Employees

As of December 31, 2015 and 2014, we had: (i) four consultants and service providers providing management and financial services, including our chief financial officer and our chairman of the board, who also fulfills duties and responsibilities of chief medical officer; (ii) one employee serving as our chief executive officer; (iii) one employee providing in-house legal services; and (iv) four consultants providing research and development services. As of December 31, 2013, we had (i) five consultants and service providers providing management and financial services, including our chief executive officer, our chief financial officer, and our chairman of the board, who also fulfills duties and responsibilities of chief medical officer; and (ii) two consultants providing research and development services.

While none of our employees is party to a collective bargaining agreement, in Israel we are subject to certain labor statutes and national labor court precedent rulings, as well as to certain provisions of the collective bargaining agreements between the Histadrut (General Federation of Labor in Israel) and the Coordination Bureau of Economic Organizations including the Industrialists' Associations. These provisions of collective bargaining agreements are applicable to our Israeli employees by virtue of extension orders issued in accordance with relevant labor laws by the Israeli Ministry of Labor and Welfare, and which apply such agreement provisions to our employees even though they are not directly part of a union that has signed a collective bargaining agreement. The laws and labor court rulings that apply to our employees principally concern the minimum wage laws, procedures for dismissing employees, determination of severance pay, leaves of absence (such as annual vacation or maternity leave), sick pay and other conditions for employment. The extension orders which apply to our employees principally concern the requirement for length of the work day and workweek, mandatory contributions to a pension fund, annual recreation allowance, travel expenses payment and other conditions of employment. We generally provide our employees with benefits and working conditions beyond the required minimums.

Israeli law generally requires severance pay, which may be funded by managers' insurance and/or a pension fund described below, upon the retirement or death of an employee or termination of employment without cause (as defined in the law). Furthermore, Israeli employees and employers are required to pay predetermined sums to the National Insurance Institute, which is similar to the United States Social Security Administration. Such amounts also include payments for national health insurance. A general practice also followed by us is the contribution of funds on behalf of most of our employees either to a fund known as managers' insurance, to a pension fund or to a combination of both.

We have never experienced labor-related work stoppages or strikes and believe that our relations with our employees are satisfactory.

E. Share Ownership

The following table sets forth information with respect to the beneficial ownership of our ordinary shares as of March 15, 2016 by:

- each of our directors, executive officers and senior management and employees individually; and
- all of our executive officers, directors, and senior management and employees as a group.

The beneficial ownership of our ordinary shares in this table is determined in accordance with the rules of the SEC. Under these rules, a person is deemed to be a beneficial owner of a security if that person has or shares voting power, which includes the power to vote or to direct the voting of the security, or investment power, which includes the power to dispose of or to direct the disposition of the security. For purposes of the table below, we deem ordinary shares issuable pursuant to options or warrants that are currently exercisable or exercisable within 60 days of March 15, 2016, if any, 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 ordinary shares beneficially owned is based on 78,075,620 ordinary shares as of March 15, 2016 (not including 21 shares held in treasury).

Unless otherwise noted below, each shareholder's address is c/o Kitov Pharmaceuticals Holdings Ltd., One Azrieli Center, Round Building, Tel Aviv, 6701101, Israel.

	Shares Beneficially Owned	
Name of Beneficial Owner	**Number**	**Percentage**
Directors		
Dr. John Paul Waymack [(1)]	2,214,969	2.84%
Isaac Israel	15,385	*%
Simcha Rock [(2)]	99,148	*%
Moran Sherf-Blau	0	*%
Alain Zeitoun	0	*%
Yair Katzir	0	*%
Senior Management and Employees		
Gil Ben-Menachem	0	*%
Avraham Ben-Tzvi	*	*%
Total (directors, senior management and employees)	**2,335,602**	**2.98%**

* Less than 1%

(1) Includes 2,184,431 ordinary shares held directly by JPW PCH LLC, a Virginia limited liability company, owned 51% by Dr. John Paul Waymack and 30,538 ordinary shares held directly by Dr. John Paul Waymack. Dr. John Paul Waymack may be deemed to beneficially own all of the shares held directly by JPW PCH LLC.

(2) Includes 91,455 ordinary shares issuable upon exercise of outstanding options currently exercisable. The exercise price of these options is NIS 10.40 per share and the options expire in July 2017**.**

2013 Option Plan

On November 27, 2013, we adopted the 2013 Kitov Pharmaceutical Holdings Ltd. Stock Option Allocation Plan, or the 2013 Option Plan. The 2013 Option Plan provides for the granting of options to our directors, officers, employees and consultants and to the directors, officers, employees and consultants of our subsidiaries and affiliates. The 2013 Option Plan provides for options to be granted at the determination of our board of directors (who is entitled to delegate its powers under the 2013 Option Plan to the Company's compensation committee) in accordance with applicable laws. The exercise price and vesting period are determined by our board of directors. As of March 15, 2016, there were 2,233,753 non-tradable options exercisable into 213,657 ordinary shares issuable upon the exercise of outstanding options under the 2013 Option Plan.

The 2013 Option Plan will be effective up to the earliest of (a) its cancellation by the board of directors and (b) October 31, 2023. Nevertheless, options granted up to the 2013 Option Plan's expiration date, whether vested or not vested up to that date, will remain effective and will not expire prior to their expiration date (within 10 (ten) years from the allocation date).

Upon termination of employment for any reason, other than in the event of death or for cause, all unvested options will expire and all vested options at time of termination will generally be exercisable for 90 days following termination, subject to the terms of the 2013 Option Plan and the governing option agreement. If we terminate a grantee for cause (as defined in the 2013 Option Plan) the grantee's right to exercise all vested and unvested the options granted to him will expire immediately. Upon termination of employment due to death, all the vested options at the time of termination will be exercisable by the grantee's heirs or estate, for twelve (12) months from the latest of: (i) death or (ii) option expiration date, subject to the terms of the 2013 Option Plan and the governing option agreement.

The 2013 Option Plan enables us to grant options through one of the following tax programs, at our discretion and subject to the applicable legal limitations: (a) according to section 102 of the Israeli Income Tax Ordinance, through a program with a trustee that is appointed by us or (b) according to the provisions of section 3(i) in the Israeli Income Tax Ordinance.

The 2013 Option Plan includes directives for protecting the option holders during the exercise period with respect to distribution of bonus stock, issue of rights, splitting or consolidating our share capital and dividend distribution. We will be entitled at our sole discretion, to change the terms of the 2013 Option Plan and/or replace it and/or terminate it regarding future grants at any time, as we deem appropriate. It is also clarified that we will be entitled to change the terms of 2013 Option Plan regarding grants that were granted to the grantees, provided that the terms of the options which were already granted will not be changed in a way that may materially impair the rights of the grantees, without the consent of the grantees. Our board of directors will determine, at its sole discretion, if a certain change may materially impair the rights of the grantee.

Without limiting the foregoing, in every case of a material event whereby (i) we will become a private company with shares no longer be traded on a stock exchange; (ii) there occurs a restructuring, including merger transaction in which we are not the surviving corporation or as a result of which there is a change in control; (iii) there occurs an arrangement between us and our creditors and/or shareholders and/or option holders; (iv) there occurs the sale of all or a substantial part of our assets; or (v) there occurs our liquidation, the board of directors, in its sole discretion, may adjust and change the terms of the options according to the plan for all the grantees or to certain grantees, in its sole discretion, including by (i) accelerating the vesting period of unvested options and (ii) replacing vested options with securities of the purchaser or any party related to the purchaser or other compensation to the grantee. Unless otherwise determined by the board of directors, non-vested options will expire soon before the material event or will be exercised, according to the decision of the board of directors. The board of directors will have the right to require the grantees to exercise all the vested options, soon before the occurrence of the material event and any option that will not be exercised will expire and will be devoid of any value.

Administration of Our 2013 Option Plan

Our 2013 Option Plan is administered by our board of directors, regarding the granting of options and the terms of option grants, including exercise price, method of payment, vesting schedule, acceleration of vesting and the other matters necessary in the administration of these plans. Options granted under the 2013 Option Plan to eligible Israeli employees, officers and directors are granted under Section 102 of the Israel Income Tax Ordinance pursuant to which the options or the ordinary shares issued upon their exercise must be allocated or issued to a trustee and be held in trust for two years from the date upon which such options were granted in order to benefit from the provisions of Section 102. Under Section 102, any tax payable by an employee from the grant or exercise of the options is deferred until the transfer of the options or ordinary shares by the trustee to the employee or upon the sale of the options or ordinary shares, and gains may qualify to be taxed as capital gains at a rate equal to 25%, subject to compliance with specified conditions.

Form S-8 registration statements

We intend to file one or more registration statements on Form S-8 under the Securities Act to register our ordinary shares issued or reserved to be issued under our 2013 Option Plan. The registration statement on Form S-8 will become effective automatically upon filing. Ordinary shares issued upon exercise of a share option or other award and registered pursuant to the Form S-8 registration statement will, subject to vesting provisions and Rule 144 volume limitations applicable to our affiliates, be available for sale in the open market immediately unless they are subject to the 180-day lock-up or, if subject to the lock-up, immediately after the 180-day lock-up period expires.

ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

A. Major Shareholders

The following table sets forth information with respect to the beneficial ownership of our ordinary shares as of March 15, 2016 by each person or entity known by us to own beneficially more than 5% of our outstanding ordinary shares.

The beneficial ownership of our ordinary shares in this table is determined in accordance with the rules of the SEC. Under these rules, a person is deemed to be a beneficial owner of a security if that person has or shares voting power, which includes the power to vote or to direct the voting of the security, or investment power, which includes the power to dispose of or to direct the disposition of the security. For purposes of the table below, we deem ordinary shares issuable pursuant to options or warrants that are currently exercisable or exercisable within 60 days of March 15, 2016, if any, 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 ordinary shares beneficially owned is based on 78,075,620 ordinary shares (not including 21 shares held in treasury). The data presented is based on information provided to us by the holders, or disclosed in public regulatory filings in the U.S. or Israel, in accordance with the applicable law.

None of our shareholders has different voting rights from other shareholders. To the best of our knowledge, we are not owned or controlled, directly or indirectly, by another corporation or by any foreign government. We are not aware of any arrangement that may, at a subsequent date, result in a change of control of our company.

	Shares Beneficially Owned	
Name of Beneficial Owner	**Number**	**Percentage**
5% or greater shareholders		
Haiku Capital Ltd. [(1)]	8,572,901	10.92%
Mr. Sheer Roichman [(2)]	2,664,060	3.41%

(1) Haiku Capital Ltd, is an Israeli private company (Haiku Capital), wholly-owned by Mr. Sheer Roichman. Based on Schedule 13G filed by Mr. Roichman and Haiku Capital with the SEC on December 16, 2015, this includes: (i) 8,172,901 ordinary shares beneficially owned by Haiku Capital, (ii) options currently exercisable issued by us to Haiku Capital representing the right to purchase 400,000 of our ordinary shares. As reported on the Schedules 13G filed as aforesaid, the shares beneficially owned by Mr. Roichman referred to below and/or by Haiku Capital do not include public warrants held by Haiku Capital representing the right to purchase 375,303 American Depositary Shares representing 7,506,060 of our ordinary shares, which are not currently exercisable.

(2) See note 1 above. Mr. Roichman may also be deemed to beneficially own all of the shares held directly and indirectly by Haiku Capital.

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.

Changes in Percentage Ownership by Major Shareholders

Mr. Sheer Roichman / Haiku Capital Ltd.

As reported on the Schedules 13G filed by Mr. Sheer Roichman and Haiku Capital, Mr. Roichman acquired beneficial ownership of 7,506,060 of our ordinary shares via the acquisition in our public offering by Haiku Capital of ADSs representing such number of ordinary shares. At such time Haiku Capital also purchased public warrants representing the right to purchase 375,303 American Depositary Shares representing 7,506,060 of our Ordinary Shares, which are not currently exercisable. Subsequent to our initial U.S. public offering, Mr. Roichman acquired beneficial ownership of an additional 3,330,901 of our ordinary shares via open market purchases (of our ordinary shares on the TASE and our ADSs on NASDAQ) by Mr. Roichman directly (2,664,060 ordinary shares comprising such additional holdings) and by Haiku Capital (666,841 ordinary shares comprising such additional holdings). Prior to the initial U.S. public offering Haiku Capital owned options currently exercisable representing the right to purchase 400,000 of our ordinary shares. To the best of our knowledge, other than these 400,000 options, Mr. Roichman had no beneficial ownership over any other of our securities immediately prior to the initial U.S. public offering.

Prior to the Share Transfer Agreement with Kitov Pharmaceuticals dated July 11, 2013, Mr. Roichman and Haiku Capital were the controlling shareholders of Kitov Holdings (then called Mainrom Line Logistics Ltd.). At the closing of the Share Transfer Agreement with Kitov Pharmaceuticals dated July 11, 2013, Mr. Roichman was the beneficial owner of 3,083,983 of our ordinary shares (prior to a 1-for-13 reverse stock split of our outstanding share capital, which we completed in November 2014) which represented 12.07% of the issued and outstanding share capital at such time. After a series of off-exchange transactions as well as direct sales on the TASE, Mr. Roichman ceased to be a significant shareholder of ours in April 2014.

Dr. John Paul Waymack

Immediately prior to our initial U.S. public offering, Dr. John Paul Waymack had beneficial ownership of 1,111,721 of our ordinary shares which represented 8.58% of our issued and outstanding share capital at the time. Such amount included 1,081,183 ordinary shares held directly by JPW PCH LLC, a Virginia limited liability company, owned 51% by Dr. John Paul Waymack and 30,538 ordinary shares held directly by Dr. John Paul Waymack. Dr. John Paul Waymack may be deemed to beneficially own all of the shares held directly by JPW PCH LLC. In December 2015, we issued 1,103,248 of our ordinary shares to JPW PCH LLC, as a result of the attainment of the milestone in connection with our Phase III clinical trial for KIT-302 (see “Item 7. Major Shareholders and Related Party Transactions – B. Related Party Transactions – Share Transfer Agreement with Kitov Pharmaceuticals"). Dr. Waymack’s holdings were reduced below 5% of our issued and outstanding share capital as a result of our initial U.S. public offering.

Dexcel Ltd.

Immediately prior to our initial U.S. public offering, Dexcel Ltd. a private company wholly owned by Dexon Holdings Ltd. which is a private company wholly owned by Mr. Dan Oren who may be deemed to beneficially own all of the shares held directly by Dexcel Ltd., was known to us to have owned 755,294 of our ordinary shares which represented 5.83% of our issued and outstanding share capital at the time. These shares were issued to Dexcel Ltd. pursuant to the achievement of milestones under our Development Services Agreement with Dexcel Ltd. 157,783 ordinary shares were issued at the first tranche. Upon completion of a milestone the second tranche of 597,511 ordinary shares was issued in May 2015. Dexcel Ltd.’s holdings were reduced below 5% of our issued and outstanding share capital as a result of our initial U.S. public offering.

Record Holders

As of the date of this Annual Report on Form 20-F, there were (i) two shareholders of record of our ordinary shares, one of which was a U.S. entity holding 0.2% of our ordinary shares and one of which was an Israeli entity holding 99.8% of our ordinary shares; (ii) one holder of record for the public warrants which was a U.S. entity, and (iii) one holder of record for our non-listed representative warrants which was a U.S. entity. As of March 4, 2016, 1,898,089 ADSs (equivalent to 37,961,780 ordinary shares, or approximately 48.6% of our total issued and outstanding ordinary shares), were held by two holders of record in the U.S., both of which had U.S. addresses.

The number of record holders is not representative of the number of beneficial holders of our ADSs, ordinary shares, and our warrants because many of the ADSs, ordinary shares and our warrants are held by brokers or other nominees. The shares for a publicly traded company such as ours, which is listed on the TASE, are generally recorded in the name of our Israeli share registrar, Registration Company of United Mizrahi Bank Ltd. or in the name of our ADS Depositary, The Bank of New York Mellon.

B. Related Party Transactions

August 2015 Loan Agreement

On August 12, 2015 we entered into a loan agreement with certain lenders, pursuant to which the lenders extended us a loan, or the August Loan, in the aggregate amount of $430,000, or the Principal Amount. Haiku Capital Ltd., who at the time was not a related party, becoming such only as a result of our initial U.S. offering in November 2015, provided us $100,000 of the August Loan. In addition, we received an option, or the Additional Financing Option, at any time until the earliest of (i) completion of our initial public offering in the United States, or a U.S. offering; (ii) the completion of a public offering on the Tel Aviv Stock Exchange, or TASE, of our securities, or an Israeli Offering; or (iii) December 31, 2015, to require that each lender advance an additional principal amount equal to the Principal Amount advanced by such lender and up to an additional aggregate of $430,000, or the Additional Principal Amount, and the Additional Principal Amount together with the Principal Amount, the Loan Amount. Such Additional Principal Amount, if any, shall have the same terms and conditions as the Principal Amount. Haiku Capital Ltd. committed to $100,000 of such Additional Principal Amount. The Principal Amount and the Additional Principal Amount did not bear interest and were not linked to any index. We did not exercise the option for the Additional Principal Amount. Each lender in the August Loan placed an order to purchase ADSs and warrants in the U.S. offering in an amount equal to or greater than such lender's Loan Amount. As such, and as we completed a U.S. Offering, we were required to repay the Loan Amount to each lender and also to pay each lender an allocation fee equal to 33% of the lender's Principal Amount advanced by such lender. The payments occurred in December 2015 following the completion of our U.S. offering.

Consulting Agreement with Lior Tamar Investments Ltd.

In August 2014, we entered into a consulting agreement with Lior Tamar Investments Ltd., or Lior Tamar, a privately held Israeli company, pursuant to which Lior Tamar provides us with various services, including introduction to Israeli investors, facilitating meetings and introductions to underwriters, assistance in locating business cooperation opportunities, and consultation with respect to raising debt and bonds. In consideration for these services, we pay Lior Tamar a monthly fee of $9,500, and 2.5% of all amounts actually raised and received by us from third parties, excluding amounts received from interested parties. However, Lior Tamar waived its rights to receive 2.5% of the amounts raised in the November 2015 offering on NASDAQ in exchange for a flat fee of $245,000 in consideration of Lior Tamar's services in connection with advising us on matters related to that offering. Lior Tamar did not serve as a finder, in any way, in connection with that offering. The agreement may be terminated by either party upon 60 days' notice, and Lior Tamar is entitled to payment for any fund raising that closes during the 90 day period following termination of the agreement.

Isaac Israel, our chief executive officer and member of our board of directors, provides consulting services to Capital Point Ltd., a public company traded on the TASE, which is co-managed by certain individuals known to us to be the principals of Lior Tamar Investments Ltd. Our audit committee and board of directors approved this consulting agreement in accordance with the requirements of the Companies Law.

Share Transfer Agreement with Kitov Pharmaceuticals

On July 11, 2013, pursuant to a Share Transfer Agreement dated April 2, 2013 between Kitov Holdings, Kitov Pharmaceuticals, Dr. Morris Laster and JPW PCH LLC (Kitov Pharmaceutical's shareholders at the time), and the controlling shareholder in Kitov Holdings at such time, Mr. Sheer Roichman and Haiku Capital Ltd. (a private company wholly owned by Mr. Roichman), Kitov Holdings (then called Mainrom Line Logistics Ltd.) acquired the shares of Kitov Pharmaceuticals in exchange for the issuance of 1,351,478 ordinary shares to Kitov Pharmaceutical's shareholders, representing at the time 63.75% of the fully diluted share capital of Kitov Holdings. In addition, pursuant to the agreement, Kitov Holdings issued to the former shareholders of Kitov Pharmaceutical a right to purchase an additional 1,379,060 ordinary shares of Kitov Holdings if within 28 months from the completion of the acquisition, or November 11, 2015, we complete our Phase III clinical trial and the data analyses have demonstrated that the reduction in blood pressure in the group treated with KIT-302 was at least half of that achieved with amlodipine monotherapy, known as the Milestone. In addition, under the terms of the Share Transfer Agreement, Mr. Roichman was entitled to receive various sums from the funds raised by us from public and private financings. This amount was paid in full by us in March 2014.

At the closing of the Share Transfer Agreement, Kitov Pharmaceutical's shareholders transferred 100% of Kitov Pharmaceuticals share capital on a fully diluted basis to us, as follows: (i) 80% of the share capital directly to us and (ii) 20% of the share capital to a trustee, to hold such shares for our sole benefit until the earlier of the occurrence of: (A) the Milestone referred to above or (B) 28 months from the closing of the Share Transfer Agreement, or November 11, 2015. On November 11, 2015 the 20% share capital held by the trustee was transferred to us, resulting in our holding 100% of the share capital of Kitov Pharmaceuticals. Furthermore, in December 2015, we issued an additional 1,379,060 of our ordinary shares to the former shareholders of Kitov Pharmaceuticals Ltd. as a result of the attainment of the Milestone, including the issuance of 1,103,248 Ordinary Shares of the Company to JPW PCH LLC, a Virginia limited liability company, owned 51% by Dr. John Paul Waymack, the chairman of the board of directors.

Pursuant to the agreement, Kitov Holdings granted to its external consultants, Lior Tamar Investments Ltd., held by Mr. Shay Itzhak Lior and Mr. Yossi Tamar, options to acquire 1,194,616 ordinary shares of Kitov Holdings and agreed to grant to Mr. Simcha Rock, our current chief financial officer and a director, options to acquire 1,370,056 ordinary shares of Kitov Holdings, subject to the adoption of an option plan (of this amount, 181,089 of the options to be granted to Mr. Rock are subject to Kitov Holdings attaining the milestone referred to above and 1,011,500 options are subject to fund raising by Kitov Holdings in the amount of NIS 1,000,000).

At closing, Mr. Sheer Roichman granted Kitov Holdings a loan in the amount of NIS 500,000, free of interest and linkage. Kitov Holdings was to repay the loan to the lender on the date on which it and/or Kitov Pharmaceuticals will raise after the transaction, an amount of no less than NIS 500,000. In the event that the loan is not paid when due, Mr. Roichman would be entitled to convert the loan to securities of Kitov Holdings at a conversion price reflecting a 30% discount to the average price of Kitov Holdings' shares during 30 trading days preceding the date on which Mr. Roichman notified Kitov Holdings of his intention to convert the loan. This loan was repaid in March 2014.

As part of the agreement, Mr. Roichman agreed that in the event Kitov Holdings issues its shares to the public and receives early commitments to purchase its securities in an amount of no less than NIS 500,000, Mr. Roichman will participate in the offering by placing an order for Kitov Holdings shares in an amount of no less than NIS 750,000. If the offering to the public will include the grant of options to acquire Kitov Holdings shares for a cash payment, Mr. Roichman will place orders for Kitov Holdings' securities offered to the public in an amount of NIS 750,000 minus the exercise price of the offered options which he will acquire (in the event that all orders placed by Mr. Roichman under the public offering will be fully received). It is noted, that insofar as the amount of the loan made by Mr. Roichman to Kitov Holdings referred to above is not repaid on issuance date, Mr. Roichman will only pay the exercise price to Kitov Holdings in exchange for the purchased options on the option exercise date insofar as he elects to exercise the options, and the purchase price will be offset against repayment of the loan. This requirement was satisfied at the time of Kitov Holdings' March 2014 offering of ordinary shares on the Tel Aviv Stock Exchange.

In addition, under the terms of the agreement, Mr. Roichman is entitled to receive out of all the funds that will be raised by the Company from public and private financings, including through convertible loans, in one or more transactions and including funds invested by Mr. Roichman himself the following sums: (a) 10% of the amounts invested up to a total cumulative sum of NIS 9 million and (b) 25% of the invested amounts exceeding NIS 9 million, up to a cumulative amount of NIS 2.5 million, also called the maximum remuneration sum, plus VAT if required. This amount was paid by the Company in March 2014.

As part of the agreement, the parties agreed that all the loans granted to Kitov Holdings and/or to Kitov Pharmaceuticals by Mr. Roichman and/or by controlling stakeholders of Kitov Pharmaceuticals, as the case may be, up to the closing, except the loan made by Mr. Roichman to Kitov Holdings on the closing date, will be repaid to Mr. Roichman and/or to the controlling stakeholders of Kitov Pharmaceuticals on a pro rata basis according to their relative share in the debts of the Company, subject to payment of the maximum remuneration sum referred to above.

Upon closing of the transaction, Dr. Paul Waymack, Dr. Morris Laster and Mr. Simcha Rock were appointed to the board of directors of Kitov Holdings, replacing Mr. Erez Goldstmidt, Mr. Hedan Orenstein and Mr. Oren Giditz, who resigned.

Kitov Holdings repaid all obligations to Mr. Sheer Roichman under the agreement and satisfied all of its obligations under the agreement to pay the maximum remuneration sum by the payment of NIS 2.5 million at such time as Kitov Holdings completed its approximately NIS 17.2 million financing in March 2014 pursuant to a prospectus published and approved by the Israel Securities Authority.

Loans from JPW PCH LLC and Dr. Morris Laster

Until the closing of the Share Transfer Agreement in July 2013, our subsidiary, Kitov Pharmaceuticals, financed its operations through shareholder loans made by Kitov Pharmaceutical's founders, JPW PCH LLC, or JPW, and Dr. Morris Laster, amounting to $356,000. These loans were made without interest and had no stated maturity date. These loans have been repaid in full.

Loans from Mr. Sheer Roichman

On February 11, 2013, Mr. Sheer Roichman, then the controlling shareholder, loaned NIS 200,000 (approximately $54,000 based on the representative rate of exchange on the date of February 11, 2013) to Kitov Holdings (then known as Mainrom Line Logistics Ltd.), and on May 30, 2013, Mr. Roichman loaned an additional amount of NIS 50,000 (approximately $13,600 based on the representative rate of exchange on the date of May 30, 2013). These loans were unsecured, did not bear interest and were linked to the Israeli consumer price index, or CPI. In July 2013, Mr. Sheer Roichman loaned Kitov Holdings NIS 500,000 (approximately $141,000 based on the representative rate of exchange on July 11, 2013), free of interest and linkage to the CPI. All of these loans have been repaid in full.

From November 2013 to February 2014, we received loans in the aggregate amount of NIS 990,000 (approximately $285,000 based on the representative rate of exchange on December 31, 2013) pursuant to a loan agreement with several lenders, including Mr. Sheer Roichman and third parties. The loans did not bear interest and were not linked to the CPI. However, we paid to the lenders a credit allocation commission in the amount of approximately NIS 330,000 (approximately $95,000 based on the representative rate of exchange on December 31, 2013), payable to the lenders together with the principal of the loan on the loan repayment date. The entire loan and commission have been repaid according to its terms.

Loans from Dr. John Paul Waymack, Dr. Morris Laster, Mr. Sheer Roichman and Others

In August 2013, we received loans in the aggregate amount of NIS 1.02 million (approximately $285,000 based on the representative rate of exchange on August 25, 2013) pursuant to a loan agreement with Dr. John Paul Waymack, our current controlling shareholder (through JPW), Dr. Morris Laster, Mr. Sheer Roichman, Mr. Isaac Israel, Mr. Simcha Rock and an additional third party. The loans were linked to the Israeli CPI and were repayable in November 2013. The loans have been repaid in full.

Other Agreements

We have entered into agreements with our executive officers and key employees. See "Item 6. Directors, Senior Management and Employees – B. Compensation".

For information on exemption and indemnification letters granted to our officers and directors, please see “Item 6. Directors, Senior Management and Employees - C. Board Practices - Exculpation, Insurance and Indemnification of Directors and Officers.”

C. Interests of Experts and Counsel

Not applicable.

ITEM 8. FINANCIAL INFORMATION

A. Consolidated Statements and Other Financial Information

See Item 18

Legal Proceedings

From time to time, we may become party to legal proceedings and claims in the ordinary course of business, or otherwise. On December 3, 2015, we announced that we received a lawsuit and motion to approve the lawsuit as a class action lawsuit pursuant to the Class Action Lawsuits Law 5766-2006 (Motion) which was filed against us and our directors at the Tel Aviv District Court (Economic Division). The Motion is with respect to asserted claims for damages to the holders of our securities listed on the Tel Aviv Stock Exchange, arising due to our initial public offering of our securities in the U.S. during November 2015. In the Motion it was claimed that the class the petitioners are seeking to represent, namely, anyone holding our shares at the start of trading on November 22, 2015 exclusive of the respondents and/or anyone acting on their behalf and/or any affiliates thereof and excluding anyone whose rights to our shares derive from ADS certificates issued in the U.S to such extent as derived therefrom; and any holders of our Series 2 TASE listed warrants as of the start of trading on November 22, 2015, exclusive of the respondents and/or anyone acting on their behalf and/or any affiliates thereof (Purported Class). The total amount claimed from all defendants, if the Motion is certified as a class action, as set forth in the motion is approximately NIS 16.4 million. In addition to this amount, the petitioners in the motion are seeking remedies in order to redress discrimination against the Purported Class owing to the dilution caused by the public offering, including the possibility that the Purported Class should be awarded from the Company amounts reflecting the losses of the Purported Class from a possible price increase in the shares of the Company following the announcement of the Phase III clinical trial results.

Under applicable Israeli law, a motion to approve a lawsuit as a class action initially needs to be approved as such by the court. Only after such approval is granted by the court, will the court proceed to the second stage of hearing the underlying claims of the class action lawsuit.

We announced that we reject the claims asserted in the Motion and plan on delivering our response to the court in accordance with applicable law.

We have been advised by our attorneys that the likelihood of the Company not incurring any financial obligation as a result of the class action exceeds the likelihood that the Company will incur a financial obligation. At this preliminary stage however, we are unable, with any degree of certainty, to make any other evaluations or any other assessments with respect to the Motion's probability of success or the scope of potential exposure, if any.

Other than the Motion, we are not currently a party to any significant legal or arbitration proceedings involving any third party, including governmental proceedings pending or known to be contemplated, which may have, or have had in the recent past, significant effects on the company’s financial position or profitability.

Dividend Policy

We anticipate that, for the foreseeable future, we will retain any future earnings to support operations and to finance the growth and development of our business. Therefore, we do not expect to pay cash dividends for at least the next several years. We did not declare dividends during the three most recent fiscal years.

The distribution of dividends may also be limited by the Companies Law, which permits the distribution of dividends only out of retained earnings or earnings derived over the two most recent fiscal years, whichever is higher, provided that there is no reasonable concern that payment of a dividend will prevent a company from satisfying its existing and foreseeable obligations as they become due. Our amended and restated articles of association provide that dividends will be paid at the discretion of, and upon resolution by, our board of directors, subject to the provision of the Companies Law.

B. Significant Changes

Except as otherwise disclosed in this Annual Report on Form 20-F, no significant change has occurred since December 31, 2015.

ITEM 9. THE OFFER AND LISTING

A. Offer and Listing Details

Our ordinary shares are currently traded on the TASE under the symbol "KTOV". Our ADSs and public warrants are currently traded on NASDAQ under the symbols "KTOV" and "KTOVW", respectively.

The following table sets forth, for the periods indicated, the reported high and low closing sales prices of our ADSs on NASDAQ.

	$ U.S. Price Per ADS	
	High	Low
Most Recent Six Months		
February 2016	2.66	2.33
January 2016	3.54	2.46
December 2015	4.47	2.47
November 2015 (commencing November 20)	3.19	2.43
Quarterly		
Fourth Quarter 2015 (commencing November 20)	4.47	2.43
Annual		
2015 (commencing November 20)	4.47	2.43

The following table sets forth, for the periods indicated, the reported high and low closing sales prices of the public warrants traded on NASDAQ.

	$ U.S. Price Per Public Warrant	
	High	Low
Most Recent Six Months		
February 2016	0.60	0.51
January 2016	0.66	0.50
December 2015	0.75	0.49
November 2015 (commencing November 20)	0.70	0.53
Quarterly		
Fourth Quarter 2015 (commencing November 20)	0.70	0.53
Annual		
2015 (commencing November 20)	0.70	0.53

The following table sets forth, for the periods indicated, the reported high and low closing sales prices of our ordinary shares on the TASE in NIS and U.S. dollars. U.S. dollar per ordinary share amounts are calculated using the U.S. dollar representative rate of exchange on the date to which the high or low market price is applicable, as reported by the Bank of Israel.

	NIS		$ U.S.	
	* Price Per Ordinary Share		* Price Per Ordinary Share	
	High	Low	High	Low
Most Recent Six Months				
February 2016	0.53	0.46	0.14	0.12
January 2016	0.67	0.49	0.17	0.12
December 2015	0.90	0.50	0.23	0.13
November 2015	2.00	0.52	0.52	0.13
October 2015	2.07	1.44	0.54	0.37
September 2015	1.55	1.30	0.40	0.33
Quarterly				
Fourth Quarter 2015	2.07	0.50	0.54	0.13
Third Quarter 2015	1.82	1.19	0.48	0.31
Second Quarter 2015	1.84	1.38	0.47	0.35
First Quarter 2015	4.13	1.51	1.05	0.38
Fourth Quarter 2014	3.35	1.34	0.90	0.34
Third Quarter 2014	6.89	3.25	2.01	0.88
Second Quarter 2014	8.35	6.01	2.41	1.75
First Quarter 2014	18.06	8.10	5.16	2.33
Annual				
2015	4.13	0.50	1.05	0.13
2014	18.06	1.34	5.16	0.34
2013	33.27	3.04	9.41	0.83
2012	9.31	3.29	2.43	0.83
2011	15.01	4.76	4.21	1.25

* Price adjusted due to the distribution of dividends in October 2012 in connection with the sale by Kitov Holdings (then known as Mainrom Line Logistics Ltd.) of all of its activities, assets, rights, obligations and liabilities to a private company held by its then controlling shareholders.

On March 15, 2016 the last reported sale price of our ADSs on NASDAQ was $ 3.22 per ADS, the last reported sale price of the public warrants on NASDAQ was $0.62 per public warrant and the last reported sale price of our ordinary shares on the TASE was NIS 0.599 per share, or $0.154 per share (based on the representative U.S. dollar – NIS rate of exchange of 3.891 on March 15, 2016).

B. Plan of Distribution

Not applicable.

C. Markets

Our ordinary shares are listed and traded on the TASE under the symbol KTOV. Our ADSs and our public warrants are currently traded on NASDAQ under the symbols “KTOV” and “KTOVW”, respectively.

D. Selling Shareholders

Not applicable.

E. Dilution

Not applicable.

F. Expenses of the Issue

Not applicable.

ITEM 10. ADDITIONAL INFORMATION

A. Share Capital

Not applicable.

B. Memorandum and Articles of Association

Securities Registers

Our registration company for our shares is Registration Company of United Mizrahi Bank Ltd, and its address is 7 Jabotinsky St., Ramat Gan, Israel.

Our transfer agent and registrar for our ADSs is the depositary for our ADRs, Bank of New York Mellon, and its address is 101 Barclay Street, New York, NY.

Objects and Purposes

According to our amended and restated articles of association, we are permitted to engage in any legal business. Our registration number with the Israeli Registrar of Companies is Public Company number 520031238.

Ordinary Shares

The following is a description of our ordinary shares. Our authorized share capital is 500,000,000 ordinary shares, with no par value.

The ordinary shares do not have preemptive rights, preferred rights or any other right to purchase our securities. Neither our amended and restated articles of association nor the laws of the State of Israel restrict the ownership or voting of ordinary shares by non-residents of Israel, except under certain circumstances for ownership by nationals of certain countries that are, or have been, in a state of war with Israel.

Transfer of Shares. Our fully paid ordinary shares may generally be freely transferred under our amended and restated articles of association, unless the transfer is restricted or prohibited by applicable law or the rules of the stock exchange on which the shares are traded.

Notices. Under the Companies Law and our amended and restated articles of association, we are required to publish notices in two Hebrew-language daily newspapers, or in any other public way as determined by the Companies Law, at least 21 days' prior notice of a shareholders' meeting. However, under regulations promulgated under the Companies Law, we are required to publish notice in two daily newspapers at least 35 calendar days prior any shareholders' meeting in which the agenda includes matters which may be voted on by voting instruments. Regulations under the Companies Law exempt companies whose shares are listed for trading both on a stock exchange in and outside of Israel, from some provisions of the Companies Law. An amendment to these regulations exempts us from the requirements of the Israeli proxy regulation, under certain circumstances.

According to the Companies Law and the regulations promulgated thereunder, for purposes of determining the shareholders entitled to notice and to vote at such meeting, the board of directors may fix the record date not more than 40 nor less than four calendar days prior to the date of the meeting, provided that an announcement regarding the general meeting shall be given prior to the record date.

Election of Directors. The number of directors on the board of directors shall be no less than four but no more than nine, including the external directors (if such are required to be appointed by law) ("Maximum Number"). The majority of the members of the Board of Directors shall be residents of Israel, unless the Company's center of management shall have been transferred to another country in accordance with a resolution of the board of directors by a majority of three quarters (75%) of the participating director votes. The number of directors may be changed, at any time and from time to time, by the shareholders with a. The general meeting is entitled, at any time and from time to time, in a resolution approved by a majority of (a) 75% of the voting rights in the Company participating and voting on the matter in the applicable general meeting and (b) more than 47.9% of all of the voting rights in the Company as of the record date established for the applicable general meeting ("Special Majority") to change the minimum or maximum number of directors as stated above. For more information, please see "Item 6 – Directors, Senior Management and Employees – C. Board Practices."

Dividend and Liquidation Rights. Our profits, in respect of which a resolution was passed to distribute them as dividend or bonus shares, shall be paid pro rata to the amount of shares held by the shareholders. In the event of our liquidation, the liquidator may, with the general meeting's approval, distribute parts of our property in specie among the shareholders and he or she may, with similar approval, deposit any part of our property with trustees in favor of the shareholders as the liquidator, with the approval mentioned above, deems fit.

Voting, Shareholders' Meetings and Resolutions. Holders of ordinary shares are entitled to one vote for each ordinary share held on all matters submitted to a vote of shareholders. The quorum required for an ordinary meeting of shareholders consists of at least two shareholders present, in person or by proxy, or who has sent us a voting instrument indicating the way in which he or she is voting, who hold or represent, in the aggregate, at least 25% of the voting rights of our outstanding share capital. A meeting adjourned for lack of a quorum is adjourned to the same day in the following week at the same time and place or any time and place as prescribed by the board of directors in notice to the shareholders. At the reconvened meeting one shareholder at least, present in person or by proxy constitutes a quorum except where such meeting was called at the demand of shareholders. With the agreement of a meeting at which a quorum is present, the chairman may, and on the demand of the meeting he must, adjourn the meeting from time to time and from place to place, as the meeting resolves. Annual general meetings of shareholders are held once every year within a period of not more than 15 months after the last preceding annual general shareholders' meeting. The board of directors may call special general meetings of shareholders. The Companies Law provides that a special general meeting of shareholders may be called by the board of directors or by a request of two directors or 25% of the directors in office, whichever is the lower, or by shareholders holding at least 5% of our issued share capital and at least 1% of the voting rights, or of shareholders holding at least 5% of our voting rights, subject to the provisions set forth in our amended and restated articles of association.

An ordinary resolution requires approval by the holders of a majority of the voting rights present, in person or by proxy, at the meeting and voting on the resolution.

Allotment of Shares. Our board of directors has the power to allot or to issue shares to any person, with restrictions and condition as it deems fit.

Board of Directors

Under our amended and restated articles of association, resolutions by the board of directors shall be decided by a majority of votes of the directors present, or participating, in the case of voting by media, and voting, each director having one vote. In the event of a tie, the chairman of the board does not hold a casting vote.

In addition, the Companies Law requires that certain transactions, actions and arrangements be approved as provided for in a company's articles of association and in certain circumstances by the audit committee or the compensation committee and by the board of directors itself. Those transactions that require such approval pursuant to a company's articles of association must be approved by its board of directors. In certain circumstances, audit committee and shareholder approval is also required. The vote required by the audit committee and the board of directors for approval of such matters, in each case, is a majority of the directors participating in a duly convened meeting. Under the Companies Law, the audit committee is to be comprised of at least three members appointed by the board of directors, which members must include all of the external directors. The majority of members of the audit committee must be independent directors (as defined in the Companies Law), and the chairman of the audit committee must be an external director.

The Companies Law requires that a member of the board of directors or senior management of the company promptly and, in any event, not later than the first board meeting at which the transaction is discussed, disclose any personal interest that he or she may have, either directly or by way of any corporation in which he or she is, directly or indirectly, a 5% or greater shareholder, director or general manager or in which he or she has the right to appoint at least one director or the general manager, as well as all related material information known to him or her, in connection with any existing or proposed transaction by the company. In addition, if the transaction is an extraordinary transaction, (that is, a transaction other than in the ordinary course of business, otherwise than on market terms, or is likely to have a material impact on the company's profitability, assets or liabilities), the member of the board of directors or senior management must also disclose any personal interest held by his or her spouse, siblings, parents, grandparents, descendants, spouse's descendants, siblings and parents, and the spouses of any of the foregoing.

Once the member of the board of directors or senior management complies with the above disclosure requirement, a company may approve the transaction in accordance with the provisions of its articles of association. Under the provisions of the Companies Law, whoever 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 this meeting or vote on this matter, unless it is not an extraordinary transaction as defined in the Companies Law. However, if the chairman of the board of directors or the chairman of the audit committee has determined that the presence of an office holder with a personal interest is required for the presentation of a matter, such officer holder may be present at the meeting. Notwithstanding the foregoing, if the majority of the directors have a personal interest in a matter, they shall be allowed to participate and vote on this matter, but the approval of the transaction by the shareholders in the general meeting is required.

Our amended and restated articles of association provide that, subject to the Companies Law, all actions executed in good faith by the board of directors or by a committee thereof or by any person acting as a director or a member of a committee of the board of directors, will be deemed to be valid even if, after their execution, it is discovered that there was a flaw in the appointment of these persons or that any one of these persons was disqualified from serving at his or her office.

Our amended and restated articles of association provide that, subject to the provisions of the Companies Law, the board of directors may appoint board of directors' committees. The committees of the board of directors shall report to the board of directors their resolutions or recommendations on a regular basis, as shall be prescribed by the board of directors. The board of directors may cancel the resolution of a committee that has been appointed by it; however, such cancellation shall not affect the validity of any resolution of a committee, pursuant to which we acted, vis-à-vis another person, who was not aware of the cancellation thereof. Decisions or recommendations of the committee of the board which require the approval of the board of directors will be brought to the directors' attention a reasonable time prior to the discussion at the board of directors.

According to the Companies Law, a contract of a company with its directors, regarding their conditions of service, including the grant to them of exemption from liability from certain actions, insurance, and indemnification as well as the company's contract with its directors on conditions of their employment, in other capacities, generally requires the approval of the compensation committee (or the audit committee acting in lieu of a compensation committee pursuant to the Companies Law), the board of directors, and the shareholders.

Under the Companies Regulations (Relief from Related Party Transactions), 5760-2000, promulgated under the Companies Law, as amended, certain extraordinary transactions between a public company and its controlling shareholder(s) do not require shareholder approval. Such extraordinary transactions must be approved by both the board of directors and the audit committee and (i) must involve the extension of an existing transaction that was duly approved and does not involve any significant change in the terms of the existing transaction or the change is solely for the benefit of the company; (ii) is solely for the benefit of the company; (iii) is with the controlling shareholder or another person in which the controlling shareholder has an interest and the transaction is in accordance with the terms of a framework agreement that was duly approved; (iv) is with the controlling shareholder or another person in which the controlling shareholder has an interest, the purpose of which is a transaction of theirs with a third party or a joint proposal to enter into a transaction with a third party, and the terms of the transaction that apply to the controlling shareholder are not significantly different from the terms that apply to the controlling shareholder or an entity controlled by him or her (while taking into account the extent of their respective involvement in the transaction); (v) is among companies controlled by the controlling shareholder, or between the public company and the controlling shareholder or another person in which the controlling shareholder has a personal interest, and the transaction is on market terms, within the ordinary course of business and does not harm the company; or (vi) on the date of approval of the extraordinary transaction by the board of directors and audit committee, the shareholders who do not have personal interest in the approval of the said transactions do not hold more than 1% of the voting rights in the company. In addition, under such regulations, directors' compensation and employment arrangements in a public company do not require the approval of the shareholders if both the compensation committee (or the audit committee acting in lieu of a compensation committee pursuant to the Companies Law) and the board of directors agree that such arrangements are solely for the benefit of the company. Also, employment and compensation arrangements for an office holder that is a controlling shareholder of a public company, or the provision of directors and officers insurance for the chief executive officer, do not require shareholder approval if certain criteria are met. The foregoing exemptions from shareholder approval will not apply if one or more shareholders holding at least 1% of the issued and outstanding share capital of the company or of the company's voting rights, objects to the use of these exemptions provided that such objection is submitted to the company in writing not later than fourteen days from the date of the filing of a report regarding the adoption of such resolution by the company. If such objection is duly and timely submitted, then the transaction or compensation arrangement of the directors will require shareholders' approval as detailed above.

Private Placements

Under the Companies Law, if (i) as a result of a private placement a person would become a controlling shareholder or (ii) a private placement will entitle investors to receive 20% or more of the voting rights of a company as calculated before the private placement, and all or part of the private placement consideration is not in cash or in public traded securities or is not in market terms and if as a result of the private placement the holdings of a substantial shareholder shall increase or as a result of it a person shall become a substantial shareholder, then in either case, the allotment must be approved by the board of directors and by the shareholders of the company. A "substantial shareholder" in connection with a private placement as set forth above, is defined as a shareholder who holds five percent or more of the company's outstanding share capital or voting rights, and which assumes the exercise of all of the securities convertible into shares either held by that person prior to such private placement or offered to such person under the private placement. In order for the private placement to be on "market terms" the board of directors has to determine, on the base of detailed explanation, that the private placement is on market terms, unless proven otherwise. Otherwise, under the Companies Law and the regulations promulgated thereunder, a private placement of securities does not require approval at a general meeting of the shareholders of a company; provided however, that in other special circumstances, such as a private placement completed in lieu of a special tender offer) or a private placement under circumstances which qualifies as a related party transaction requiring shareholder approval, approval at a general meeting of the shareholders of a company is then also required.

Access to corporate records

Under the Companies Law, shareholders are provided access to minutes of our general meetings, our shareholders register and principal shareholders register, our amended and restated articles of association, our financial statements and any document that we are required by law to file publicly with the Israeli Companies Registrar or the Israel Securities Authority. In addition, shareholders may request to be provided with any document related to an action or transaction requiring shareholder approval under the related party transaction provisions of the Companies Law. We may deny this request if we believe it has not been made in good faith or if such denial is necessary to protect our interest or protect a trade secret or patent.

Modification of class rights

Under the Companies Law and our amended and restated articles of association, the rights attached to any class of share, such as voting, liquidation and dividend rights, may be amended by adoption of a resolution by the holders of a majority of the shares of that class present at a separate class meeting, or otherwise in accordance with the rights attached to such class of shares, as set forth in our amended and restated articles of association. 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.

Pursuant to Israel's securities laws, a company whose shares are registered for trade on the TASE may not have more than one class of shares for a period of one year following initial registration of the company on the TASE, after which it is permitted to issue preferred shares, if the preference of those shares is limited to a preference in the distribution of dividends and these preferred shares have no voting rights.

Provisions Restricting Change in Control of Our Company

As described below, certain provisions of the Companies Law and/or our amended and restated articles of association may have an effect of delaying, deferring or preventing a change in control.

Full Tender Offer

A person wishing to acquire shares of an Israeli public company and who would as a result hold over 90% of the target company's issued and outstanding share capital is required by the Companies Law to make a tender offer to all of the company's shareholders for the purchase of all of the issued and outstanding shares of the company.

A person wishing to acquire shares of an Israeli public company and who would as a result hold over 90% of the issued and outstanding share capital of a certain class of shares is required to make a tender offer to all of the shareholders who hold shares of the same class for the purchase of all of the issued and outstanding shares of the same class.

If the shareholders who do not respond to or accept the offer hold less than 5% of the issued and outstanding share capital of the company or of the applicable class of the shares, and more than half of the shareholders who do not have a personal interest in the offer accept the offer, all of the shares that the acquirer offered to purchase will be transferred to the acquirer by operation of law. However, a tender offer will be accepted if the shareholders who do not accept it hold less than 2% of the issued and outstanding share capital of the company or of the applicable class of the shares.

Upon a successful completion of such a full tender offer, any shareholder that was an offeree in such tender offer, whether such shareholder accepted the tender offer or not, may, within six months from the date of acceptance of the tender offer, petition the Israeli court to determine whether the tender offer was for less than fair value and that the fair value should be paid as determined by the court. However, under certain conditions, the offeror may determine in the terms of the tender offer that an offeree who accepted the offer will not be entitled to petition the Israeli court as described above.

If the shareholders who did not respond or accept the tender offer hold at least 5% of the issued and outstanding share capital of the company or of the applicable class, the acquirer may not acquire shares of the company that will increase its holdings to more than 90% of the company's issued and outstanding share capital or of the applicable class from shareholders who accepted the tender offer.

The description above regarding a full tender offer shall also apply, with necessary changes, when a full tender offer is accepted and the offeror has also offered to acquire all of the company's securities.

Special Tender Offer

The Companies Law provides that an acquisition of shares of an Israeli public company must be made by means of a special tender offer if as a result of the acquisition the purchaser would become a holder of at least 25% of the voting rights in the company. This rule does not apply if there is already another holder of at least 25% of the voting rights in the company.

Similarly, the Companies Law 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 the purchaser would become a holder of more than 45% of the voting rights in the company, if there is no other shareholder of the company who holds more than 45% of the voting rights in the company.

These requirements do not apply if the acquisition (i) occurs in the context of a private offering, on the condition that the shareholders' meeting approved the acquisition as a private offering whose purpose is to give the acquirer at least 25% of the voting rights in the company if there is no person who holds at least 25% of the voting rights in the company, or as a private offering whose purpose is to give the acquirer 45% of the voting rights in the company, if there is no person who holds 45% of the voting rights in the company; (ii) was from a shareholder holding at least 25% of the voting rights in the company and resulted in the acquirer becoming a holder of at least 25% of the voting rights in the company; or (iii) was from a holder of more than 45% of the voting rights in the company and resulted in the acquirer becoming a holder of more than 45% of the voting rights in the company.

The special tender offer may be consummated only if (i) at least 5% of the voting power attached to the company's outstanding shares will be acquired by the offeror and (ii) the special tender offer is accepted by a majority of the votes of those offerees who gave notice of their position in respect of the offer; in counting the votes of offerees, the votes of a holder in control of the offeror, a person who has personal interest in acceptance of the special tender offer, a holder of at least 25% of the voting rights in the company, or any person acting on their or on the offeror's behalf, including their relatives or companies under their control, are not taken into account.

In the event that a special tender offer is made, a company's board of directors is required to express its opinion on the advisability of the offer or shall abstain from expressing any opinion if it is unable to do so, provided that it gives the reasons for its abstention.

An office holder in a target company who, in his or her capacity as an office holder, performs an action the purpose of which is to cause the failure of an existing or foreseeable special tender offer or is to impair the chances of its acceptance, is liable to the potential purchaser and shareholders for damages resulting from his or her acts, unless such office holder acted in good faith and had reasonable grounds to believe he or she was acting for the benefit of the company. However, office holders of the target company may negotiate with the potential purchaser in order to improve the terms of the special tender offer, and may further negotiate with third parties in order to obtain a competing offer.

If a special tender offer was accepted by a majority of the shareholders who announced their stand on such offer, then shareholders who did not respond to the special offer or had objected to the special tender offer may accept the offer within four days of the last day set for the acceptance of the offer. In the event that a special tender offer is accepted, then the purchaser or any person or entity controlling it and any corporation controlled by them shall refrain from making a subsequent tender offer for the purchase of shares of the target company and may not execute a merger with the target company for a period of one year from the date of the offer, unless the purchaser or such person or entity undertook to effect such an offer or merger in the initial special tender offer.

Under the Companies Regulations (Relief for Public Companies whose Shared are Traded on Exchanges outside of Israel) the above requirements for a special tender offer do not apply in instances whereby according to the laws of the foreign jurisdiction there are limitations regarding the acquisition of a controlling interest in the company of any specified portion or the acquisition of a controlling interest of any specified portion necessitates an offer by the potential acquirer of a controlling interest to acquire shares from amongst the publicly traded shares. The Israeli Securities Authority is of the view that US securities laws and exchange regulations of various exchanges do not purport to limit the acquisition of controlling interests in a company, do not require the potential acquirer of a controlling interest to make an offer to acquire shares from the public, and as such Israeli companies that are publicly traded in the United States of America cannot benefit from these relief regulations and are thus subject to the general provisions of the Companies Law which require a special tender offer as outlined above.

Merger

The Companies Law permits merger transactions if approved by each party's board of directors and, unless certain requirements described under the Companies Law are met, a majority of each party's shareholders, by a majority of each party's shares that are voted on the proposed merger at a shareholders' meeting.

The board of directors of a merging company is required pursuant to the Companies Law to discuss and determine whether in its opinion there exists a reasonable concern that, as a result of a proposed merger, the surviving company will not be able to satisfy its obligations towards its creditors, taking into account the financial condition of the merging companies. If the board of directors has determined that such a concern exists, it may not approve a proposed merger. Following the approval of the board of directors of each of the merging companies, the boards of directors must jointly prepare a merger proposal for submission to the Israeli Registrar of Companies.

For purposes of the shareholder vote, unless a court rules otherwise, the merger will not be deemed approved if a majority of the shares voting at the shareholders' meeting (excluding abstentions) that are held by parties other than the other party to the merger, any person who holds 25% or more of the means of control (See "Management – Audit Committee – Approval of Transactions with Related Parties" for a definition of means of control) of the other party to the merger or any one on their behalf including their relatives (See "Item 6. Directors, Senior Management and Employees - C. Board Practices - External Directors – Qualifications of External Directors" for a definition of relatives) or corporations controlled by any of them, vote against the merger.

In addition, if the non-surviving entity of the merger has more than one class of shares, the merger must be approved by each class of shareholders.

If the transaction would have been approved but for the separate approval of each class of shares or the exclusion of the votes of certain shareholders as provided above, a court may still rule that the company has approved the merger upon the request of holders of at least 25% of the voting rights of a company, if the court holds that the merger is fair and reasonable, taking into account the appraisal of the merging companies' value and the consideration offered to the shareholders.

Under the Companies Law, each merging company must send a copy of the proposed merger plan to its secured creditors. Unsecured creditors are entitled to receive notice of the merger, as provided by the regulations promulgated under the Companies Law. 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 the target company. The court may also give instructions in order to secure the rights of creditors.

In addition, a merger may not be completed unless at least 50 days have passed from the date that a proposal for approval of the merger was filed with the Israeli Registrar of Companies and 30 days from the date that shareholder approval of both merging companies was obtained.

Tax Issues

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 treat them. 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.

Amended and Restated Articles of Association

Our amended and restated articles of association contain provisions that could delay or prevent changes in control or changes in our management. These provisions include the following:

- no cumulative voting in the election of directors, which limits the ability of minority shareholders to elect director candidates;
- the right of our board of directors to elect a director to fill a vacancy, which may prevent shareholders from being able to fill vacancies on our board of directors;
- a majority of the members of our board of directors are required to be residents of Israel, unless our center of management has been transferred to another country by a decision of our board of directors resolved by a supermajority of three-quarters of the participating votes at such board of directors meeting;
- the size of our board of directors shall be no more than nine (including any external directors required under applicable law);
- the directors, except for our external directors, are divided into three classes, as nearly equal in number as possible; and, at each annual general meeting, the term of one class of directors expires, and the directors of such class are re-nominated to serve an additional three year term that expires at the annual general meeting held in the third year following such election, with this process continues indefinitely; and
- the provisions in our amended and restated articles of association governing the number of directors, the election and removal of directors, the division of the board of directors into classes, and the establishment of the center of management may only be changed by the shareholders with a majority of (a) 75% of the voting rights participating and voting on the matter in the applicable general meeting and (b) more than 47.9% of all of the voting rights in the Company as of the record date established for the applicable general meeting.

Changes in Our Capital

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

- increase the Company's 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 its share capital into shares of larger nominal value than its existing shares;
- subdivide the Company's existing shares or any of them, the Company's share capital or any of it, into shares of smaller nominal value than is fixed;
- reduce the Company's 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 the issued and outstanding share capital of the Company, in such manner that those shares shall be cancelled and any nominal par value paid for those shares will be registered at the Company's books as capital fund, which shall be deemed as a premium paid on those shares which shall remain in the issued and outstanding share capital of the Company.

C. Material Contracts

Master Research Services Agreement with Java Clinical Research Ltd.

On February 9, 2014, we entered into a Master Research Services Agreement with Java Clinical Research Ltd., or Java, a contract research organization based in Dublin, Ireland. According to the terms of the agreement, Java will manage the Phase III clinical trial for KIT-302, including preparation and filing of the requests to the ethics boards and the necessary regulatory bodies of the European Union, recruiting the tested subjects, employment of the primary researchers, identification and evaluation of the medical centers and their subsequent management throughout the trial period and overall management of the trial process through its completion. We engage with third party medical centers for the performance of our Phase III clinical trial through Java. The total cost of the agreement with Java including the cost of all service providers with which we have engaged through Java, will amount to approximately $2.5 million.

The Master Research Services Agreement will remain in effect until Java has provided all services through the completion of our Phase III trial of KIT-302. However, the parties have customary termination rights and either party may terminate the agreement (or any work thereunder) upon 60 days' notice.

Services Agreement with DABL Limited

On August 2, 2013, we entered into a services agreement with DABL Limited, or DABL, an Irish company based in Dublin, Ireland, in the ambulatory blood pressure monitoring technologies field. According to the agreement, DABL will provide protocol consultation services and coordinate the ambulatory blood pressure monitoring (ABPM) procedures and the analysis of the blood pressure tests during and after our Phase III trial of KIT-302. DABL's technology enables the collection of data from hundreds of blood pressure tests during the day on each patient during the clinical trials as opposed to the traditional individual tests that yield many fewer results for statistical analysis during the same time frame.

The services agreement will remain in effect until DABL has provided all services including the statistical analysis of results the blood pressure tests following our Phase III trial of KIT-302. However, we may terminate the agreement at any time upon 90 days' notice, and both parties have customary termination rights.

Development Services Agreement with Dexcel

On April 1, 2014, we entered into a Development Services Agreement with Dexcel Ltd., or Dexcel, a global pharmaceutical company, which has been involved in the manufacture and marketing of more than 55 branded and generic products. The agreement provides for Dexcel to develop the formulation for KIT-302 and the subsequent stability testing and manufacturing scale-up in quantities adequate for submission of an NDA to the FDA. Dexcel's services include performing compatibility testing of APIs with excipients, screening to find at least two prototypes and identifying analytical methods for product analysis. We agreed to bear the cost of the APIs as well as other materials or means required for Dexcel to perform the services under the agreement. In exchange for these services, we will pay Dexcel: (i) $2 million in cash in four equal installments ($500,000 which was paid upon execution of the agreement, $500,000 which was paid upon attainment of the second milestone in May 2015, and the remaining to be paid in two equal payments based on the remaining milestones during the development and manufacturing period); and (ii) in our ordinary shares having an aggregate value of $1.5 million issued in three equal installments (the first issuance of 157,783 ordinary shares was made upon execution of the agreement, the second issuance of 597,511 ordinary shares was made upon attainment of the second milestone in May 2015, and the remaining issuance is due upon the attainment of the remaining milestones during the development and manufacturing period).

In addition, in exchange for a right of first negotiation with regard to future global marketing rights for KIT-302 and for an option to negotiate the future commercial manufacture of KIT-302 Dexcel agreed to pay us $500,000 in two equal installments based on milestones during the development and manufacturing period (of which the first payment of $250,000 was made in May 2015 upon the attainment of the second development milestone). Under the terms of the agreement, in the event we intend to enter into negotiations with any third party to enter into a commercial marketing or licensing agreement for the product, we are obligated to notify Dexcel of our intention to do so, and Dexcel has the right, within 21 days, to notify us whether it wishes to negotiate with us on mutually agreeable and commercially reasonable terms for the rights, in which case we are required to negotiate exclusively with Dexcel in good faith in an attempt to reach a mutual agreement with 60 days. If Dexcel does not so notify us, or if upon expiration of this 60 day period the parties are unable to agree in good faith upon its terms and conditions, we will be free to enter into a commercial agreement with any party on any terms we determine.

On June 9, 2015 we, together with Dexcel, successfully completed the performance of a pilot pharmacokinetic clinical trial, or Pilot PK Study, which commenced on March 31, 2015 in Ichilov Medical Center in Tel Aviv. The objective of the Pilot PK Study was to demonstrate that the concentration of KIT-302 in the blood of the subjects is comparable to the concentrations observed in the administration of the two existing, approved drugs (celecoxib and amlodipine besylate, which are the active components of KIT-302). For the purpose of this Pilot PK Study, Dexcel manufactured two prototypes of the KIT-302 final formulation, based on the two existing approved drugs. The Pilot PK Study was performed with 15 subjects who were each treated with two different prototypes of the final formulation of KIT-302. During the course of the Pilot PK Study, blood samples were taken from the subjects following treatment with each of the two prototype formulations and following treatment with the two existing approved drugs (celecoxib and amlodipine besylate) separately for purposes of comparison, over a period of approximately six weeks. The Pilot PK Study demonstrated successful levels in the blood of the two prototype formulations, and one of the two final formulations that were tested met all the objectives of the study protocol and was selected for purposes of continuing the clinical development of KIT-302. In addition, based on the positive results achieved, we expect that the scope of the final PK study will be lower than originally expected.

The Development Services Agreement will remain in effect until Dexcel has provided all services through the completion of manufacturing scale-up in quantities adequate for submission of an NDA to the FDA. However, the parties have customary termination rights and either party may terminate the agreement upon 90 days' notice.

Manufacturing Agreement with Sterling Pharmaceuticals Services

In September 2013, we entered into an agreement with Sterling Pharmaceuticals Services LLC to produce the drugs for the Phase III trial of KIT-302. The clinical trial supplies include over encapsulated celecoxib, over encapsulated amlodipine besylate, and an over encapsulated placebo. Pursuant to the terms of the agreement, Sterling will manufacture the drugs and perform the stability and release tests, the packaging and the delivery to the various sites where the clinical trial is be performed. In January 2014, Sterling notified us that the drug production process was completed successfully, and it subsequently notified us that the primary stability tests were completed successfully. In June 2014, the drugs were shipped to the medical center where the trial began. In addition, pursuant to our decision to conduct the clinical trial according to the ATD method, we ordered the manufacture of additional drugs for the clinical trial.

Other Agreements

For a description of other agreements, please see "Item 4. Information on the Company – B. Business Overview – Services and License Agreements", "Item 5. Operating and Financial Review and Prospects – B. Liquidity and Capital Resources" and "Item 7. Major Shareholders and Related Party Transactions – B. Related Party Transactions" – August 2015 Loan Agreements", "Item 7. Major Shareholders and Related Party Transactions – B. Related Party Transactions – Consulting Agreement with Lior Tamar Investments Ltd.", "Item 7. Major Shareholders and Related Party Transactions – B. Related Party Transactions – Share Transfer Agreement with Kitov Pharmaceuticals".

For information on exemption and indemnification letters granted to our officers and directors, please see "Item 6 – Directors, Senior Management and Employees – C. Board Practices – Exemption, Insurance and Indemnification of Directors and Officers."

D. Exchange Controls

Exchange Controls

There are currently no material Israeli currency control restrictions on payments of dividends or other distributions with respect to our securities or the proceeds from the sale of our securities, except under certain circumstances, for shareholders who are subjects of countries that are, or have been, in a state of war with Israel or otherwise as set forth in this section and under "Item 10E. Additional Information — Taxation." However, legislation remains in effect pursuant to which currency controls can be imposed by administrative action at any time. Israeli residents have an obligation to file reports with the Bank of Israel regarding certain transactions.

E. Taxation

The following description is not intended to constitute a complete analysis of all tax consequences relating to the acquisition, ownership and disposition of our ordinary shares, ADSs or warrants (the "Shares"). You should consult your own tax advisor concerning the tax consequences of your particular situation, as well as any tax consequences that may arise under the laws of any state, local, foreign or other taxing jurisdiction.

Israeli Tax Considerations and Government Programs

The following is a summary of the material Israeli tax laws applicable to us, and some Israeli Government programs benefiting us. This section also contains a discussion of some Israeli tax consequences to persons owning our Shares. This summary does not discuss all the aspects of Israeli tax law that may be relevant to a particular investor in light of his or her personal investment circumstances or to some types of investors subject to special treatment under Israeli law. Examples of this kind of investor include traders in securities or persons that own, directly or indirectly, 10% or more of our outstanding voting capital, all of whom are subject to special tax regimes not covered in this discussion. Some parts of this discussion are based on a new tax legislation which has not been subject to judicial or administrative interpretation. The discussion should not be construed as legal or professional tax advice and does not cover all possible tax considerations.

SHAREHOLDERS ARE URGED TO CONSULT THEIR OWN TAX ADVISORS AS TO THE ISRAELI OR OTHER TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF OUR SHARES, INCLUDING, IN PARTICULAR, THE EFFECT OF ANY FOREIGN, STATE OR LOCAL TAXES.

General Corporate Tax Structure in Israel

Israeli resident companies are generally subject to corporate tax, currently at the rate of 26.5% of a company's taxable income. However, the effective tax rate payable by a company that derives income from a Preferred Enterprise (as discussed below) may be considerably less. Capital gains derived by an Israeli resident company are subject to tax at the prevailing corporate tax rate.

Under Israeli tax legislation, a corporation will be considered as an "Israeli resident company" if it meets one of the following: (i) it was incorporated in Israel; or (ii) the control and management of its business are exercised in Israel.

Taxation of Our Shareholders

Capital Gains

Capital gain tax is imposed on the disposal of capital assets by an Israeli resident, and on the disposal of such assets by a non- Israel resident if those assets are either (i) located in Israel; (ii) are shares or a right to a share in an Israeli resident corporation, or (iii) represent, directly or indirectly, rights to assets located in Israel. The Israeli Income Tax Ordinance of 1961 (New Version) (the "Ordinance") distinguishes between "Real Gain" and the "Inflationary Surplus." Real Gain is the excess of the total capital gain over Inflationary Surplus computed generally on the basis of the increase in the Israeli CPI between the date of purchase and the date of disposal.

In 2015, the capital gain accrued by individuals on the sale of our Shares will be taxed at the rate of 25%. However, if the individual shareholder is a "Controlling Shareholder" (i.e., a person who holds, directly or indirectly, alone or together with another, 10% or more of one of the Israeli resident company's means of control) at the time of sale or at any time during the preceding 12 months period, such gain will be taxed at the rate of 30%.

The real capital gain derived by corporations will be generally subject to a corporate tax rate of 26.5% in 2015.

Individual and corporate shareholder dealing in securities in Israel are taxed at the tax rates applicable to business income – 26.5% for corporations in 2015 and a marginal tax rate of up to 48% in 2015 for individuals, plus a 2% excess tax which is levied on individuals whose taxable income in Israel exceeds NIS 810,720 in 2015. Notwithstanding the foregoing, capital gain derived from the sale of our Shares by a non-Israeli shareholder may be exempt under the Ordinance from Israeli taxation provided that the following cumulative conditions are met: (i) the shares were purchased upon or after the registration of the securities on the stock exchange (this condition shall not apply to shares purchased on or after January 1, 2009), (ii) the seller does not have a permanent establishment in Israel to which the derived capital gain is attributed, (iii) if the seller is a corporation, no more than 25% of its means of control are held, directly and indirectly, by an Israeli resident shareholders, and (iv) if the seller is a corporation, there is no Israeli Resident that is entitled to 25% or more of the revenues or profits of the corporation directly or indirectly. In addition, the sale of shares may be exempt from Israeli capital gain tax under the provisions of an applicable tax treaty. For example, the U.S.-Israel Double Tax Treaty exempts U.S. resident from Israeli capital gain tax in connection with such sale, provided (i) the U.S. resident owned, directly or indirectly, less than 10% of an Israeli resident company's voting power at any time within the 12 month period preceding such sale; (ii) the seller, being an individual, is present in Israel for a period or periods of less than 183 days at the taxable year; and (iii) the capital gain from the sale was not derived through a permanent establishment of the U.S. resident in Israel.

Either the purchaser, the Israeli stockbrokers or financial institution through which the shares are held is obliged, subject to the above mentioned exemptions, to withhold tax upon the sale of securities from the real capital gain at the rate of 25% in respect of a corporation and/or an individual.

At the sale of securities traded on a stock exchange a detailed return, including a computation of the tax due, must be filed and an advanced payment must be paid on January 31 and June 30 of every tax year in respect of sales of securities made within the previous six months. However, if all tax due was withheld at source according to applicable provisions of the Ordinance and regulations promulgated thereunder the aforementioned return need not be filed and no advance payment must be paid. Capital gain is also reportable on the annual income tax return.

Dividends

A distribution of dividend by our company from income attributed to a Preferred Enterprise will generally be subject to withholding tax in Israel at the following tax rates: Israeli resident individuals - 20% with respect to dividends to be distributed as of 2014; Israeli resident companies – 0% for a Preferred Enterprise; Non-Israeli residents – 20% with respect to dividends to be distributed as of 2014, subject to a reduced rate under the provisions of any applicable double tax treaty, subject to an approval from the Israeli Tax Authorities. A distribution of dividends from income, which is not attributed to a Preferred Enterprise to an Israeli resident individual, will generally be subject to income tax at a rate of 25%. However, a 30% tax rate will apply if the dividend recipient is a "Controlling Shareholder" (as defined above) at the time of distribution or at any time during the preceding 12 months period. If the recipient of the dividend is an Israeli resident corporation, such dividend will be exempt from income tax provided the income from which such dividend is distributed was derived or accrued within Israel.

The Ordinance provides that a non-Israeli resident (either individual or corporation) is generally subject to an Israeli income tax on the receipt of dividends at the rate of 25% (30% if the dividends recipient is a "Controlling Shareholder" (as defined above), at the time of distribution or at any time during the preceding 12 months period); those rates are subject to a reduced tax rate under the provisions of an applicable double tax treaty. Thus, under the U.S.-Israel Double Tax Treaty the following rates will apply in respect of dividends distributed by an Israeli resident company to a U.S. resident: (i) if the U.S. resident is a corporation which holds during that portion of the taxable year which precedes the date of payment of the dividend and during the whole of its prior taxable year (if any), at least 10% of the outstanding shares of the voting stock of the Israeli resident paying corporation and not more than 25% of the gross income of the Israeli resident paying corporation for such prior taxable year (if any) consists of certain type of interest or dividends (other than dividend or interest received from subsidiary corporations, 50 percent or more of the outstanding shares of the voting stock of which is owned by the paying corporation at the time such dividends or interest is received) – the tax rate is 12.5%, (ii) if both the conditions mentioned in section (i) above are met and the dividend is paid from an Israeli resident company's income which was entitled to a reduced tax rate applicable to a Preferred Enterprise as defined in the Israel's Encouragement of Capital Investments Law (1959) – the tax rate is 15% and (iii) in all other cases, the tax rate is 25%. The aforementioned rates under the Israel U.S. Double Tax Treaty will not apply if the dividend income was derived through a permanent establishment of the U.S. resident in Israel.

A non-Israeli resident who receives dividends from which tax was withheld is generally exempt from the obligation to file tax returns in Israel with respect to such income, provided that (i) such income was not generated from business conducted in Israel by the taxpayer, and (ii) the taxpayer has no other taxable sources of income in Israel with respect to which a tax return is required to be filed.

Financial institutions through which shareholders typically hold securities are generally required, subject to any of the foregoing exemptions, reduced tax rates and the demonstration of a shareholder regarding his, her or its foreign residency, to withhold tax upon the distribution of dividend at the rate of 25%, so long as the shares are registered with a Nominee Company (for corporations and individuals).

Foreign Exchange Regulations

Non-residents of Israel who hold our Shares are able to receive any dividends, and any amounts payable upon the dissolution, liquidation and winding up of our affairs, repayable in non-Israeli currency at the rate of exchange prevailing at the time of conversion. However, Israeli income tax is generally required to have been paid or withheld on these amounts. In addition, the statutory framework for the potential imposition of currency exchange control has not been eliminated, and may be restored at any time by administrative action.

Estate and Gift Tax

Israeli law presently does not impose estate or gift taxes.

U.S. Federal Income Tax Considerations

The following is a description of certain U.S. federal income tax consequences relating to the acquisition, ownership and disposition of our ADSs and warrants by a holder. This description addresses only the U.S. federal income tax consequences to holders that are initial purchasers of our ADSs and warrants pursuant to this offering and that will hold such ADSs and warrants as capital assets. This description does not address tax considerations applicable to holders that may be subject to special tax rules, including, without limitation:

- banks, financial institutions or insurance companies;
- real estate investment trusts, regulated investment companies or grantor trusts;
- dealers or traders in securities, commodities or currencies;
- tax exempt entities or organizations;
- certain former citizens or residents of the United States;
- persons that received our ADSs or warrants as compensation for the performance of services;
- persons that will hold our ADSs or warrants as part of a “hedging,” “integrated” or “conversion” transaction or as a position in a “straddle” for U.S. federal income tax purposes;
- partnerships (including entities classified as partnerships for U.S. federal income tax purposes) or other pass-through entities, or holders that will hold our ADSs or warrants through such an entity;
- U.S. Holders (as defined below) whose “functional currency” is not the U.S. dollar; or
- holders that own directly, indirectly or through attribution 10% or more of the voting power or value of our shares.

Moreover, this description does not address the U.S. federal estate, gift, or alternative minimum tax consequences, or any U.S. state, local or non-U.S. tax consequences of the acquisition, ownership and disposition of our ADSs and warrants.

This description is based on the U.S. Internal Revenue Code of 1986, as amended, or the Code, existing, proposed and temporary U.S. Treasury Regulations promulgated thereunder and administrative and judicial interpretations thereof, in each case as in effect and available on the date hereof. All the foregoing is subject to change, which change could apply retroactively and could affect the tax consequences described below. There can be no assurances that the U.S. Internal Revenue Service, or IRS, will not take a different position concerning the tax consequences of the acquisition, ownership and disposition of our ADSs and warrants or that such a position would not be sustained. Holders should consult their own tax advisers concerning the U.S. federal, state, local and foreign tax consequences of acquiring, owning and disposing of our ADSs and warrants in their particular circumstances.

For purposes of this description, the term "U.S. Holder" means a beneficial owner of our ADSs or warrants that, for U.S. federal income tax purposes, is (i) a citizen or resident of the United States, (ii) a corporation (or entity treated 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 (x) 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 (y) that has elected to be treated as a domestic trust for U.S. federal income tax purposes.

A "Non-U.S. Holder" is a beneficial owner of our ADSs or warrants that is neither a U.S. Holder nor a partnership (or other entity treated as a partnership for U.S. federal income tax purposes).

If a partnership (or any other entity treated as a partnership for U.S. federal income tax purposes) holds our ADSs and warrants, the U.S. federal income tax consequences relating to an investment in our ADSs and warrants will depend in part upon the status of the partner and the activities of the partnership. Such a partner or partnership should consult its tax advisor regarding the U.S. federal income tax consequences of acquiring, owning and disposing of our ADSs and warrants in its particular circumstances.

In general, if you hold ADSs, you will be treated as the holder of the underlying ordinary shares represented by those ADSs for U.S. federal income tax purposes. Accordingly, gain or loss generally will not be recognized if you exchange ADSs for the underlying ordinary shares represented by those ADSs.

Persons considering an investment in our ADSs or warrants should consult their own tax advisors as to the particular tax consequences applicable to them relating to the acquisition, ownership and disposition of our ADSs and warrants, including the applicability of U.S. federal, state and local tax laws and non-U.S. tax laws.

Taxation of Dividends and Other Distributions on Our ADSs

Subject to the discussion below under "Passive Foreign Investment Company Consequences," if you are a U.S. Holder, the gross amount of any distribution made to you with respect to our ADSs before reduction for any Israeli taxes withheld therefrom, generally will be includible in your income as dividend income to the extent such distribution is paid out of our current or accumulated earnings and profits as determined under U.S. federal income tax principles. Non-corporate U.S. Holders may qualify for the lower rates of taxation with respect to dividends on ADSs applicable to long-term capital gains (i.e., gains from the sale of capital assets held for more than one year), provided that certain conditions are met, including certain holding period requirements and the absence of certain risk reduction transactions. Moreover, such lower rate of taxation shall not apply if we are a PFIC for the taxable year in which it pays a dividend, or was a PFIC for the preceding taxable year. However, such dividends will not be eligible for the dividends received deduction generally allowed to corporate U.S. Holders. To the extent that the amount of any distribution by us exceeds our current and accumulated earnings and profits as determined under U.S. federal income tax principles, it will be treated first as a tax-free return of your adjusted tax basis in our ADSs and thereafter as either long-term or short-term capital gain depending upon whether the U.S. Holder has held our ADSs for more than one year as of the time such distribution is received.

If you are a U.S. Holder, dividends paid to you with respect to our ADSs will be foreign source income for foreign tax credit purposes. Subject to certain conditions and limitations, Israeli tax withheld on dividends may be deducted from your taxable income or credited against your U.S. federal income tax liability. The limitation on foreign taxes eligible for credit is calculated separately with respect to specific classes of income. For this purpose, dividends generally constitute "passive category income," or, in the case of certain U.S. Holders, "general category income." A foreign tax credit for foreign taxes imposed on distributions may be denied if you do not satisfy certain minimum holding period requirements. The rules relating to the determination of the foreign tax credit are complex, and you should consult your tax advisor to determine whether and to what extent you will be entitled to this credit.

The amount of a distribution paid to a U.S. Holder in a foreign currency will be the dollar value of the foreign currency calculated by reference to the spot exchange rate on the day the U.S. Holder receives the distribution, regardless of whether the foreign currency is converted into U.S. dollars at that time. Any foreign currency gain or loss a U.S. Holder realizes on a subsequent conversion of foreign currency into U.S. dollars will be U.S. source ordinary income or loss. If dividends received in foreign currency are converted into U.S. dollars on the day they are received, a U.S. Holder generally should not be required to recognize foreign currency gain or loss in respect of the dividend.

Subject to certain limitations, including the Medicare tax, discussed below, "qualified dividend income" received by a non-corporate U.S. Holder should be subject to tax at a preferential maximum tax rate of 20 percent. Distributions taxable as dividends paid on the our ADSs should qualify for the preferential 20 percent rate provided that either: (i) we are entitled to benefits under the income tax treaty between the United States and Israel (the "Treaty") or (ii) our ADSs will be treated as readily tradable on an established securities market in the United States and certain other requirements are met. We believe that we will be entitled to benefits under the Treaty and that our ADSs will become readily tradable on an established securities market in the United States, and therefore any dividend distributions with respect to our ADSs should be "qualified dividends" eligible for the preferential tax rate. However, no assurance can be given that our ADSs will be treated as readily tradable. The preferential rate does not apply unless certain holding period requirements are satisfied. With respect to our ADSs, the U.S. Holder must have held such ADSs for at least 61 days during the 121-day period beginning 60 days before the ex-dividend date. The preferential rate also does not apply to dividends received from a passive foreign investment company (or classified as a passive foreign investment company in the preceding taxable year) or in respect of certain hedged positions or in certain other situations. The legislation enacting the preferential tax rate on qualified dividends contains special rules for computing the foreign tax credit limitation of a taxpayer who receives dividends subject to the preferential tax rate. U.S. Holders of our ADSs should consult their own tax advisors regarding the effect of these rules in their particular circumstances.

Subject to the discussion below under "Backup Withholding Tax and Information Reporting Requirements," if you are a Non-U.S. Holder, you generally will not be subject to U.S. federal income (or withholding) tax on dividends received by you on your ADSs, unless:

- you conduct a trade or business in the U.S. and such income is effectively connected with that trade or business (and, if required by an applicable income tax treaty, the dividends are attributable to a permanent establishment or fixed base that such holder maintains in the U.S.); or

- you are an individual and have been present in the U.S. for 183 days or more in the taxable year of such sale or exchange and certain other conditions are met.

Sale, Exchange or Other Disposition of Our ADSs and Warrants

Subject to the discussion below under "Passive Foreign Investment Company Consequences," if you are a U.S. Holder, you generally will recognize gain or loss on the sale, exchange or other disposition of our ADSs and warrants equal to the difference between the amount realized on such sale, exchange or other disposition and your adjusted tax basis in our ADSs and warrants, and such gain or loss will be capital gain or loss. The adjusted tax basis in an ADS and warrant generally will be equal to the cost of such ADS and warrant. If you are a non-corporate U.S. Holder, capital gain from the sale, exchange or other disposition of an ADS or warrant is generally eligible for a preferential rate of taxation applicable to capital gains, if your holding period determined at the time of such sale, exchange or other disposition for such ADS or warrant exceeds one year (i.e., such gain is long-term capital gain). The deductibility of capital losses is subject to limitations. Any such gain or loss generally will be treated as U.S. source income or loss for foreign tax credit limitation purposes. A foreign tax credit for foreign taxes imposed on capital gains may be denied if you do not satisfy certain minimum holding period requirements. The rules relating to the determination of the foreign tax credit are complex, and it is possible that the ability of a U.S. Holder to claim a foreign tax credit for any such Israeli tax will be limited. You should consult your tax advisor to determine whether, and to what extent, you will be entitled to this credit.

Subject to the discussion below under "Backup Withholding Tax and Information Reporting Requirements," if you are a Non-U.S. Holder, you generally will not be subject to U.S. federal income or withholding tax on any gain realized on the sale or exchange of such ADSs and warrants unless:

- such gain is effectively connected with your conduct of a trade or business in the United States (and, if required by an applicable income tax treaty, the gain is attributable to a permanent establishment or fixed base that you maintain in the United States); or

- you are an individual and have been present in the United States for 183 days or more in the taxable year of such sale or exchange and certain other conditions are met.

Passive Foreign Investment Company Consequences

We may be classified as a Passive Foreign Investment Company (PFIC). If we were to be so classified in any taxable year, a U.S. Holder would be subject to special rules generally intended to reduce or eliminate any benefits from the deferral of U.S. federal income tax that a U.S. Holder could derive from investing in a non-U.S. company that does not distribute all of its earnings on a current basis.

A non-U.S. corporation will be classified as a PFIC for federal income tax purposes in any taxable year in which, after applying certain look-through rules with respect to the income and assets of subsidiaries, either:

- at least 75% of its gross income is "passive income"; or

- at least 50% of the average quarterly value of its total gross assets (which may be determined in part by the market value of our ADSs and warrants, which is subject to change) is attributable to assets that produce "passive income" or are held for the production of passive income.

Passive income for this purpose generally includes dividends, interest, royalties, rents, gains from commodities and securities transactions, the excess of gains over losses from the disposition of assets which produce passive income, and includes amounts derived by reason of the temporary investment of funds raised in offerings of our ADSs and warrants. If a non-U.S. corporation owns directly or indirectly at least 25% by value of the stock of another corporation, the non-U.S. corporation is treated for purposes of the PFIC tests as owning its proportionate share of the assets of the other corporation and as receiving directly its proportionate share of the other corporation's income. If we are classified as a PFIC in any year with respect to which a U.S. Holder owns our ADSs or warrants, we will generally continue to be treated as a PFIC with respect to such U.S. Holder in all succeeding years during which the U.S. Holder owns our ADSs or warrants, regardless of whether we continue to meet the tests described above.

We were not classified as a PFIC in the year ended December 31, 2014. We have not performed tests to determine whether we will be classified as a PFIC, and we therefore do not know whether we will be classified as a PFIC for the taxable year ending December 31, 2015. Furthermore, because PFIC status is based on our income, assets and activities for the entire taxable year, it is not possible to determine whether we will be characterized as a PFIC for the 2015 taxable year until after the close of the year. Moreover, we must determine our PFIC status annually based on tests which are factual in nature, and our status in future years will depend on our income, assets and activities in those years. In addition, our status as a PFIC may depend on how quickly we utilize the cash proceeds from this offering in our business. There can be no assurance that we will not be considered a PFIC for any taxable year.

If we were a PFIC, and you are a U.S. Holder, then unless you make one of the elections described below, a special tax regime will apply to both (a) any "excess distribution" by us to you (generally, your ratable portion of distributions in any year which are greater than 125% of the average annual distribution received by you in the shorter of the three preceding years or your holding period for our ADSs or warrants) and (b) any gain realized on the sale or other disposition of the ADSs or warrants. Under this regime, any excess distribution and realized gain will be treated as ordinary income and will be subject to tax as if (i) the excess distribution or gain had been realized ratably over your holding period, (ii) the amount deemed realized in each year had been subject to tax in each year of that holding period at the highest marginal rate for such year (other than income allocated to the current period or any taxable period before we became a PFIC, which would be subject to tax, at the U.S. Holder's regular ordinary income rate for the current year and would not be subject to the interest change discussed below), and (iii) the interest charge generally applicable to underpayments of tax had been imposed on the taxes deemed to have been payable in those years. In addition, dividend distributions made to you will not qualify for the lower rates of taxation applicable to long-term capital gains discussed above under "Distributions." Certain elections may be available that would result in an alternative treatment (such as mark-to-market treatment) of our ADSs or warrants.

If a U.S. Holder makes the mark-to-market election, then, in lieu of being subject to the tax and interest charge rules discussed above, the U.S. Holder generally will recognize as ordinary income any excess of the fair market value of the ADSs or warrants at the end of each taxable year over their adjusted tax basis, and will recognize an ordinary loss in respect of any excess of the adjusted tax basis of the ADSs or warrants over their fair market value at the end of the taxable year (but only to the extent of the net amount of income previously included as a result of the mark-to-market election). If a U.S. Holder makes the election, the U.S. Holder's tax basis in its ADSs or warrants will be adjusted to reflect these income or loss amounts. Any gain recognized on the sale or other disposition of ADSs or warrants in a year when we are a PFIC will be treated as ordinary income and any loss will be treated as an ordinary loss (but only to the extent of the net amount of income previously included as a result of the mark-to-market election).

The mark-to-market election is available only if we are a PFIC and our ADSs or warrants are "regularly traded" on a "qualified exchange." Our ADSs and warrants will be treated as "regularly traded" in any calendar year in which more than a de minimis quantity of our ADSs and warrants are traded on a qualified exchange on at least 15 days during each calendar quarter. The NASDAQ is a qualified exchange for this purpose. Because a mark-to-market election cannot be made for any lower-tier PFICs that we may own, a U.S. Holder may continue to be subject to the tax and interest charge rules discussed above with respect to such holder's indirect interest in any investments held by us that are treated as an equity interest in a PFIC for U.S. federal income tax purposes, including stock in any of our subsidiaries that are treated as PFICs. If a U.S. Holder makes a mark-to market election, it will be effective for the taxable year for which the election is made and all subsequent taxable years unless our ADSs or warrants are no longer regularly traded on a qualified exchange or the IRS consents to the revocation of the election.

We do not intend to provide the information necessary for U.S. Holders to make qualified electing fund elections if we are classified as a PFIC. U.S. Holders should consult their tax advisors to determine whether any of these elections would be available and if so, what the consequences of the alternative treatments would be in their particular circumstances.

If we are determined to be a PFIC, the general tax treatment for U.S. Holders described in this section would apply to indirect distributions and gains deemed to be realized by U.S. Holders in respect of any of our subsidiaries that also may be determined to be PFICs.

If a U.S. Holder owns ADSs or warrants during any year in which we are a PFIC, the U.S. Holder generally will be required to file an IRS Form 8621 (Information Return by a Shareholder of a Passive Foreign Investment Company or Qualified Electing Fund) with respect to us, generally with the U.S. Holder's federal income tax return for that year.

U.S. Holders should consult their tax advisors regarding whether we are a PFIC and the potential application of the PFIC rules.

Medicare Tax

Certain U.S. Holders that are individuals, estates or trusts are subject to a 3.8% tax on all or a portion of their "net investment income," which may include all or a portion of their dividend income and net gains from the disposition of ADSs and warrants. Each U.S. Holder that is an individual, estate or trust is urged to consult its tax advisors regarding the applicability of the Medicare tax to its income and gains in respect of its investment in our ADSs and warrants.

Certain Reporting Requirements with Respect to Payments of Offer Price

U.S. Holders paying more than $100,000 for our ADSs and warrants generally will be required to file IRS Form 926 reporting the payment of the Offer Price for our ADSs and warrants to us. Substantial penalties may be imposed upon a U.S. Holder that fails to comply. Each U.S. Holder should consult its own tax advisor as to the possible obligation to file IRS Form 926.

Backup Withholding Tax and Information Reporting Requirements

U.S. backup withholding tax and information reporting requirements may apply to certain payments to certain holders of our ADSs and warrants. Information reporting generally will apply to payments of dividends on our ADSs, and to proceeds from the sale or redemption of our ADSs and warrants made within the United States, or by a U.S. payer or U.S. middleman, to a holder of our ADSs and warrants, other than an exempt recipient (including a payee that is not a U.S. person that provides an appropriate certification and certain other persons). A payer may be required to withhold backup withholding tax from any payments of dividends on our ADSs, or the proceeds from the sale or redemption of our ADSs and warrants within the United States, or by a U.S. payer or U.S. middleman, to a holder, other than an exempt recipient, if such holder fails to furnish its correct taxpayer identification number or otherwise fails to comply with, or establish an exemption from, such backup withholding tax requirements. Any amounts withheld under the backup withholding rules will be allowed as a credit against the beneficial owner's U.S. federal income tax liability, if any, and any excess amounts withheld under the backup withholding rules may be refunded, provided that the required information is timely furnished to the IRS.

Foreign Asset Reporting

Certain U.S. Holders who are individuals are required to report information relating to an interest in our ADSs and warrants, subject to certain exceptions (including an exception for shares held in accounts maintained by financial institutions) by filing IRS Form 8938 (Statement of Specified Foreign Financial Assets) with their federal income tax return. U.S. Holders are urged to consult their tax advisors regarding their information reporting obligations, if any, with respect to their ownership and disposition of our ADSs and warrants.

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 TO IT OF AN INVESTMENT IN OUR ADSs AND WARRANTS IN LIGHT OF THE INVESTOR'S OWN CIRCUMSTANCES.

F. Dividends and Paying Agents

Not applicable.

G. Statement by Experts

Not applicable.

H. Documents on Display

We are required to file reports and other information with the Securities and Exchange Commission (the "SEC") under the Securities Exchange Act of 1934 (the "Exchange Act") and the regulations thereunder applicable to foreign private issuers.

You may read and copy our 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, D.C. 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., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the public reference room. The SEC also maintains an Internet site that contains reports and other information regarding issuers that file electronically with the SEC. Our filings with the SEC are also available to the public through this web site at http://www.sec.gov. These SEC filings are also available to the public on (i) the Israel Securities Authority's Magna website at www.magna.isa.gov.il, (ii) the Tel Aviv Stock Exchange website at http://www.maya.tase.co.il, and (iii) from commercial document retrieval services.

As a foreign private issuer, we will be exempt from the rules under the Exchange Act relating 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 will not be required under the Exchange Act to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act. However, we intend to file with the SEC, within 120 days after the end of our fiscal year ended December 31, 2015 and each subsequent fiscal year, an annual report on Form 20-F containing financial statements which will be examined and reported on, with an opinion expressed, by an independent registered public accounting firm. Furthermore, we have committed to the underwriters of our initial U.S public offering which was completed in November 2015 that for a period of three (3) years from November 25, 2015, the Company, at its expense, will announce its financial information for each of the first three fiscal quarters consistent with the practices of companies dual-listed on the Tel Aviv Stock Exchange and a domestic U.S. securities exchange; provided that the foregoing shall not apply in the event the Company enters into a merger transaction in which the Company is the non-surviving entity that would cause our ADSs and warrants to no longer be registered under the Exchange Act. We will furnish this periodic information with the SEC under cover of Form 6-K.

Any statement in this Annual Report on Form 20-F about any of our contracts or other documents is not necessarily complete. If the contract or document is filed as an exhibit to the Annual Report on Form 20-F the contract or document is deemed to modify the description contained in this annual report. We urge you to review the exhibits themselves for a complete description of the contract or document.

We maintain a corporate website at www.kitovpharma.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. We have included our website address in this Annual Report on Form 20-F solely as an inactive textual reference. We will post on our website any materials required to be posted on such website under applicable corporate or securities laws and regulations, including posting any notices of general meetings of our shareholders.

I. Subsidiary Information

Not applicable.

ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Market risk is the risk of loss related to changes in market prices, including interest rates and foreign exchange rates, of financial instruments that may adversely impact our financial position, results of operations or cash flows. Our overall risk management program focuses on the unpredictability of financial markets and seeks to minimize potential adverse effects on our financial performance.

Risk of Interest Rate Fluctuation and Credit Exposure Risk

We do not anticipate undertaking any significant long-term borrowings. At present, our credit and interest risk arises from cash and cash equivalents, deposits with banks as well as accounts receivable. A substantial portion of our liquid instruments is invested in short-term deposits with Bank Leumi le- Israel Ltd., a major Israeli banking institution.

We estimate that because the liquid instruments are invested mainly for the short-term and with highly-rated institutions, the credit and interest risk associated with these balances is immaterial. The primary objective of our investment activities is to preserve principal while maximizing the income we receive from our investments without significantly increasing risk and loss. Our investments are exposed to market risk due to fluctuations in interest rates, which may affect our interest income and the fair market value of our investments. We manage this exposure by performing ongoing evaluations of our investments.

Equity Price Risk

We are not exposed to equity securities price risk because we have never invested in equity securities.

Foreign Currency Exchange Risk

Our foreign currency exposures give rise to market risk associated with exchange rate movements of the U.S. dollar, our functional and reporting currency, mainly against the NIS and other currencies. Although the U.S. dollar is our functional currency and reporting currency, a portion of our expenses are denominated in NIS. Our NIS expenses consist principally of payments to employees or service providers and short term investments in currencies other than the U.S. dollar. We anticipate that a sizable portion of our expenses will continue to be denominated in currencies other than the U.S. dollar. If the U.S. dollar fluctuates significantly against the NIS it may have a negative impact on our results of operations. We manage our foreign exchange risk by aligning the currencies for holding short term investments with the currencies of expected expenses, based on our expected cash flows.

Portfolio diversification is performed based on risk level limits that we set. To date, we have not engaged in hedging transactions. In the future, we may enter into 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.

(A) Set forth below is a sensitivity test to possible changes in U.S. dollars/NIS exchange rate as of December 31, 2015:

Sensitive instrument	Income (loss) from change in exchange rate (U.S. dollars in thousands)		Value (U.S. dollars in thousands)	Income (loss) from change in exchange rate (U.S. dollars in thousands)	
	Down 2%	Down 5%		Up 5%	Up 2%
Cash	(7)	(18)	358	18	7
Accounts receivable	(5)	(12)	246	12	5
Accounts payable	1	2	(47)	(2)	(1)
Other payables	12	30	(607)	(30)	(12)
Post employment benefit liabilities	1	4	(74)	(4)	(1)
Total income (loss)	2	6	(124)	(6)	(2)

(B) As of the date of this Annual Report on Form 20-F, our interest rate risk exposure is in respect to bank deposits, which expose us to risk due to change in fair value interest rates. As of December 31, 2015 we had no interest bearing bank deposits.

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

The Bank of New York Mellon, as depositary, will register and deliver American Depositary Shares, also referred to as ADSs. Each ADS will represent 20 shares (or a right to receive 20 shares) deposited with a local bank in Israel, as custodian for the depositary in Israel. Each ADS will also represent any other securities, cash or other property which may be held by the depositary. The depositary's office at which the ADSs will be administered is located at 101 Barclay Street, New York, New York 10286. The Bank of New York Mellon's principal executive office is located at One Wall Street, New York, New York 10286.

You may hold ADSs either (A) directly (i) by having an American Depositary Receipt, also referred to as an ADR, which is a certificate evidencing a specific number of ADSs, registered in your name, or (ii) by having uncertificated ADSs registered in your name, or (B) indirectly by holding a security entitlement in ADSs through your broker or other financial institution that is a direct or indirect participant in The Depository Trust Company, also called DTC. If you hold ADSs directly, you are a registered ADS holder, also referred to as an ADS holder. This description assumes you are an ADS holder. If you hold the ADSs indirectly, you must rely on the procedures of your broker or other financial institution to assert the rights of ADS holders described in this section. You should consult with your broker or financial institution to find out what those procedures are.

Registered holders of uncertificated ADSs will receive statements from the depositary confirming their holdings.

As an ADS holder, we will not treat you as one of our shareholders and you will not have shareholder rights. Israeli law governs shareholder rights. The depositary will be the holder of the shares underlying your ADSs. As a registered holder of ADSs, you will have ADS holder rights. A deposit agreement among us, the depositary, ADS holders and all other persons indirectly or beneficially holding ADSs sets out ADS holder rights as well as the rights and obligations of the depositary. New York law governs the deposit agreement and the ADSs.

The following is a summary of the material provisions of the deposit agreement. For more complete information, you should read the entire deposit agreement and the form of ADR, attached as exhibits to this Annual Report on Form 20-F.

Dividends and Other Distributions

How will you receive dividends and other distributions on the shares?

The depositary has agreed to pay or distribute to ADS holders the cash dividends or other distributions it or the custodian receives on shares or other deposited securities, upon payment or deduction of its fees and expenses. You will receive these distributions in proportion to the number of shares your ADSs represent.

Cash. The depositary will convert any cash dividend or other cash distribution we pay on the shares into U.S. dollars, if it can do so on a reasonable basis and can transfer the U.S. dollars to the United States. If that is not possible or if any government approval is needed and cannot be obtained, the deposit agreement allows the depositary to distribute the foreign currency only to those ADS holders to whom it is possible to do so. It will hold the foreign currency it cannot convert for the account of the ADS holders who have not been paid. It will not invest the foreign currency and it will not be liable for any interest.

Before making a distribution, any withholding taxes, or other governmental charges that must be paid will be deducted. See "Item 10. Additional Information – E. Taxation - Taxation of our Shareholders" for more detail. It will distribute only whole U.S. dollars and cents and will round fractional cents to the nearest whole cent. If the exchange rates fluctuate during a time when the depositary cannot convert the foreign currency, you may lose some of the value of the distribution.

Shares. The depositary may distribute additional ADSs representing any shares we distribute as a dividend or free distribution. The depositary will only distribute whole ADSs. It will sell shares which would require it to deliver a fraction of an ADS (or ADSs representing those shares) and distribute the net proceeds in the same way as it does with cash. If the depositary does not distribute additional ADSs, the outstanding ADSs will also represent the new shares. The depositary may sell a portion of the distributed shares (or ADSs representing those shares) sufficient to pay its fees and expenses in connection with that distribution.

Rights to purchase additional shares. If we offer holders of our securities any rights to subscribe for additional shares or any other rights, the depositary may (i) exercise those rights on behalf of ADS holders, (ii) distribute those rights to ADS holders or (iii) sell those rights and distribute the net proceeds to ADS holders, in each case after deduction or upon payment of its fees and expenses. To the extent the depositary does not do any of those things, it will allow the rights to lapse. In that case, you will receive no value for them. The depositary will exercise or distribute rights only if we ask it to and provide satisfactory assurances to the depositary that it is legal to do so. If the depositary will exercise rights, it will purchase the securities to which the rights relate and distribute those securities or, in the case of shares, new ADSs representing the new shares, to subscribing ADS holders, but only if ADS holders have paid the exercise price to the depositary. U.S. securities laws may restrict the ability of the depositary to distribute rights or ADSs or other securities issued on exercise of rights to all or certain ADS holders, and the securities distributed may be subject to restrictions on transfer.

Other Distributions. The depositary will send to ADS holders anything else we distribute on deposited securities by any means it thinks is legal, fair and practical. If it cannot make the distribution in that way, the depositary has a choice. It may decide to sell what we distributed and distribute the net proceeds, in the same way as it does with cash. Or, it may decide to hold what we distributed, in which case ADSs will also represent the newly distributed property. However, the depositary is not required to distribute any securities (other than ADSs) to ADS holders unless it receives satisfactory evidence from us that it is legal to make that distribution. The depositary may sell a portion of the distributed securities or property sufficient to pay its fees and expenses in connection with that distribution. U.S. securities laws may restrict the ability of the depositary to distribute securities to all or certain ADS holders, and the securities distributed may be subject to restrictions on transfer.

The depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any ADS holders. We have no obligation to register ADSs, shares, rights or other securities under the Securities Act. We also have no obligation to take any other action to permit the distribution of ADSs, shares, rights or anything else to ADS holders. *This means that you may not receive the distributions we make on our shares or any value for them if it is illegal or impractical for us to make them available to you.*

Deposit, Withdrawal and Cancellation

How are ADSs issued?

The depositary will deliver ADSs if you or your broker deposits shares or evidence of rights to receive shares with the custodian. Upon payment of its fees and expenses and of any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will register the appropriate number of ADSs in the names you request and will deliver the ADSs to or upon the order of the person or persons that made the deposit.

How can ADS holders withdraw the deposited securities?

You may surrender your ADSs for the purpose of withdrawal at the depositary's office. Upon payment of its fees and expenses and of any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will deliver the shares and any other deposited securities underlying the ADSs to the ADS holder or a person the ADS holder designates at the office of the custodian. Or, at your request, risk and expense, the depositary will deliver the deposited securities at its office, if feasible. The depositary may charge you a fee and its expenses for instructing the custodian regarding delivery of deposited securities.

How do ADS holders interchange between certificated ADSs and uncertificated ADSs?

You may surrender your ADR to the depositary for the purpose of exchanging your ADR for uncertificated ADSs. The depositary will cancel that ADR and will send to the ADS holder a statement confirming that the ADS holder is the registered holder of uncertificated ADSs. Alternatively, upon receipt by the depositary of a proper instruction from a registered holder of uncertificated ADSs requesting the exchange of uncertificated ADSs for certificated ADSs, the depositary will execute and deliver to the ADS holder an ADR evidencing those ADSs.

Voting Rights

How do you vote?

ADS holders may instruct the depositary how to vote the number of deposited shares their ADSs represent. If we request the depositary to solicit your voting instructions (and we are not required to do so), the depositary will notify you of a shareholders' meeting and send or make voting materials available to you. Those materials will describe the matters to be voted on and explain how ADS holders may instruct the depositary how to vote. For instructions to be valid, they must reach the depositary by a date set by the depositary. The depositary will try, as far as practical, subject to the laws of Israel and the provisions of our amended and restated articles of association or similar documents, to vote or to have its agents vote the shares or other deposited securities as instructed by ADS holders. If we do not request the depositary to solicit your voting instructions, you can still send voting instructions, and, in that case, the depositary may try to vote as you instruct, but it is not required to do so.

Except by instructing the depositary as described above, you won't be able to exercise voting rights unless you surrender your ADSs and withdraw the shares. However, you may not know about the meeting enough in advance to withdraw the shares. In any event, the depositary will not exercise any discretion in voting deposited securities and it will only vote or attempt to vote as instructed by the holder of the ADSs or as described in the following sentence. If we asked the depositary to solicit your instructions at least 30 days before the meeting date but the depositary does not receive voting instructions from you by the specified date, it will consider you to have authorized and directed it to give a discretionary proxy to a person designated by us to vote the number of deposited securities represented by your ADSs. The depositary will give a discretionary proxy in those circumstances to vote on all questions at to be voted upon unless we notify the depositary that:

- we do not wish to receive a discretionary proxy;
- there is substantial shareholder opposition to the particular question; or
- the particular question would have an adverse impact on our shareholders.

We are required to notify the depositary if one of the conditions specified above exists.

We cannot assure you that you will receive the voting materials in time to ensure that you can instruct the depositary to vote your shares. In addition, the depositary and its agents are not responsible for failing to carry out voting instructions or for the manner of carrying out voting instructions. *This means that you may not be able to exercise voting rights and there may be nothing you can do if your shares are not voted as you requested.*

In order to give you a reasonable opportunity to instruct the depositary as to the exercise of voting rights relating to deposited securities, if we request the depositary to act, we agree to give the depositary notice of any such meeting and details concerning the matters to be voted upon at least 30 days in advance of the meeting date.

Fees and Expenses

Persons depositing or withdrawing shares or ADS holders must pay:	*For:*
$5.00 (or less) per 100 ADSs (or portion of 100 ADSs)	Issuance of ADSs, including issuances resulting from a distribution of shares or rights or other property
	Cancellation of ADSs for the purpose of withdrawal, including if the deposit agreement terminates
$.05 (or less) per ADS	Any cash distribution to ADS holders
A fee equivalent to the fee that would be payable if securities distributed to you had been shares and the shares had been deposited for issuance of ADSs	Distribution of securities distributed to holders of deposited securities (including rights) that are distributed by the depositary to ADS holders
$.05 (or less) per ADS per calendar year	Depositary services
Registration or transfer fees	Transfer and registration of shares on our share register to or from the name of the depositary or its agent when you deposit or withdraw shares
Expenses of the depositary	Cable, telex and facsimile transmissions (when expressly provided in the deposit agreement)
	converting foreign currency to U.S. dollars
Taxes and other governmental charges the depositary or the custodian has to pay on any ADSs or shares underlying ADSs, such as stock transfer taxes, stamp duty or withholding taxes	As necessary
Any charges incurred by the depositary or its agents for servicing the deposited securities	As necessary

The depositary collects its fees for delivery and surrender of ADSs directly from investors depositing shares or surrendering ADSs for the purpose of withdrawal or from intermediaries acting for them. The depositary collects fees for making distributions to investors by deducting those fees from the amounts distributed or by selling a portion of distributable property to pay the fees. The depositary may collect its annual fee for depositary services by deduction from cash distributions or by directly billing investors or by charging the book-entry system accounts of participants acting for them. The depositary may collect any of its fees by deduction from any cash distribution payable (or by selling a portion of securities or other property distributable) to ADS holders that are obligated to pay those fees. The depositary may generally refuse to provide fee-attracting services until its fees for those services are paid.

From time to time, the depositary may make payments to us to reimburse us for costs and expenses generally arising out of establishment and maintenance of the ADS program, waive fees and expenses for services provided to us by the depositary or share revenue from the fees collected from ADS holders. In performing its duties under the deposit agreement, the depositary may use brokers, dealers, foreign currency or other service providers that are owned by or affiliated with the depositary and that may earn or share fees, spreads or commissions.

The depositary may convert foreign currency itself or through any of its affiliates and, in those cases, acts as principal for its own account and not as an agent, fiduciary or broker on behalf of any other person and earns revenue, including, without limitation, fees and spreads that it will retain for its own account. The spread is the difference between the exchange rate assigned to the currency conversion made under the deposit agreement and the rate that the depositary or its affiliate receives in an offsetting foreign currency trade. The depositary makes no representation that the exchange rate used or obtained in any currency conversion under the deposit agreement will be the most favorable rate that could be obtained at the time or as to the method by which that rate will be determined, subject to its obligations under the deposit agreement.

Payment of Taxes

You will be responsible for any taxes or other governmental charges payable on your ADSs or on the deposited securities represented by any of your ADSs. The depositary may refuse to register any transfer of your ADSs or allow you to withdraw the deposited securities represented by your ADSs until those taxes or other charges are paid. It may apply payments owed to you or sell deposited securities represented by your ADSs to pay any taxes owed and you will remain liable for any deficiency. If the depositary sells deposited securities, it will, if appropriate, reduce the number of ADSs to reflect the sale and pay to ADS holders any proceeds, or send to ADS holders any property, remaining after it has paid the taxes.

Amendment and Termination

How may the deposit agreement be amended?

We may agree with the depositary to amend the deposit agreement and the ADRs without your consent for any reason. If an amendment adds or increases fees or charges, except for taxes and other governmental charges or expenses of the depositary for registration fees, facsimile costs, delivery charges or similar items, or prejudices a substantial right of ADS holders, it will not become effective for outstanding ADSs until 30 days after the depositary notifies ADS holders of the amendment. *At the time an amendment becomes effective, you are considered, by continuing to hold your ADSs, to agree to the amendment and to be bound by the ADRs and the deposit agreement as amended.*

How may the deposit agreement be terminated?

The depositary will initiate termination of the deposit agreement if we instruct it to do so. The depositary may initiate termination of the deposit agreement if:

- 60 days have passed since the depositary told us it wants to resign but a successor depositary has not been appointed and accepted its appointment;
- we delist our shares from an exchange on which they were listed and do not list the shares on another exchange;
- we appear to be insolvent or enter insolvency proceedings
- all or substantially all the value of the deposited securities has been distributed either in cash or in the form of securities;
- there are no deposited securities underlying the ADSs or the underlying deposited securities have become apparently worthless; or
- there has been a replacement of deposited securities.

If the deposit agreement will terminate, the depositary will notify ADS holders at least 90 days before the termination date. At any time after the termination date, the depositary may sell the deposited securities. After that, the depositary will hold the money it received on the sale, as well as any other cash it is holding under the deposit agreement, unsegregated and without liability for interest, for the prorata benefit of the ADS holders that have not surrendered their ADSs. Normally, the depositary will sell as soon as practicable after the termination date.

After the termination date and before the depositary sells, ADS holders can still surrender their ADSs and receive delivery of deposited securities, except that the depositary may refuse to accept a surrender for the purpose of withdrawing deposited securities if it would interfere with the selling process. The depositary may refuse to accept a surrender for the purpose of withdrawing sale proceeds until all the deposited securities have been sold. The depositary will continue to collect distributions on deposited securities, but, after the termination date, the depositary is not required to register any transfer of ADSs or distribute any dividends or other distributions on deposited securities to the ADSs holder (until they surrender their ADSs) or give any notices or perform any other duties under the deposit agreement except as described in this paragraph.

Limitations on Obligations and Liability

Limits on our Obligations and the Obligations of the Depositary; Limits on Liability to Holders of ADSs

The deposit agreement expressly limits our obligations and the obligations of the depositary. It also limits our liability and the liability of the depositary. We and the depositary:

- are only obligated to take the actions specifically set forth in the deposit agreement without negligence or bad faith;
- are not liable if we are or it is prevented or delayed by law or circumstances beyond our or its control from performing our or its obligations under the deposit agreement;
- are not liable if we or it exercises discretion permitted under the deposit agreement;
- are not liable for the inability of any holder of ADSs to benefit from any distribution on deposited securities that is not made available to holders of ADSs under the terms of the deposit agreement, or for any special, consequential or punitive damages for any breach of the terms of the deposit agreement;
- have no obligation to become involved in a lawsuit or other proceeding related to the ADSs or the deposit agreement on your behalf or on behalf of any other person;
- are not liable for the acts or omissions of any securities depository, clearing agency or settlement system; and
- may rely upon any documents we believe or it believes in good faith to be genuine and to have been signed or presented by the proper person.

In the deposit agreement, we and the depositary agree to indemnify each other under certain circumstances.

Requirements for Depositary Actions

Before the depositary will deliver or register a transfer of ADSs, make a distribution on ADSs, or permit withdrawal of shares, the depositary may require:

- payment of stock transfer or other taxes or other governmental charges and transfer or registration fees charged by third parties for the transfer of any shares or other deposited securities;
- satisfactory proof of the identity and genuineness of any signature or other information it deems necessary; and
- compliance with regulations it may establish, from time to time, consistent with the deposit agreement, including presentation of transfer documents.

The depositary may refuse to deliver ADSs or register transfers of ADSs when the transfer books of the depositary or our transfer books are closed or at any time if the depositary or we think it advisable to do so.

Your Right to Receive the Shares Underlying your ADSs

ADS holders have the right to cancel their ADSs and withdraw the underlying shares at any time except:

- when temporary delays arise because: (i) the depositary has closed its transfer books or we have closed our transfer books; (ii) the transfer of shares is blocked to permit voting at a shareholders' meeting; or (iii) we are paying a dividend on our shares;
- when you owe money to pay fees, taxes and similar charges; or
- when it is necessary to prohibit withdrawals in order to comply with any laws or governmental regulations that apply to ADSs or to the withdrawal of shares or other deposited securities.

This right of withdrawal may not be limited by any other provision of the deposit agreement.

Public Warrants

The following summary of certain terms and provisions of our public warrants is not complete and is subject to, and qualified in its entirety by the provisions of the Warrant Agent Agreement, also referred to as the warrant agreement, and form of Warrant Certificate, which are filed as exhibits to this Annual Report on Form 20-F. Our public warrants are administered by the Bank of New York Mellon, as warrant agent.

Exercisability. The public warrants are exercisable immediately upon issuance and at any time up to the date that is five years from the date of issuance. The public warrants will be exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice accompanied by payment in full for the number of ADSs purchased upon such exercise (except in the case of a cashless exercise as discussed below), together with the ADS issuance fee of $0.05 per ADS and other applicable charges and taxes. Unless otherwise specified in the public warrant, the holder will not have the right to exercise the public warrants, in whole or in part, if the holder (together with its affiliates) would beneficially own in excess of 4.99% of the number of our ordinary shares outstanding immediately after giving effect to the exercise, as such percentage is determined in accordance with the terms of the public warrants , provided that, upon notice to the Company, such beneficial ownership limitation may be increased or decreased to any other percentage not in excess of 9.99%, provided that any increase in the beneficial ownership limitation will not be effective until the sixty first day after such notice to the Company is delivered.

Cashless Exercise. In the event that a registration statement covering ordinary shares underlying the public warrants is not effective, and an exemption from registration is not available for the resale of such ordinary shares underlying the public warrants, the holder may, in its sole discretion, exercise public warrants and, in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, elect instead to receive upon such exercise the net number of ADSs determined according to the formula set forth in the warrant agreement. The issuance fee of $0.05 per ADS, as well as other applicable charges and taxes, are due and payable upon any cashless exercise.

Exercise Price. The initial exercise price per ADS purchasable upon exercise of the public warrants is equal to $4.13 per ADS. In addition to the exercise price per ADS, the $0.05 issuance fee per ADS and other applicable charges and taxes are due and payable upon exercise.

Anti-Dilution Provisions. The exercise price is subject to adjustment in the event of sales of our ADSs or an equivalent number of ordinary shares during the one-year period following the closing at a price per share less than the exercise price then in effect (or securities convertible or exercisable into ADSs or equivalent number of ordinary shares at a conversion or exercise price less than the exercise price then in effect subject to customary exceptions). In addition, the exercise price and the number of ADSs issuable upon exercise are subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock subdivisions and combinations, reclassifications or similar events affecting our ADSs or ordinary shares.

Transferability. Subject to applicable laws, the public warrants may be transferred at the option of the holders upon surrender of the warrants to the warrant agent, together with the appropriate instruments of transfer.

Warrant Agent and Exchange Listing. The public warrants will be issued in registered form under the warrant agent agreement between us and the warrant agent.

Rights as a Stockholder. Except as otherwise provided in the warrant agreement or by virtue of such holder’s ownership of ADSs or ordinary shares, the holder of public warrants does not have rights or privileges of a holder of ADSs or ordinary shares, including any voting rights, until the holder exercises the warrants.

PART II

ITEM 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES

Not applicable

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

A. Below is a summary of the changes to our articles of association effected by the recent adoption of our English language amended and restated articles of association on March 2, 2016, replacing our previous Hebrew language articles of association which were in effect until March 2, 2016.

- An addition to the charitable donations clause to allow us to issue securities to charity.
- 75% of the participating directors at a vote of the board of directors will be required to determine that our center of management will be outside of Israel.
- The addition of a clause permitting the board of directors to issue redeemable securities.
- The addition of the chief executive officer and Company secretary to the authored signatories on share certificates.
- Share transfer instruments can be approved by our management instead of needing full board of directors approval.
- The addition of a provision stating that the board of directors can decline to approve transfers if not allowed under law, TASE rules or otherwise.
- The addition and revision of miscellaneous technical provisions governing submission of proof or ownership and proxies for shareholder meetings.
- Shareholder meetings shall be held in Israel unless our center of management has been changed as set forth in the amended and restated articles of association.
- Revised so that if the chairman of the board of directors is not present for a shareholder meeting then the chief executive officer or company secretary, or someone appointed by either of them, shall be chair of a shareholder meeting, before submitting the chair selection matter to those present at the shareholders meeting.
- Reduction in the maximum number of directors from 12 to 9.
- A majority of directors shall be Israeli residents unless our center of management has been changed as set forth in the amended and restated articles of association.
- Directors shall be appointed for three year terms with one third of the board of director member's terms expiring every year.
- Changing the director appointment provisions in the amended and restated articles of association will be subject to a special majority of 75% of the votes cast at a shareholders meeting and which majority comprises at least 47.9% of the Company's voting rights.
- Removal of the provision requiring external directors (this matter will now be subject to the requirements of the Companies Law and Regulations).
- Establishes that the audit committee of the board of directors is delegated with authority to approve the compensation of auditors as long as our securities are traded in U.S. markets.
- Shorten time period for receiving unclaimed dividends from 7 years to 3 years.
- Added provision that notices to shareholders may be publicized as specified by law (i.e. not only newspaper ads).
- Transactions in which officers have a personal interest but not extraordinary transactions can be approved by chief executive officer and chief financial officer (unless they have the personal interest; in which case it will be a director instead), as opposed the default provision in the Companies Law which requires full board of directors approval unless the articles of association state otherwise.

B. Not Applicable

C. Not Applicable

D. Not Applicable

E. Use of Proceeds.

Initial Public Offering

The effective date of the registration statement (File no. 333-207117) for our initial U.S public offering of our ADSs and warrants, was November 20, 2015. The offering with respect to our ADSs and warrants commenced on November 20, 2015 and was closed on November 25, 2015. Rodman & Renshaw, a unit of H.C. Wainwright & Co., and Joseph Gunnar & Co., LLC were joint bookrunning managers for the offering, We registered 3,158,900 American Depository Shares (ADSs), each representing 20 of our ordinary shares, and public warrants to purchase up to 3,158,900 ADSs, and granted the underwriters a 45-day option to purchase up to an additional 473,835 ADSs and/or warrants to purchase an additional 473,835 ADSs to cover over-allotments, if any, at the public offering price of $4.12 per ADS and $.01 per public warrant. The over-allotment was partially exercised by the underwriters for 220,074 warrants on November 25, 2015.

The gross proceeds received by us from this offering were approximately $13 million, prior to deducting underwriting discounts, commissions and other estimated offering expenses. Under the terms of the offering, we incurred aggregate underwriting discounts of approximately $900,000 (including the over-allotment option) and expenses of approximately $1.5 million in connection with the offering, resulting in net proceeds to us of approximately $10.6 million. None of the expenses was paid directly or indirectly to any director, officer, general partner of ours or to their associates, persons owning ten percent or more of any class of our equity securities, or to any of our affiliates, except for bonuses paid to certain of our executives in accordance with their compensation arrangements (see “Item 6. Directors, Senior Management and Employees B. Compensation – Executive Compensation”).

The primary purposes of this offering were to raise additional capital, create a U.S. public market for our ADSs and warrants, allow potential future access to the U.S. public markets should we need more capital in the future, increase the profile and prestige of our company with existing and possible strategic partners and make our shares more valuable and attractive to our employees and potential employees for compensation purposes.

As of February 29, 2016, we have used approximately $0.8 million of the net proceeds of this offering for research and development activities, approximately $0.6 million to repay the August Loans, and approximately $1.6 million for general corporate purposes. None of the net proceeds of the offering used for research and development activities; repayment of indebtedness; working capital; and any other purposes for which at least $100,000 has been used, was paid directly or indirectly to any director, officer, general partner of ours or to their associates, persons owning ten percent or more of any class of our equity securities, or to any of our affiliates, except for payments in connection with the $100,000 Principal Amount of the August Loans held by Haiku Capital Ltd., which, together with Mr. Sheer Roichman (who is deemed to beneficially own the shares held by Haiku Capital), became a holder of more than ten percent of our issued an outstanding share capital as a result of the acquisition of such holdings via participation in the offering. See “Item 7. Major Shareholders and Related Party Transactions – A. Major Shareholders - Changes in Percentage Ownership by Major Shareholders - Mr. Sheer Roichman / Haiku Capital Ltd.” and “Item 7. Major Shareholders and Related Party Transactions – B. Related Party Transactions – August 2015 Loan Agreement.”

We expect to use the additional net proceeds from this offering as follows:

(i) approximately $1.0 million to expand our clinical development program, specifically with respect to the Phase III clinical trial for our leading therapeutic candidate , KIT-302;
(ii) approximately $1.0 million to finance the CMC activities required for submitting a New Drug Application (NDA) for KIT-302 to the FDA;
(iii) approximately $0.5 million to perform the final PK (pharmacokinetic) trial for the selected formulation of KIT-302;
(iv) approximately $0.5 million finance our business development activities to enable out-licensing of our leading therapeutic candidate, KIT-302;

(v) approximately $1 to $3 million to expand our clinical development pipeline for additional drug products; and
(vi) the balance of the net proceeds for general corporate purposes, including working capital requirements.

We believe that the net proceeds from the offering, together with our cash reserves preceding the offering, should be sufficient to complete the Phase III clinical trial for KIT-302, perform the final PK trial for KIT-302, and perform the scale-up and ancillary work required to submit an NDA for KIT-302 to the FDA.

Our expected use of net proceeds from the offering represents our current intentions based upon our present plans and business condition. As of the date of this Annual Report on Form 20-F, we cannot predict with certainty any or all of the particular uses for the net proceeds we received upon the completion of the offering, or the amounts, if any, that we will actually spend on the uses set forth above. The amounts and timing of our actual use of the net proceeds will vary depending on numerous factors, including, the results of the final PK trial and our ability to identify additional therapeutic candidates to be developed. As a result, our management will have broad discretion in the application of the net proceeds, which may include uses not set forth above, and investors in our securities will be relying on our judgment regarding the application of the net proceeds from the offering.

ITEM 15. CONTROLS AND PROCEDURES

(a) Disclosure Controls and Procedures

We have performed an evaluation of the effectiveness of our disclosure controls and procedures that are designed to ensure that the material financial and non-financial information required to be disclosed to the SEC is recorded, processed, summarized and reported timely. Based on our evaluation, our management, including the chief executive officer and chief financial officer, has concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this report are effective. Notwithstanding the foregoing, there can be no assurance that our disclosure controls and procedures will detect or uncover all failures of persons within the Company to disclose material information otherwise required to be set forth in our reports.

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

This annual report does not include a report on management's assessment regarding internal control over financial reporting or an attestation report of the Company's registered public accounting firm due to a transition period established by the rules of the Securities and Exchange Commission for newly public companies.

(c) Attestation Report of Registered Public Accounting Firm

This annual report does not include a report on management's assessment regarding internal control over financial reporting or an attestation report of the Company's registered public accounting firm due to a transition period established by the rules of the Securities and Exchange Commission for newly public companies.

(d) Changes in Internal Controls over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the year ended December 31, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 16. [RESERVED]

ITEM 16A. AUDIT COMMITTEE FINANCIAL EXPERT

Our board of directors has determined that Ms. Sherf-Blau and Mr. Katzir are audit committee financial experts as defined by the SEC rules and have the requisite financial experience as defined by the NASDAQ Listing Rules. Dr. Zeitoun, Ms. Sherf-Blau and Mr. Katzir qualify as independent directors under the corporate governance standards of the NASDAQ Listing Rules and the independence requirements of Rule 10A-3 of the Exchange Act.

ITEM 16B. CODE OF ETHICS

Our Board of Directors adopted a Code of Business Conduct and Ethics (the "Code") that applies to all our employees, including without limitation our chief executive officer, chief financial officer and controller. A copy of the Code is attached as an exhibit to this Annual Report on Form 20-F and may also be viewed on our website at www.kitovpharma.com.

ITEM 16C. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Under the Companies Law, the board of directors is required to report to the annual general meeting the compensation paid to the auditors. The following table sets forth the approximate total compensation that was paid by the Company and its subsidiaries to the Company's independent auditors, Somekh Chaikin, Certified Public Accountants (Israel), a member of KPMG International, for each of the years ended December 31:

	(in thousands of U.S. dollars)	
	2015	2014
Audit fees[1]	42	35
Audit-related fees[2]	83	50
Tax [3]	8	
Total	133	85

(1) "Audit fees" include fees for services performed in connection with the Company's annual audit, certain procedures regarding the Company's quarterly financial results, consultation concerning financial accounting and reporting standards.
(2) "Audit-related fees" relate to assurance and associated services that are traditionally performed by the independent auditor, including fees related to our public offerings.
(3) These fees relate to services provided regarding tax compliance and review of tax returns.

100% of the audit related services, tax and other fees described in the table above were approved by the audit committee in accordance with paragraph (c)(7)(i)(C) of Rule 2-01 of Regulation S-X.

Audit committee's pre-approval policies and procedures

Under the Companies Law and our amended and restated articles of association, our shareholders are authorized to appoint our independent auditors. Under the Companies Law and our amended and restated articles of association, the shareholders may appoint our independent auditors to hold office for a longer period of time that will not extend beyond the end of the third annual meeting following that at which the auditor was appointed. At our 2014 annual general meeting of the shareholders, our shareholders appointed Somekh Chaikin, Certified Public Accountants (Israel), a member of KPMG International, as the independent public accountants of the Company for such longer period of time not to extend beyond the 2017 annual general meeting at which time the appointment of an auditor will be presented to the shareholders once again.

Under the Companies Law and our amended and restated articles of association, the board of directors is authorized to determine the independent auditor's remuneration. In addition, the NASDAQ Listing Rules require that a listed company's audit committee approve the re-appointment and remuneration of the independent auditor. Our amended and restated articles of association include a provision which states that for so long as our securities are listed for trading on an exchange in the United States of America, such authority of the board of directors to set the remuneration of the auditor for audit activity and/or for additional services to us not being audit-related, will be deemed to have been delegated by the board of directors to the audit committee of the board of directors.

This policy, which is designed to assure that such engagements do not impair the independence of our auditors, requires pre-approval from the audit committee on an annual basis for the various audit and non-audit services that may be performed by our auditors. Our audit committee is not permitted to approve the engagement of our auditors for any services that would be inconsistent with maintaining the auditor's independence or that are not permitted by applicable law.

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

Home Country Practices

As a foreign private issuer, we are permitted to follow Israeli corporate governance practices instead of NASDAQ Listing Rules, provided that we disclose which requirements we are not following and the equivalent Israeli requirement. We intend to rely on this "foreign private issuer exemption" with respect to the following items:

- *Distribution of annual and quarterly reports to shareholders*. Under Israeli law, as a public company whose shares are traded on the TASE, we are not required to distribute annual and quarterly reports directly to shareholders and the generally accepted business practice in Israel is not to distribute such reports to shareholders but to make such reports publicly available through the website of the Israeli Securities Authority and the TASE. In addition, we make our audited financial statements available to our shareholders at our offices.

- *Independent Directors.* Our board of directors includes two external directors in accordance with the Israeli Companies Law, but does not require that a majority of our board members be independent as required by the NASDAQ Listing Rules. Furthermore, Israeli law does not require, nor do our independent directors conduct, regularly scheduled meetings at which only our independent directors are present. We are required, however, to ensure that all members of our audit committee are "independent" under the applicable Nasdaq and SEC criteria for independence, and we must also ensure that a majority of the members of our Audit Committee are unaffiliated directors as defined in the Companies Law.

- *Audit Committee*. While our board of directors has adopted an audit committee charter, Israeli law, and our amended and restated articles of association, do not require that we adopt and file an audit committee charter. Consistent with Israeli law, the independent auditors are elected at a meeting of shareholders instead of being appointed by the audit committee.

- *Compensation Committee and Compensation of Officers.* Under NASDAQ Listing Rules, the Company must establish a compensation committee and adopt a formal written compensation committee charter addressing the scope of the compensation committee's responsibilities, including structure, processes and membership requirements, among others. We do not have such a formal written charter. Israeli laws, and our amended and restated articles of association, do not require that the Company adopt and file a compensation committee charter. Under Amendment 27 to the Companies Law, which became effective as of February 17, 2016, the audit committee of an Israeli public company which meets the has been established and conducts itself also in accordance with provisions governing the composition of the compensation committee as set forth in the Companies Law, may act in lieu of a compensation committee with respect to the responsibilities of a compensation committee which are set forth in the Companies Law. Our audit committee presently meets this requirement and our board of directors resolved on March 16, 2016 to have the audit committee as assume the responsibilities of the compensation committee pursuant to this new provision in the Companies Law. Additionally, we comply with the requirements set forth under the Companies Law, pursuant to which transactions with office holders regarding their terms of office and employment, and transactions with a controlling shareholder in a company regarding his or her employment and/or his or her terms of office with the company, may require the approval of the compensation committee (or the audit committee acting in lieu of a compensation committee in accordance with the Companies Law), the board of directors and under certain circumstances the shareholders, either in accordance with our previously approved compensation policy or, in special circumstances in deviation therefrom, taking into account certain considerations set forth in the Companies Law. The requirements for shareholder approval of any office holder compensation, and the relevant majority or special majority for such approval, are all as set forth in the Companies Law. Thus, we will seek shareholder approval for all corporate actions with respect to office holder compensation requiring such approval under the requirements of the Companies Law, including seeking prior approval of the shareholders for the compensation policy and for certain office holder compensation, rather than seeking approval for such corporate actions in accordance with NASDAQ Listing Rules.

- *Shareholder Approval.* We seek shareholder approval for all corporate actions requiring such approval in accordance with the requirements of the Companies Law, which are different from the shareholder approval requirements under the NASDAQ Listing Rules, including NASDAQ Listing Rule 5635. The NASDAQ Listing Rules require that we obtain shareholder approval for certain dilutive events, such as for the establishment or amendment of certain equity-based compensation plans and arrangements, issuances that will result in a change of control of a company, certain transactions other than a public offering involving issuances of 20% or more of the shares or voting power in a company, and certain acquisitions of the stock or assets of another company involving issuances of 20% or more of the shares or voting power in a company or if any director, officer or holder of 5% or more of the shares or voting power of the company has a 5% or greater interest in the company or assets to be acquired or consideration to be paid and the transaction could result in an increase in the outstanding common shares or voting power by 5% or more.

  Under the Companies Law, shareholder approval is required for any transaction, including any grant of equity-based compensation, to a director or a controlling shareholder, but is not generally required to establish or amend an equity based compensation plan. Similarly, shareholder approval is required for a private placement that is deemed a “extraordinary private placement” or that involves a director or controlling shareholder. A “extraordinary private placement” is a private placement in which a company issues securities representing 20% or more of its voting rights prior to the issuance and the consideration received pursuant to such issuance is not comprised, in whole or in part, solely of cash or securities registered for trade on an exchange or which is not made pursuant to market conditions, and as a result of which the shareholdings of a 5% holder of the shares or voting rights of the company increases or as a result of which a person will become a holder of 5% of the shares or voting rights of the company or a controlling shareholder after the issuance. We will attempt to seek shareholder approval for our stock option or equity compensation plans (and the relevant annexes thereto) to the extent required in order to ensure they are tax qualified for any employees in the U.S. or who are U.S. citizens. However, even if such approval is not received, then the stock option or equity compensation plans will continue to be in effect, but the Company will be unable to grant options to its U.S. resident and/or citizen employees that qualify as Incentive Stock Options for U.S. federal tax purpose. Our stock option or other equity compensation plans are also available to our non-U.S. employees, and provide features necessary to comply with applicable non-U.S. tax laws.

- *Approval of Related Party Transactions.* All related party transactions are approved in accordance with the requirements and procedures for approval of interested party acts and transactions, set forth in sections 268 to 275 of the Companies Law, and the regulations promulgated thereunder, which require the approval of the audit committee, the compensation committee (or the audit committee acting in lieu of a compensation committee pursuant to the Companies Law), the board of directors and shareholders, as may be applicable, for specified transactions, rather than approval by the audit committee or other independent body of our Board of Directors as required under the NASDAQ Listing Rules.

- *Meetings of Shareholders: Annual Meetings; Proxy Solicitations; Quorum.* The NASDAQ Listing Rules require that each company listing common stock, and their equivalents, hold an annual meeting of shareholders within one year of the end of each fiscal year, and that at such meeting, shareholders must be afforded the opportunity to discuss company affairs with management and, if required by the Company's governing documents, to elect directors. They further require that each company shall solicit proxies and provide proxy statements for all meetings of shareholders and shall provide copies of such proxy solicitation to NASDAQ. Under the NASDAQ Listing rules, the quorum required for an ordinary meeting of shareholders consists of 33 1/3% of the issued share capital. We will follow our home country practices with respect to the above as follows:

    - *Annual Meetings*. As permitted under the Companies Law and Regulations enacted pursuant to such law, and as set forth in our amended and restated articles of association, we are required to hold an annual meeting each year and provided that it is no later than 15 months from the prior annual meeting. At the annual meeting we are required to elect directors (other than external directors) and to present the annual financial statements and annual report, as well as presenting the fees paid to our auditors.

    - *Proxy Solicitations*. As permitted under the Companies Law and Regulations enacted pursuant to such law, and as set forth in our amended and restated articles of association, we are not required to physically deliver a notice of a shareholders meeting and a proxy statement. We will prepare notices of general meeting of our shareholders, as well as the accompanying proxy statement and voting instruction forms, (collectively, the "Proxy Materials") in accordance with applicable rules, regulations and disclosure requirements in the State of Israel, as such are applicable to a Company whose shares are traded on both the TASE and the NASDAQ. Our Proxy Materials may not necessarily be be mailed to beneficial shareholders in Israel, nor to beneficial ADS holders in the U.S. Forms of the Proxy Materials will be furnished to the SEC on Form 6-K, and will be available to the public on the SEC's website at http://www.sec.gov. The proxy materials will also be filed with the Israeli Securities Authority and TASE and available on the websites: www.magna.isa.gov.il or www.maya.tase.co.il. The Proxy Materials will also be made available on our corporate website at www.kitovpharma.com, as required under the Companies Law and Regulations governing distribution of the Proxy Materials.

    - *Quorum*. As permitted under the Companies Law, pursuant to our amended and restated articles of association, the quorum required for an ordinary meeting of shareholders consists of at least two shareholders present in person or by proxy who hold or represent at least 25% of the voting rights of our shares (and in an adjourned meeting, with some exceptions, any number of shareholders), instead of 33 1/3% of the issued share capital required under the NASDAQ Listing Rules.

- *Nominations Committee and Nominations of our Directors.* Directors are not selected, or recommended for board of director selection, by independent directors constituting a majority of the board's independent directors or by a nominations committee comprised solely of independent directors as required by the NASDAQ Listing Rules With the exception of our external directors and directors elected by our Board of Directors due to vacancy, our directors are elected by a general or special meeting of our shareholders. The nominations for directors, which are presented to our shareholders, are generally made by our directors, but nominations may be made by one or more of our shareholders as provided in our amended and restated articles of association, under the Companies Law or in an agreement between us and our shareholders. Currently, there is no agreement between us and any shareholder regarding the nomination of directors. In accordance with our amended and restated articles of association, under the Companies Law, any one or more shareholders holding, in the aggregate, either (1) 5% of our outstanding shares and 1% of our outstanding voting power or (2) 5% of our outstanding voting power, may nominate one or more persons for election as directors at a general meeting by delivering a written notice of such shareholder's intent to make such nomination or nominations to our registered office. Each such notice must set forth all of the details and information as required to be provided by our amended and restated articles of association.

- *Nominations Committee Charter or Board Resolution.* Under NASDAQ Listing Rules, U.S. domestic listed companies, must adopt a formal written charter or board resolution, as applicable, addressing the nominations process and such related matters as may be required under the federal securities laws. We do not have such a formal written charter or board resolution.

Otherwise, we intend to comply with the rules generally applicable to U.S. domestic companies listed on NASDAQ. We may in the future decide to use the foreign private issuer exemption with respect to some or all of the other NASDAQ Listing Rules related to corporate governance. We also intend to comply with Israeli corporate governance requirements under the Companies Law applicable to public companies.

ITEM 16H. MINE SAFETY DISCLOSURE

Not applicable

PART III

ITEM 17. FINANCIAL STATEMENTS

The Registrant has responded to Item 18 in lieu of responding to this Item.

ITEM 18. FINANCIAL STATEMENTS

See the financial statements beginning on page F-1. The financial statements and financial statement schedules are filed as part of this Annual Report on Form 20-F together with the report of the independent registered public accounting firm.

ITEM 19. EXHIBITS

The exhibits filed with or incorporated into this Annual Report on Form 20-F are listed in the index of exhibits below**:**

Exhibit Number	**Exhibit Description**
1.1	Amended and Restated Articles of Association of the Registrant (included as Exhibit 99.1 to our Form 6-k furnished to the Securities and Exchange Commission on March 3, 2016, and incorporated herein by reference).
1.2	Certificate of Company Name Change (unofficial English translations from Hebrew) (included as part of Exhibit 3.1 to our Registration Statement on Form F-1 as filed with the Securities and Exchange Commission on September 24, 2015, and incorporated herein by reference).
2.1	Form of Deposit Agreement among the Registrant, the Bank of New York Mellon, as Depositary, and all Owners and Holders from time to time of American Depositary Shares issued hereunder (included as Exhibit 4.1to our Registration Statement on Form F-1 as filed with the Securities and Exchange Commission on September 24, 2015, and incorporated herein by reference).
2.2	Form of Warrant Agent Agreement (included as Exhibit 4.2 to our Registration Statement on Form F-1/A as filed with the Securities and Exchange Commission on November 18, 2015, and incorporated herein by reference).
2.3	Form of American Depositary Receipt (included in Exhibit 2.1).
2.4	Form of Underwriters' Warrant, (included as Exhibit 4.4 to our Registration Statement on Form F-1/A as filed with the Securities and Exchange Commission on November 18, 2015, and incorporated herein by reference).
4.1†	Development Services Agreement, dated as of April 1, 2014, by and between Kitov Pharmaceuticals Holdings Ltd. and Dexcel Ltd. (included as Exhibit 10.1 to our Registration Statement on Form F-1 as filed with the Securities and Exchange Commission on September 24, 2015, and incorporated herein by reference).
4.2	Master Research Services Agreement, dated February 4, 2014, between Kitov Pharmaceuticals Holdings Ltd. and Java Clinical Research Limited (included as Exhibit 10.2 to our Registration Statement on Form F-1 filed with the Securities and Exchange Commission on September 24, 2015, and incorporated herein by reference).

4.3	Change Order Forms under Master Research Services Agreement between Kitov Pharmaceuticals Holdings Ltd. and Java Clinical Research Limited dated March 26, 2014, September 22, 2014, and April 2, 2015 (included as Exhibit 10.3 to our Registration Statement on Form F-1 as filed with the Securities and Exchange Commission on September 24, 2015, and incorporated herein by reference).
4.4	Share Transfer Agreement, dated as of April 2, 2013, Kitov Pharmaceuticals Holdings Ltd. (then known as Mainron Line Logisitics Ltd.), Kitov Pharmaceuticals Ltd., the shareholders of Kitov Pharmaceuticals, Sheer Roichman and Haiku Capital Ltd. (included as Exhibit 10.4 to our Registration Statement on Form F-1 filed with the Securities and Exchange Commission on September 24, 2015, and incorporated herein by reference).
4.5	Form of Letter of Exemption adopted on July 2013 (unofficial English translation from Hebrew) (included as Exhibit 10.5 to our Registration Statement on Form F-1 filed with the Securities and Exchange Commission on September 24, 2015, and incorporated herein by reference).
4.6	Form of Letter of Indemnity adopted on July 2013 (unofficial English translation from Hebrew) (included as Exhibit 10.6 to our Registration Statement on Form F-1 as filed with the Securities and Exchange Commission on September 24, 2015, and incorporated herein by reference).
4.7	2013 Stock Option Plan, as amended (unofficial English translation from Hebrew (included as Exhibit 10.7 to our Registration Statement on Form F-1 filed with the Securities and Exchange Commission on September 24, 2015, and incorporated herein by reference).
4.8	Loan Agreement, dated August 12, 2015 between Kitov Pharmaceuticals Holdings Ltd. and certain lenders (included as Exhibit 10.8 to our Registration Statement on Form F-1 filed with the Securities and Exchange Commission on September 24, 2015, and incorporated herein by reference).
4.9	Kitov Pharmaceuticals Holdings Ltd. Office Holders' Compensation Policy (unofficial translation to English from Hebrew original).
4.10	Form of Underwriting Agreement (included as Exhibit 1.1 to our Registration Statement on Form F-1/A filed with the Securities and Exchange Commission on November 18, 2015, and incorporated herein by reference).
8.1	List of subsidiaries of the Registrant (included as Exhibit 21.1 to our Registration Statement on Form F-1 filed with the Securities and Exchange Commission on September 24, 2015, and incorporated herein by reference).
11.1	Code of Ethics
12.1	Certification by Chief Executive Officer pursuant to section 302 of the Sarbanes-Oxley Act of 2002.
12.2	Certification by Chief Financial Officer pursuant to section 302 of the Sarbanes-Oxley Act of 2002.
13.1	Certification by Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
13.2	Certification by Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

† Portions of this exhibit have been omitted and filed separately with the Securities and Exchange Commission pursuant to a confidential treatment request.

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 on its behalf.

KITOV PHARMACEUTICALS HOLDINGS LTD.

By: /s/ Isaac Israel
Name: Isaac Israel
Title: Chief Executive Officer
Date: March 18, 2016

Kitov Pharmaceuticals Holdings Ltd.

Consolidated Financial Statements
As of December 31, 2015

Contents

Report of Independent Registered Public Accounting Firm

The Board of Directors and Shareholders
Kitov Pharmaceuticals Holdings Ltd.

We have audited the accompanying consolidated statements of financial position of Kitov Pharmaceuticals Holdings Ltd and its subsidiary (hereinafter – "the Company") as of December 31, 2015 and 2014, and the related consolidated statements of operations, changes in equity (deficit) and cash flows for each of the years in the three-year period ended December 31, 2015. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. Our audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2015 and 2014, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2015, in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

/s/ Somekh Chaikin
Somekh Chaikin
Certified Public Accountants (Isr.)
Member firm of KPMG International
Tel-Aviv, Israel

March 16, 2016

Consolidated Statements of financial position

	Note	December 31 2015 USD thousands	December 31 2014 USD thousands
Assets			
Cash	4	**10,558**	1,313
Other receivables	5	**246**	446
Total current assets		**10,804**	1,759
Fixed assets, net		**8**	-
Total assets		**10,812**	1,759
Liabilities			
Accounts payable		**353**	500
Other payables	7,11	**704**	114
Loans from related parties	8,11	**-**	294
Derivative instruments	9	**141**	78
Total current liabilities		**1,198**	986
Non-current liabilities			
Post employment benefit liabilities	18,11	**185**	-
Equity			
Share capital, no par value		**-**	-
Share premium	9	**22,159**	9,104
Receipts on account of warrants		**27**	200
Capital reserve for share-based payments	10	**536**	560
Capital reserve from transactions with related parties		**761**	761
Accumulated loss		**(14,054)**	(9,852)
Total equity		**9,429**	773
Total liabilities and equity		**10,812**	1,759

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

Consolidated Statements of Changes in Equity (Deficit)

	Note	2015 USD thousands	2014 USD thousands	2013 USD thousands
Research and development expenses	13	**2,560**	3,192	109
General and administrative expenses	14	**1,509**	1,269	1,061
Stock exchange listing expense		**-**	-	1,383
Other expenses	15	**-**	720	-
Operating Loss		**4,069**	5,181	2,553
Finance expense	16	**227**	345	75
Finance income		**(94)**	(274)	-
Financial expenses, net		**133**	71	75
Loss for the year		**4,202**	5,252	2,628
Loss per share data				
Basic and diluted loss per share – USD		**0.22**	1.17	1.60
Number of shares used in calculating basic and diluted loss per share		**19,250,340**	4,481,684	1,641,177

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

Consolidated Statements of Changes in Equity (Deficit)

	Share Capital	Share premium	Receipts on account of warrants	Capital reserve for share-based payments	Capital reserve from transactions with related parties	Accumulated loss	Total
For the year ended December 31, 2015:							
Balance as of January 1, 2015							
Changes for the year ended December 31, 2015:	-	**9,104**	**200**	**560**	**761**	**(9,852)**	**773**
Issuance of shares, net of issuance costs	-	**1,821**	-	-	-	-	**1,821**
Exercise and expiration of warrants (series 1)	-	**201**	**(200)**	-	-	-	**1**
Share issuance deriving from a strategic cooperation agreement (see note 12)	-	**500**	-	**(83)**	-	-	**417**
Share-based payments	-	-	-	**59**	-	-	**59**
Exercise of warrants (series 2)	-	**2**	-	-	-	-	**2**
Issuance of American Depository Shares (ADSs) on the NASDAQ, net of issuance costs	-	10,531	-	-	-	-	10,531
Issuance of warrants, net of issuance costs	-	-	**27**	-	-	-	**27**
Loss for the year	-	-	-	-	-	**(4,202)**	**(4,202)**
Balance as of December 31, 2015	-	**22,159**	**27**	**536**	**761**	**(14,054)**	**9,429**

	Share Capital	Share premium	Receipts on account of warrants	Capital reserve for share-based payments	Capital reserve from transactions with related parties	Accumulated loss	Total
For the year ended December 31, 2014:							
Balance as of January 1, 2014	-	**2,654**	-	**141**	**859**	**(4,600)**	**(946)**
Changes for the year ended December 31, 2014:							
Issuance of shares, net of issuance costs	-	**6,200**		**57**	-	-	**6,257**
Issuance of warrants in a rights offering	-	**(200)**	**200**	-	-	-	-
Share issuance deriving from a strategic cooperation agreement (see note 12)	-	**327**	-	**333**	-	-	**660**
Share-based payments	-	-	-	**88**	-	-	**88**
Options exercised	-	**123**	-	**(59)**	-	-	**64**
Capital reserve from transactions with related parties	-	-	-	-	43	-	43
Return of funds to a related party	-	-	-	-	**(141)**	-	**(141)**
Loss for the year	-	-	-	-	-	**(5,252)**	**(5,252)**
Balance as of December 31, 2014	-	**9,104**	**200**	**560**	**761**	**(9,852)**	**773**

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

Consolidated Statements of Changes in Equity (Deficit)

	Share Capital	Share premium	Capital reserve for share-based payments	Capital reserve from transactions with related parties	Accumulated loss	Total
For the year ended December 31, 2013:						
Balance as of January 1, 2013	-	1,089	-	476	(1,972)	(407)
Changes for the year ended December 31, 2013:						
Issuance of shares pursuant to share purchase transaction	-	1,383	-	-	-	1,383
Share based payments	-	-	296	-	-	296
Options exercise	-	182	(155)	-	-	27
Capital reserve from transactions with related parties	-	-	-	383	-	383
Loss for the year	-	-	-	-	(2,628)	(2,628)
Balance as of December 31, 2013	-	2,654	141	859	(4,600)	(946)

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

Consolidated Statements of Cash Flows for the year ended December 31,

	2015	2014	2013
		USD thousands	
Cash flows from operating activities:			
Loss for the year	**(4,202)**	(5,252)	(2,628)
Adjustments:			
Depreciation	**1**	-	-
Finance expense, net	**133**	71	75
Stock exchange listing expense	**-**	-	1,383
Share-based payments	**59**	88	296
Expenses in regard to a strategic cooperation agreement (see note 12)	417	660	-
Non-remunerable services provided by related parties	-	37	228
	(3,592)	(4,396)	646
Changes in assets and liabilities:			
Changes in receivables	**197**	(375)	(110)
Changes in accounts payable	**(152)**	453	(11)
Changes in other payables	**54**	(208)	255
Changes in post employment benefit liabilities	**185**	-	-
	284	(130)	134
Net cash used in operating activities	**(3,308)**	(4,526)	(512)
Cash flows from investing activities:			
Acquisition of fixed assets	**(9)**	-	-
Net cash used in investing activities	**(9)**	-	-
Cash flows from financing activities:			
Loan received from related parties	**-**	-	578
Repayment of loans from related parties	**(294)**	(622)	-
Loans received from third parties	**-**	132	108
Repayment of loans from third parties	-	(246)	-
Proceeds from issuance of shares and ADSs	**14,942**	6,848	-
Share and ADS issuance expenses paid	**(2,059)**	(571)	-
Proceeds from issuance of warrants	**190**	349	-
Warrants issuance expenses paid	**(10)**	(25)	-
Receipts from option exercise	**2**	57	27
Interest paid	**(145)**	(100)	(12)
Net cash provided by financing activities:	**12,632**	5,822	701
Net increase in cash	**9,315**	1,296	189
Cash at the beginning of the year	**1,313**	193	-
Effect of translation adjustments on cash	**(70)**	(176)	4
Cash at end of the year	**10,558**	1,313	193

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

Note 1 - General

Reporting entity

Kitov Pharmaceuticals Holdings Ltd. (hereinafter: **"the Company**") is an Israeli company, that was incorporated in Israel as a private company in August 1968, and has been listed for trading on the Tel Aviv Stock Exchange since September 1978. In October 2012, the Company disposed of all of its previous operations, and in July, 2013, the Company acquired shares of Kitov Pharmaceuticals Ltd. (hereinafter: "**Kitov**") from its shareholders, in exchange for the Company's shares (hereinafter: **"the Acquisition"**).

The Company's securities were listed for trading on the NASDAQ in November 2015.

The Company's address is Azrieli Towers, the Round Tower, 132 Menachem Begin Road, Tel Aviv.

The Company together with Kitov are referred to, in these financial statements, as "the Group".

As of the date of the financial statements, the Company is engaged, through Kitov, in the development of combination drugs that treat two clinical conditions simultaneously, pain caused by osteoarthritis and hypertension.

Since incorporation through December 31, 2015, the Company has incurred losses and negative cash flows from operations mainly attributed to its development efforts and has an accumulated deficit of USD 14.0 million. The Company has financed its operations mainly through private and public financing rounds. In November 2015, the Company raised USD 10.6 million net, which management believes will allow the Company to complete its current development plans. The Company currently has no revenue and may require additional funding for future plans.

Note 2 - Basis of Preparation of the Financial Statements

A. Statement of compliance with International Financial Reporting Standards

The Company has prepared the financial statements in accordance with International Financial Reporting Standards (hereinafter: "IFRS"), as issued by the International Accounting Standard Board ("IASB").

B. Functional and presentation currency

These financial statements are presented in US dollars (USD), which is the Group's functional currency, rounded to the nearest one thousand, unless otherwise noted. The USD is the currency that represents the principal economic environment in which the Group operates.

C. Use of estimates and judgment

The preparation of financial statements in conformity with IFRS requires management to make judgments, estimates and assumptions that affect the application of accounting policies and the reported amounts of assets, liabilities, income and expenses. Actual results may differ from these estimates.

Management prepares the estimates on the basis of past experience, various facts, external circumstances, and reasonable assumptions according to the pertinent circumstances of each estimate.

Estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognized in the period in which the estimates are revised and in any future periods affected.

Note 2 - Basis of Preparation of the Financial Statements (continued)

D. Fair value determination - share-based payments

In preparing these financial statements, the Group is required to determine the fair value of share-based payment arrangements. In order to determine the fair value, the Company conducted an independent valuation. For more information about assumptions used in determination of the fair value of granted options, see Note 10.

E. Exchange rates and linkage bases

Balances in foreign currency or linked thereto are included in the financial statements at the representative exchange rates, as published by the Bank of Israel, which were prevailing as of the statement of financial position date.

Data on exchange rates are as follows:

	Representative exchange rate of $ (NIS/$ 1)
Date of financial statements:	
December 31, 2015	3.902
December 31, 2014	3.889
December 31, 2013	3.471

Changes in exchange rates for the Year ended:	**%**
December 31, 2015	0.3
December 31, 2014	12.0
December 31, 2013	(7.0)

Note 3 - Significant Accounting Policies

The accounting policies set out below have been consistently applied for all periods presented in these consolidated financial statements

A. Subsidiary

A subsidiary is an entity controlled by the Company. The Company controls an entity when it is exposed to, or has rights to, variable returns from its involvement with the entity and has the ability to affect those returns through its power over the entity. The financial statements of the subsidiary are included in the consolidated financial statements from the date that control commences until the date that control is lost.

B. Foreign currency transactions

Transactions in foreign currency are translated to the functional currency of Group companies at exchange rates as of the transaction dates. Monetary assets and liabilities denominated in foreign currency as of the reporting date are translated into the functional currency at the exchange rate as of the said date. Exchange rate differences with respect to monetary items are the differences between the amortized cost in the functional currency as of the start of the year, adjusted for the effective interest

Note 3 - Significant Accounting Policies (continued)

during the year, and the amortized cost in foreign currency, translated at the exchange rate as of the end of the year. Non-monetary items denominated in foreign currency and measured at historical cost, are translated using the exchange rate as of the transaction date. Exchange rate differences arising from translation into the functional currency are recognized on the statement of operations as financial expenses.

C. Non-derivative financial instruments

1. Non-derivative financial assets

Non-derivative financial assets include: cash and cash equivalents and other receivables.

Cash and cash equivalents include cash balances available for immediate use and call deposits. Cash equivalents include short-term highly liquid investments (with original maturities of three months or less) that are readily convertible into known amounts of cash and are exposed to insignificant risks of change in value.

2. Non-derivative financial liabilities

Non-derivative financial liabilities include: trade payables and other accounts payable.

Initial recognition of financial liabilities
The Group initially recognizes debt instruments issued as they are created. Other financial liabilities are initially recognized on the trade date on which the Group becomes party to contractual terms of the instrument.

Financial liabilities are initially recognized at fair value less any attributable transaction costs. Subsequent to initial recognition, financial liabilities are measured at amortized cost using the effective interest method.

Transaction costs directly attributable to an expected issuance of an instrument that will be classified as a financial liability are recognized as an asset as part of deferred expenses in the statement of financial position. These transaction costs are deducted from the financial liability upon their initial recognition, or are amortized as financing expenses in the statement of operations when the issuance is no longer expected to occur.

De-recognition of financial liabilities
Financial liabilities are de-recognized upon expiration of the Group's liability, as set forth in the agreement, or when reversed or cancelled.

D. Derivative financial liabilities

The Group holds derivative financial instruments that do not serve hedging purposes, including separable embedded derivatives.

Measurement of derivative financial instruments

Derivatives are recognized initially at fair value; attributable transaction costs are recognized in profit or loss as incurred. Subsequent to initial recognition, derivatives are measured at fair value, and changes therein are accounted for as described below.

Note 3 - Significant Accounting Policies (continued)

The changes in fair value of these derivatives are recognized in profit or loss, as financing income or expense. Included in this accounting treatment are changes in the fair value of the conversion component of NIS-linked warrants that do not have a fixed exercise price. The fair value of these derivatives is based on market price, and classified as level 1.

E. Intangible assets – research and development costs

Expenditure on research activities, undertaken with the prospect of gaining new scientific or technical knowledge and understanding, is recognized in profit or loss when incurred.

Development activities involve a plan or design for the production of new or substantially improved products and processes. Development expenditure is capitalized only if development costs can be measured reliably, the product or process is technically and commercially feasible, future economic benefits are probable, and the Group has the intention and sufficient resources to complete development and to use or sell the asset. The expenditure capitalized in respect of development activities includes the cost of materials, direct labor and overhead costs that are directly attributable to preparing the asset for its intended use, and capitalized borrowing costs. Other development expenditure is recognized in profit or loss as incurred. In subsequent periods, any capitalized development expenditure is measured at cost less accumulated amortization and accumulated impairment losses.

As the Company has not met the criteria mentioned above, all development costs are currently recognized in profit and loss as expense.

F. Loss per share

The Group presents loss per share data for its ordinary share capital. Loss per share is calculated by dividing the loss attributable to holders of ordinary shares, by the weighted average number of ordinary shares outstanding during the period.

G. Transactions with controlling shareholder

Assets and liabilities included in a transaction with a controlling shareholder are measured at fair value on the date of the transaction. As the transaction is on the equity level, the Company includes the difference between the fair value and the consideration from the transaction in its equity.

H. Share-based payment transactions

The fair value of share-based payment grants to employees and officers is recognized as payroll expense, against equity, over the period in which non-contingent eligibility for such grant is earned. The amount charged as share-based payment grants expense is contingent on vesting conditions, which are service or performance conditions and is adjusted to reflect the number of grants expected to vest. As for share-based payment grants contingent on non-vesting conditions, or on vesting conditions which are performance conditions connected to market conditions, the Company accounts for these conditions when estimating the fair value of such grants; therefore the Company recognizes an expense with respect to these grants, regardless of fulfillment of these conditions.

I. Financing income and expense

Finance income comprises changes in the fair value of the financial liability through profit and loss.

Finance expenses include loss from exchange rate differences and interest paid on loans received. Interest expense is recognized, using the effective interest method. In the statements of cash flows, interest paid is presented as part of cash flows from financing activities.

Note 3 - Significant Accounting Policies (continued)

J. Share capital

Incremental costs directly attributable to an expected issuance of an instrument that will be classified as equity are recognized as an asset in deferred expenses in the statement of financial position. The costs are deducted from the equity upon the initial recognition of the equity instruments, or are expensed as financing expenses in the statement of operations when the issuance is no longer expected to take place.

K. Share issuance expense

Share issuance expense is recognized when incurred, as pre-paid expenses, when an issuance is expected to take place. Expenses are recognized under Share Premium upon the issuance of shares.

L. Issuance of units of securities

The consideration received from the issuance of units of securities is attributed initially to financial liabilities that are measured each period at fair value through profit or loss, and then to financial liabilities that are measured only upon initial recognition at fair value. The remaining amount is the value of the equity component.

Direct issuance costs are attributed to the specific securities in respect of which they were incurred, whereas joint issuance costs are attributed to the securities on a proportionate basis according to the allocation of the consideration from the issuance of the units, as described above.

M. Employee benefits

The Group has a number of post-employment benefit plans. The plans are usually financed by deposits with insurance companies or with funds managed by a trustee, and they are classified as defined contribution plans and as defined benefit plans.

A defined contribution plan is a post-employment benefit plan under which an entity pays fixed contributions into a separate entity and has no legal or constructive obligation to pay further amounts. Obligations for contributions to defined contribution pension plans are recognized as an expense in profit or loss in the periods during which related services are rendered by employees.

Other long-term employee benefits

The Group's net obligation in respect of long-term employee benefits other than pension plans is the amount of future benefit that employees have earned in return for their service in the current and prior periods; that benefit is discounted to determine its present value, and the fair value of any related assets is deducted.

Note 4 - Cash

	As of December 31	
	2015	**2014**
	USD thousands	
Balance in USD	**10,199**	165
Balance in other currencies (primarily NIS)	**359**	1,148
Total cash	**10,558**	1,313

Note 5 - Other Receivables

	As of December 31	
	2015	2014
	USD thousands	
Government authorities - VAT	**124**	420
Prepaid expenses	**122**	26
Total receivables	**246**	446

Note 6 - Subsidiary

The following is condensed information regarding the subsidiary directly held by the Company:

	Incorporated and operates in Israel	Group's ownership equity	Company's direct ownership of equity	Amounts provided by the Company to the subsidiary		Total investment in subsidiary
				Loans	Guarantees	
				USD thousands		
Kitov Pharmaceuticals Ltd.	Israel	100%	100%	8,227	-	(8,911)

Note 7- Other Payables

	As of December 31	
	2015	2014
	USD thousands	
Due to related parties (note 11)	**549**	82
Accrued expenses	**123**	10
Payroll related government authorities	**32**	22
	704	114

Note 8 - Loans from Related Parties and Others

The loans were received from related parties in Kitov for financing operations prior to the date of Kitov's Acquisition by the Company. These loans had been fully repaid by March 2015.

Note 9 - Equity

A. The Company's share capital

	As of December 31, 2015		As of December 31, 2014	
	Authorized	Issued and paid-in	Authorized	Issued and paid-in
Ordinary shares, no par value*	500,000,000	77,755,641	500,000,000	5,971,467

* In a public offering on the NASDAQ that closed on November 25, 2015, the Company issued 3,158,900 American Depository Shares (hereinafter: "ADS") that represent 63,178,000 ordinary shares with no par value. As to details regarding the public offering, see note 9C5.

B. During the year, the Group recognized the following amounts under share capital, share premium and reserves

	For the year ended December 31		
	2015	2014	2013
	Number of shares thousand		
Opening balance	**5,972**	2,011	1,352
Issuance of ADSs and warrants, net of issuance costs	**63,178**	-	-
Issuance of shares, net of issuance costs	**6,388**	3,760	585
Share issuance deriving from a strategic cooperation agreement (see note 12)	**597**	158	-
Share issuance due to meeting of milestone (see note 9D4)	**1,379**	-	-
Share-based payments	**-**	-	-
Exercise of warrants	**242**	-	-
Exercise of options	**-**	43	74
Repayment of a loan from a related party	**-**	-	-
Capital reserve from related parties*	**-**	-	-
	77,756	5,972	2,011

* The change in capital reserve from related parties consists of non-remunerable services provided by related parties. See note 11D. 1 and 2.

Note 9 - Equity (continued)

C. Financing rounds

1. In March 2014, the Company issued 2,211,538 shares at a price of Israeli Shekel (NIS) 7.80 per share. Total gross proceeds amounted to NIS 17,250,000 (USD 4.9 million). In addition, in August 2014, the Company issued to the underwriters 1,437,500 warrants (series 1) at an exercise price of NIS 9.75 per share, exercisable into 110,577 shares for their services. The warrants were exercisable through June 30, 2015. The fair value of these warrants at the time of their issuance was $57 thousand.

2. In May 2014 the Company filed a rights offering prospectus, in which it issued 5,717,074 warrants (series 1) on a pro-rata basis to all its shareholders, exercisable from their issuance date through June 30, 2015. Each 13 warrants are exercisable into one share, for a cash payment of NIS 9.75 per share. The exercise price is not linked to any index. The warrants were registered for trading on June 11, 2014. Any warrant that is not exercised during the exercise period will expire, and the holder will not have any right or claim on it. Company's management estimated the value of the warrants at USD 200 thousand. This amount was recorded as payments on account of warrants against premium on shares.

3. In September 2014 the Company issued 1,548,000 shares and 25,156,250 warrants (series 2) exercisable into 1,627,339 shares at a price per unit of NIS 5.20. The warrants were exercisable from their issuance date through September 2, 2015. Total gross proceeds amounted to NIS 8,050,000 (USD 2.2 million). Net proceeds amounted to USD 2,072 thousand, of which USD 349 thousand, which represents the market value of the warrants at their first day of trade, were attributed to liabilities. Warrant issuance cost of USD 25 thousand were charged to finance expenses in the statement of operations and the remaining USD 1,748 thousand were attributed to share premium. As of December 31, 2015, the fair market value of the warrants was USD 71 thousand (2014 - 78 thousand). These warrants are presented in the balance sheets as derivative instruments. The change in value since issuance has been recorded as finance income. In August 2015 the court approved the Company's board of directors' decision to extend the exercise period of warrants (series 2) by six months until March 1. 2016. As of the date of approval of these financial statements, these warrants have expired.

4. On March 30, 2015 the Company issued 6,388,000 shares at a price per share of NIS 1.30 and 24,913,200 warrants (series 2) exercisable into 1,916,400 shares for an exercise price of NIS 0.40 and 3,194,000 warrants (series 3) exercisable into 3,194,000 shares for an exercise price of NIS 2.20 per share, for no consideration. Total gross proceeds amounted to NIS 8,304,400 (USD 2.1 million).

As of December 31, 2015, the fair market value of the warrants was USD 70 thousand. These warrants are presented in the balance sheets as derivative instruments The change in value since issuance has been recorded as finance income.
The warrants (series 3) expired on April 30, 2015. In August 2015 the court approved the Company's board of directors' decision to extend the exercise period of warrants (series 2) by six months until March 1. 2016. As of the date of approval of these financial statements, these warrants have expired.

Net proceeds amounted to USD 1,974 thousand, of which USD 157 thousand, which represent the market value of the warrants at their first day of trade, were attributed to liabilities, warrant issuance cost of USD 4 thousand were charged to finance expense in the statement of operations and the remaining USD 1,821 thousand were attributed to share premium.

Note 9 - Equity (continued)

C. Financing rounds (continued)

5. In November 2015, in the a public offering in the NASDAQ, the Company raised USD 13,046,257 (approximately USD 10.6 million after deduction of underwriters' commissions and public offering related expenses). On November 20, 2015, the Company's ADSs and warrants commenced trading on the NASDAQ under the symbols KTOV and KTOVW, respectively. The public offering was completed on November 25, 2015.

In the Public Offering the Company issued 3,158,900 ADSs and 3,158,900 warrants to purchase 3,158,900 ADSs. Each ADS represents 20 ordinary shares with no par value. Each warrant enables the purchase of 1 ADS. The public offering was completed at a price of USD 4.13 for a unit of 1 ADS and 1 warrant. Each warrant is exercisable for a period of 5 years for an exercise price of USD 4.13. In addition, the Company granted the underwriters the right to sell within 45 days up to 473,835 ADSs and/or 473,835 warrants at the same terms as the public offering (of which the underwriters exercised the right to sell 220,074 warrants). The Company also granted the underwriters non-trading warrants to purchase up to 157,945 ADSs for an exercise price of USD 4.956.

D. Other equity transactions

1. During 2015 4,571 warrants (series 1) were exercised into 352 shares for proceeds of approximately USD 1 thousand.

2. During 2015 16,000 warrants (series 2) were exercised into 1,231 shares for proceeds of approximately USD 1 thousand.

3. In May 2015, following the meeting of milestones, the Company issued 597,511 shares to Dexcel Ltd. in exchange for formulation development services, and paid Dexcel a net amount of USD 0.25 million, see note 12.

4. In August 2015 the Company issued 1,720,000 warrants to purchase 1,720,000 ordinary shares to the Lenders (see Note 16). These warrants were exercisable immediately upon issuance, have an expiry date of August 31, 2016, and an exercise price of NIS 1.80 ($0.46).

5. On December 24, 2015, the Company issued 1,379,060 ordinary shares to the former shareholders of Kitov Pharmaceuticals Ltd. as a result of the meeting of milestones as set forth in the Acquisition agreement.

Note 10 - Share-based Payment Arrangements

The Company grants options to employees as well as service providers under the 2013 Option Plan. On November 27, 2013, the Company adopted the 2013 Kitov Pharmaceutical Holdings Ltd. Stock Option Allocation Plan, or the 2013 Option Plan. The 2013 Option Plan provides for the granting of options to directors, officers, employees and consultants and to the directors, officers, employees and consultants of subsidiaries and affiliates. The 2013 Option Plan provides for options to be granted at the determination of the board of directors (which is entitled to delegate its powers under the 2013 Option Plan to the Company's compensation committee) in accordance with applicable laws. The exercise price and vesting period are determined by the board of directors.

Note 10 - Share-based Payment Arrangements (continued)

A. Below are details of options granted during the reporting period.

1. 1,195 thousand options granted in July 2013 to Lior Tamar Investments Ltd., serving as advisors to the Company. Each option may be immediately exercised into one ordinary share at an exercise price of NIS 0.10 per share. These options were exercised in 2013 and 2014.

2. 1,370 thousand options granted to the Company's CFO and Board member, Mr. Simcha Rock. Each 13 options may be exercised into one ordinary share, at an exercise price of NIS 10.40 per share. Exercise period is 36 months from date of issuance.

- 1,012 thousand options vest over 18 months (in equal monthly portions) starting from the date the Company raises NIS 1,000,000 or more. (This condition was met with the public issuance in March 2014, see Note 9.C.1.)
- 181 thousand options subject to the achievement of a milestone (success in clinical trial), which was achieved in December 2015. In 2016 Mr. Rock waived his right to these options.
- 177 thousand options immediately exercisable.

3. 400 thousand options granted to an external advisor of the Company. Each 13 options may be exercised into one ordinary share. The grant includes 200 thousand options which may be immediately exercised into ordinary shares, at an exercise price of NIS 5.85 per share and 200 thousand options which may be immediately exercised into ordinary shares at an exercise price of NIS 7.15 per share. Exercise period is 24 months from date of issuance. These options expired in December 2015.

4. 933 thousand options granted to an external consultant in August 2014. The grant was comprised of:

- 600 thousand options of which each 13 options may be exercised into one ordinary share, at an exercise price of NIS 15.60 per share over a vesting period of 2 years. Exercise period is 48 months from date of issuance.
- 333 thousand options of which each option may be immediately exercised into one ordinary share, at an exercise price of NIS 0.60 per share. These options were exercised in 2014.

5. 250 thousand options granted to an employee in August 2014. Each 13 options may be exercised into one ordinary share, at an exercise price of NIS 8.45 per share over a vesting period of 3 years. Exercise period is 120 months from date of issuance. As of the date of the approval of these financial statements, these options had expired due to the employee’s leaving the Company.

6. In February 2015, the Company's board of directors decided to grant 44,786 options to two consultants in return for their services. The options are exercisable into 44,786 shares for an exercise price of NIS 4.00 for a period of 24 months. The options vested immediately on the grant date, May 14, 2015. The fair value of these options at the date of granting was measured at USD 31 thousand.

B. Other share based payment arrangements

See note 12 with regard to share based payments to a strategic cooperation service provider.

Note 10 - Share-based Payment Arrangements (continued)

C. The number and weighted average exercise prices (in NIS) of share options are as follows:

	Weighted average exercise price			Number of options		
	2015	2014	2013	2015	2014	2013
Outstanding at January 1	**0.78**	0.46	-	**3,872,359**	1,819,475	-
Forfeited during the year	**0.80**	-	-	**-**	-	-
Expired during the year	**-**	-	-	**406,416**	-	-
Exercised during the year	-	0.21	0.10	-	567,949	960,000
Granted during the year	**-**	0.8	0.46	**44,786**	2,620,833	2,779,475
Outstanding at December 31	**0.78**	0.78	0.46	**3,510,729**	3,872,359	1,819,475
Exercisable at December 31	**0.83**	0.54	0.65	**3,285,729**	2,977,068	909,044

D. Options to services providers were measured at the fair value of the service, when available.
The fair value of the Company's share options granted to employees, directors and service providers, where fair value of service was not measurable, was estimated by applying the Black Scholes model using the following assumptions**:**

	2015	2014	2013
Share Price - NIS	-	0.52 - 0.60	0.65
Expected volatility (%)	-	56 -115	72-97
Expected duration (years)	-	4-10	2-5
Dividend yield (%)	-	0	0
Risk free rate interest rate (%)	-	0.75 - 3	1.2-2.3

The expected volatility of the share prices reflects the assumption that the historical volatility of the share price is reasonably indicative of expected future trends. The expected term of the instruments has been based on general option holder behavior.

E. Expenses recognized in the financial statements:

	For the year ended December 31		
	2015	2014	2013
		USD thousands	
Total share based general and administrative expense recognized	**59**	88	296

Note 11- Transactions and Balances with Related Parties

A. Related party balances are included in the balance sheet under the following items:

	As of December 31	
	2015	2014
	USD thousands	
Other payables	**549**	82
Loans from related parties	**-**	294
Post employment benefit liabilities	**185**	-

Note 11 - Transactions and Balances with Related Parties (continued)

B. The statement of operations includes amounts referring to transactions with related parties, as follows:

	For the year ended December 31		
	2015	**2014**	**2013**
	USD thousands		
General and administrative expenses*	**552**	477	382
Research and development expenses*	**321**	-	47
Interest and linkage expenses	-	6	31

* Amounts in 2014 and 2013 include non-remunerable service expense. See note 9B and notes C1 and C2 below.

C. The statement of changes in equity for the year ended December 31, 2015 includes amounts referring to transactions with related parties of USD 526 thousand, which are included in the issuance costs of the ADSs. See also note 12C.

D. Service agreement with related parties

Upon the closing of the Acquisition, employment agreements were signed with the controlling shareholder and with Company officers, as follows:

1. Agreement for consulting services with a company owned by Dr. Paul Waymack. The monthly payment amounts to NIS 30 thousand (USD 9 thousand). Actual payments commenced in March 2014, after completion of a funding round. Expenses for services rendered by Dr. Waymack, for the months of January and February 2014, are included in the financial statements against capital reserves as these services were not remunerable. In November 2014 the general shareholders' meeting approved a raise in the monthly payment to USD 14 thousand, retroactive from September 2014.

2. Agreement with Mr. Simcha Rock for his full time services to the Company as the Company's CFO. The monthly payment amounts to NIS 35 thousand (USD 10 thousand). Actual payments commenced in March 2014 after completion of a funding round. Expenses with respect to services rendered by Mr. Rock in the months of January and February 2014 are included in the financial statements against capital reserves as these services were not remunerable. In November 2014 the general shareholders' meeting approved a raise in the monthly payment to NIS 50 thousand (USD 13 thousand), retroactive from September 2014.

3. On November 20, 2014 the general shareholders' meeting approved the employment of Mr. Isaac Israel (replacing his existing engagement as a service provider). Mr. Israel's basic salary will be NIS 40 thousand per month (USD 10 thousand) and will be linked to the Consumer Price Index.

   In addition, Dr. Waymack, Mr. Rock, and Mr. Israel are entitled to annual and special bonuses, as well as retirement grants see Note 12.C and D.

Note 11 - Transactions and Balances with Related Parties (continued)

E. The Company made payments to key management:

	For the year ended December 31		
	2015	**2014**	**2013**
		USD thousands	
Short –term employee benefits	**1,207**	443	360
Post-employment benefits	**185**	-	-
Share based payments	**7**	47	64
	1,399	490	424

Note 12 – Commitments and contingent liabilities

A. In April 2014, the Company signed a strategic cooperation agreement with Dexcel Ltd. (hereinafter: "**Dexcel**"), including for formulation development services for the drug KIT-302 (hereinafter: **"the drug")**, the right to negotiate the commercial manufacture of the drug, and the right to negotiate the marketing of the drug.

In consideration for the services provided by Dexcel, the Company agreed to pay USD 2 million in 4 equal USD 0.5 million payments. The first payment was made 30 days after the date of the signing of the agreement, and the second payment was made on completion of a milestone in May 2015. The other two payments will be made in accordance with predetermined milestones, the first of which is expected to be completed at the end of the second quarter in 2016, and the final milestone is estimated to conclude 4 to 9 months later. In addition, the Company agreed to pay USD 1.5 million worth of shares in 3 tranches of USD 0.5 million each. The first tranche of 157,783 shares was issued at a price of NIS 11.05 per share. Upon completion of a milestone, the second tranche of 597,511 shares was issued in May 2015 at a price of NIS 3.359 per share.. The final tranche will be issued upon reaching another milestone, based on the average price per share during the 45 days prior to the date of completing the milestone.

Dexcel is required to pay the Company USD 0.5 million in 2 payments upon completion of milestones, for the right to negotiate the global marketing rights and the commercial manufacturing of the drug. The first payment was received in May 2015, and the second payment in due with the completion of the next milestone.

Payments made to Dexcel, net of receipts from Dexcel, are charged to research and development expenses based on milestones achieved, in addition to expenses accrued on account of progress of work done towards the next milestone.

The intellectual property (hereinafter **-"IP")** owned by the Company prior to this agreement will continue to be owned by the Company. Dexcel was granted the right to use the Company's IP for the purpose of development of the drug. Any IP developed in the process of the drug's development and manufacturing will be owned jointly by the Company and Dexcel, and the Company and Dexcel will give each other the right to use this IP. In addition, any IP developed by Dexcel in the process of the drug's development and manufacturing, and which is not under the joint IP, will be owned by Dexcel, and Dexcel will give the Company the right to use it in connection with the drug.

Note 12 – Commitments and contingent liabilities (continued)

B. The Company has an annual commitment under a lease agreement for its office premises of approximately NIS 240 thousand per year (approximately USD 64 thousand) for a period of five years beginning January 1, 2015.

C. The Company's Chairman of the Board, Chief Executive Officer, and Chief Financial Officer are entitled to annual and special bonuses under the terms of their employment and consulting agreements. These bonuses will become due upon the achievement of certain milestones, including fund raising, merger transactions, and agreements for the commercialization of the Company's products. These financial statements include bonuses in the amount of USD 599 thousand, of which USD 526 thousand are included in the statement of changes in equity as part of issuance costs of ADSs.

D. The Company's Chairman of the Board, Chief Executive Officer, and Chief Financial Officer are entitled to retirement grants under the terms of their employment and consulting agreements. These grants are measured based on the time of service and their monthly pay. These financial statements include a liability of USD185 thousand due to these grants.

E. In December 2015, a lawsuit and a motion to approve such lawsuit as a class action was filed against the Company and its directors by shareholders who were holding the Company's Tel Aviv Stock Exchange listed securities before the offering mentioned in note 9C5, claiming damages for the purported class in the motion totaling NIS 16.4 million (USD 4.2 million) due to the said offering. The Company's management rejects the claims and, in consultation with its legal advisors, believes that the likelihood of the Company not incurring any financial obligation as a result of this class action exceeds the likelihood that the Company will incur a financial obligation. Therefore, no provision for this matter was recorded in these financial statements.

Note 13 - Research and Development Expenses

Research and development expenses include consulting expenses for development of drug formulation and for non-clinical, clinical, regulatory and project management work required for the Company's drug portfolio.

Note 14 - General and Administrative Expenses

	For the year ended December 31		
	2015	**2014**	**2013**
		USD thousands	
Payroll expenses (see also Note 10 with regard to share-based payment arrangements)	**541**	523	554
Professional consulting	**720**	532	385
Board member remuneration and insurance	**67**	54	57
Rent and office maintenance	**139**	52	26
Amortization	**1**	-	-
Other general and administrative expenses	**41**	108	39
	1,509	1,269	1,061

Note 15 - Other Expenses

As part of the Acquisition, Haiku, a wholly owned company of the controlling shareholder at the time of the transaction, was eligible to receive, out of all funds raised by the Company in one or multiple transactions, an amount of up to NIS 2,500 thousand. Following the share issuance described in Note 9C1, an amount of NIS 2,500 thousand (USD 720 thousand) was paid to Haiku. This amount was recorded as other expenses in 2014.

Note 16 – Finance Expense (Income)

	For the year ended December 31		
	2015	**2014**	**2013**
	USD thousands		
Finance expense			
Fees and interest expense	**3**	21	17
Loss from exchange rate differences, net	**79**	216	27
Interest and linkage on related party loans	**-**	-	31
Credit allocation fee *	**141**	83	-
Warrant issuance costs	**4**	25	-
	227	345	75

* In August 2015 the Company entered into loan agreements with several third parties (the “Lenders") pursuant to which, they extended the Company loans of USD 430 thousand. The loans were repaid in November 2015 with an addition of credit allocation fees in the amount of $141 thousand.

	For the year ended December 31		
	2015	**2014**	**2013**
	USD thousands		
Finance income			
Net change in fair value of financial instruments measured at fair value throughout profit and loss	**94**	274	-
	94	274	-

Note 17 - Taxes on Income

A. Corporate tax rate

The tax rate applicable to the Company for 2015 is 26.5%. The tax rate in 2016 is expected to be 25%.

B. The Company and its subsidiary incurred losses in 2015, as well as carry-forward losses from previous years, which are not expected to be utilized in the foreseeable future. Therefore the Group companies did not record current taxes or deferred taxes.

The carry-forward loss for tax purposes for the Company and its subsidiary, and the unrecognized deferred taxes from research and development expenses, amounts to USD 9 million as of December 31, 2015 (2014 – USD 5 million, 2013 – USD 1 million).

Note 17 - Taxes on Income (continued)

C. The Company's 2010 tax assessment is deemed finalized, pursuant to section 145 of the Income Tax Ordinance. The subsidiary has no finalized tax assessments to date.

Note 18 - Employee benefits

A. Employee benefits include post-employment benefits and short term benefits.
Post-employment benefits are part of key management compensation – see note 11 on related and interested parties. Balances include:

	December 31.	
	2015	2014
	USD thousands	USD thousands
Short-term benefits	**556**	90
Post-employment benefits	**185**	

B. Post-employment benefit plans – defined contribution plan

The Company has a defined contribution plan in respect of the Company's liability in respect of its employees who are subject to Section 14 of the Severance Pay Law – 1963.

	Year ended December 31		
	2015	2014	2013
	USD thousands	USD thousands	USD thousands
Amount recognized as general and administrative expense in respect of defined contribution plan	**25**	3	-

Exhibit 4.9

Kitov Pharmaceuticals Holdings Ltd.

Office Holder Compensation Policy

1. **General**

1.1. Definitions

1.1.1. "**The Company"** – Kitov Pharmaceuticals Holdings Ltd. and subsidiaries as defined below.

1.1.2. "**Subsidiaries**" – Companies whose financial results are fully consolidated in the consolidated financial reports of the Company.

1.1.3. "**The Companies Law**" – The Companies Law 5759 – 1999.

1.1.4. "**Office Holders**" – As per the definition of this term in the Companies Law.

1.1.5. "**Terms of Office and Employment**" – The terms of office and employment of an Office Holder, including the provision of an exemption, insurance, undertaking for an indemnity or an indemnity under permission for indemnity, resignation grant, and any benefit or other payment or undertaking to pay as mentioned, which are granted due to the office or employment as mentioned.

1.2. Every term which is not defined in this Compensation Policy explicitly, shall have the meaning accorded thereto in the Companies Law.

1.3. In accordance with the provisions of the Companies Law, the board of directors of the Company established this Compensation Policy with regard to the Terms of Office and Employment of Office Holders in the Company (hereinafter: "**Compensation Policy**").

1.4. The Compensation Policy is based upon the following principles and considerations: (a) Promotion of the interests of the Company, the work plan and long-term policies thereof. (b) Creation of proper incentives for Office Holders in the Company, taking into account, amongst other things, the risk management policy of the Company. (c) Adaptation of the incentives and the compensation to the size of the Company and the nature of its activity. (d) With regard to Terms of Office and Employment, which include variable components – adjustment of incentives and compensation to the contribution of the Office Holder to the achievement of the aims of the Company and the maximisation of its profits, and all with the long-term view and in accordance with the position of the Office Holder.

1.5. This Compensation Policy shall be valid for three years from the date of the approval thereof by the general assembly of shareholders of the Company.

1.6. **For the sake of removal of doubt it is clarified that this Compensation Policy does not, by itself, accord and is not intended to accord rights to Office Holders in the Company and no Office Holder in the Company shall have any right accorded to him by virtue of the adoption of this Compensation Policy and/or right to receive any components of the compensation set out in the Compensation Policy. The compensation components to which an Office Holder shall be entitled shall be solely and exclusively those which shall be determined with regard to him specifically by the competent corporate bodies of the Company and subject to the provisions of any law.**

1.7. **It is clarified that in any event where an Office Holder will be granted compensation which is less than the terms which are described in the outline of compensation in accordance with this Compensation Policy, this shall not be deemed deviation or exception from the Compensation Policy of the Company.**

1.8. The principles of the Compensation Policy shall apply in full also in instances where the engagement with the Office Holder is by means of a company in the stead of engagement in an employment agreement with the Office Holder, with the required adjustments mutatis mutandis.

1.9. The Policy is written in the masculine form for purposes of convenience only and is intended to be implemented with regard to men and women jointly, without distinction or difference.

2. **The Compensation Policy**

2.1. Parameters for examination of compensation terms.

In general, the terms of compensation for Office Holders will be examined under the following parameters

2.1.1. Education, skills, expertise, tenure (in the Company specifically and in the profession generally), professional experience and achievements of the Office Holder.

2.1.2. Fulfilment of the Office Holder of targets determined for him, as relevant.

2.1.3. The position of the Office Holder, fields of responsibility, previous employment agreements signed with him.

2.1.4. The contribution of the Office Holder to the business of the Company, including contribution, directly or indirectly, to subsidiaries.

2.1.5. Level of responsibility imposed upon the Office Holder.

2.1.6. The need of the Company to retain the Office Holder in light of his importance to the Company.

2.1.7. Compensation to which an Office Holder is entitled in subsidiary companies, as relevant.

2.1.8. The proportion between the cost of the Terms of the Office and Employment of the Office Holder and the wage cost[1] of the remainder of the employees of the Company and of contract workers[2] employed by the Company (to such extent as are employed at the time of approval of the compensation) (hereinafter: "**the remainder of employees of the Company**"), and particularly the ratio to the average and median wages of employees as mentioned and the effect of the gap between them on the work relations at the Company.

[1] "**Wage cost**" – any payment in respect of employment, including provisions of the employer, payment in respect of retirement, vehicle and use expenses thereof and any other benefit or payment.

[2] "**Contract employees employed by the Company**" – employees of a manpower contractor whom the Company is the actual employer thereof, and service contractor employees employed in providing services at the Company. For this matter, "manpower contractor", "service contractor" and "actual employer" – as per the definition thereof in the Law of Employment by Manpower Contractors – 1996.

2.1.9. With regard to variable components, as relevant, the possibility to decrease variable components in accordance with the discretion of the Board of Directors and the possibility to determine a ceiling for the exercise value of cashless equity based variable compensation components.

2.1.10. With regard to severance grants, as relevant, the duration of the office or employment of an Office Holder, the Terms of Office and Employment during this period, performance of the Company in such period, the contribution of the Office Holder to the maximization of the targets and profits of the Company and the circumstances of departure.

2.2. **Components of Compensation**

The total compensation of the Office Holders in the Company will be composed of a number of compensation components in the manner that each component is intended to remunerate the Office Holder for a different aspect of his contribution to the Company. Compensation can include all or part of the compensation components set out below:

2.2.1. Fixed components:

2.2.1.1. Basic salary or monthly payment in the event that the Office Holder is not an employee but rather a service provider.

2.2.1.2. Ancillary conditions – the ancillary conditions compensation components are composed of two levels: (1) The basic level – comprises the ancillary condition set out in the relevant laws, such as: provisions for managers' insurance or pension fund, provisions for severance pay, disability insurance, vacation days, sick days, recuperation days, travel expenses, overtime pay, and all as relevant and in accordance with the determination of the Office Holder as an employee of the Company or a service provider thereof, as the case may be. (2) The expanded level – additional ancillary conditions such as: Provisions to continued education fund, vehicle expenses or entitlement to operational leasing vehicles, membership fees to professional guilds, participation in professional seminars, subscription to daily papers and conditions which are intended to indemnify the Office Holder in respect of expenses which he makes as a result of fulfilment of his position or which are required for fulfilment of the position such as: mobile phone, mobile computer, and all in accordance with the position and the determination as an employee or a service provider, as the case may be.

2.2.2. Variable components (non-equity) (hereinafter: "**grant**", "**grants**").

2.2.3. Variable components (equity) (hereinafter: "**share based compensation**").

2.3. **Terms of compensation for Office Holders**

2.3.1. General**:** In general, the terms for compensation for a new Office Holder will be approved in accordance with the provisions of the relevant law prior to the date of commencement of the employment thereof in the Company and not in retrospect.

Fixed Components

2.3.2. Base salary: The base salary for a new Office Holder in the Company will be determined based upon the parameters in Clause 2.1 above: The base salary for the CEO of the Company and an active chairman of the Board of Directors shall not exceed NIS 60,000 gross in respect of a full position. The base salary of vice presidents and other Office Holders in the Company shall not exceed NIS 50,000 gross in respect of a full position. The base salary will be in absolute numbers and may include a mechanism for linkage to the Consumer Prices Index. In any event, a base salary, whether it is linked to the Consumer Prices Index or not, shall not exceed the ceiling on the basis set out in this Clause 2.3.2 above.

Save if stated otherwise, the parameters regarding the base salary for compensation relate to a salaried Office Holder employed in a full-time position. In the event that the Office Holder is not a salaried employee or is not in a fill-time position, the required adjustments must be made.

2.3.3. Ancillary conditions
The compensation package may include ancillary conditions such as: Provisions for directors insurance or pension fund, continued education fund, severance pay, disability insurance, vacation days, sick days, recuperation days, vehicle expenses or entitlement to operational leasing vehicles, membership fees to professional guilds, participation in professional seminars, subscription to daily papers, mobile computer, and all in accordance with the position of the Office Holder in the Company

2.3.3.1. Vehicle – operational lease: To such extent as the general compensation package includes entitlement to an operationally leased vehicle, a ceiling for cost of the operational lease will be set as follows:

- Active chairman of the Board of Directors: Monthly operational leased cost to the Company shall not exceed NIS 7,000.
- CEO: Monthly operational leased cost to the Company shall not exceed NIS 7,000.
- Other Office Holders: Monthly operational leased cost to the Company shall not exceed NIS 5,000.

2.3.3.2. Vehicle – grossing up for vehicle: To such extent as the Company makes a personal vehicle available to the Office Holder, the Company is entitled to bear components of the grossing up of the value of the vehicle, in full or in part, as determined in the employment agreement of the Office Holder.

2.3.3.3. Annual vacation: An Office Holder will be entitled to an annual vacation which shall not be less than that required at law and not more than 22 vacation days per calendar year. An Office Holder will be entitled to accumulate vacation days which were not used by him until the end of the year. The accumulated vacation days will transfer as an opening balance to the amount of vacation days available to such Office Holder in the following year.

2.3.3.4. Recuperation days: The Office Holder will be entitled to payment for recuperation days in accordance with the law. It is clarified that the number of recuperation days shall not be less than the number of recuperation days set out at law. The recuperation payment shall be in accordance with the amount determined at law.

2.3.3.5. Exemption and indemnification: Office holders in the Company shall be entitled to benefit from exemption and indemnification as set out in the articles of incorporation of the Company. The exemption and indemnification letters accord with the provisions of the articles of incorporation of the Company and are drafted under terms which are identical for the entirety of the Office Holders, including the controlling shareholder or a director in whom the controlling shareholder has a personal interest in granting same.

2.3.3.6. Insurance: Office holders of the Company shall be entitled to insurance arrangements subject to the provisions of the articles of incorporation of the Company, as well as arrangements for professional insurance, as relevant to the position filled by the Office Holder in the Company. Additionally, the Company shall be entitled to acquire directors and Office Holders insurance policies (including for a controlling shareholder and/or a director with respect to whom the controlling shareholder has a personal interest), as these shall be from time to time, which include also the Office Holders and the directors serving at the subsidiaries of the Company, and to extend and/or to renew existing insurance policies or to engage in a new policy at the date of the renewal or during the course of the insurance period, with such same insurer or another insurer in Israel or overseas, under conditions as specified below, and provided that the engagement as mentioned shall be on the basis of the principle conditions set out below and the compensation committee and the board of directors of the Company have approved it:

An insurance policy shall be on the basis of submission of a claim, within a limit of liability of up to $8 million per event and for the period (with an addition with up to 20% of the limit of liability in respect of legal expenses in Israel only), for all of the directors and Office Holders who shall serve in the Company from time to time. The engagement of the Company in insurance policies shall be at total annual premiums of up to USD 20,000 and a deductible of the Company in an amount of up to USD 15,000 with the exception of: (a) Deductible regarding claims filed in the United States and/or Canada in an amount of up to USD75,000, and (b) Deductible in regard to claims regarding Securities Law in Israel in an amount of USD 75,000.

Insurance policies may include, in accordance with the provisions of Article 153 of the articles of incorporation of the Company, also the following instances:

Coverage of expenses made by Office Holders in the Company in connection with a proceeding conducted in their matter, including reasonable litigation expenses and including lawyers' professional fees. With regard to this clause, "**proceedings**" – proceedings in accordance with Chapter H3 of the Securities Law – 1968 (hereinafter: "**The Securities Law**") (imposition of monetary fine in Securities Laws), proceedings under Chapter H4 of the Securities Law (imposition of administrative enforcement measures by the administrative enforcement committee), proceedings under Chapter I1 of the Securities Law (settlement for prevention of adoption of proceedings or cessation of proceedings, which is subjected to conditions) and proceedings in accordance with mark D (imposition of monetary fine in Securities Laws) of the fourth chapter (remedies, monetary fine and registration of a company as a company in breach) of the 9th section of the Companies Law).

In an instance where the Company shall register its shares for trading in a United States stock exchange, it shall be entitled to acquire directors' and Office Holders liability insurance (including controlling interest and/or a director with whom the controlling interest has a personal matter) as shall be from time to time (including a designated public offering of securities insurance), which includes also the Office Holders and directors who are serving at subsidiary companies, to extend and/or renew existing insurance policies and/or engage in new policies at the date of the renewal or during the course of the insurance period, with such same insurer, or another insurer in Israel or overseas, under terms as specified below, and provided that the engagement as mentioned shall be on the basis of the principle conditions set out below and the compensation committee and the Board of Directors of the Company have approved same:

The insurance policy shall be on the basis of submission of a claim within the limits of liability of up to $30 million per instance and per period and $10 million per instance and per period for side A DIC coverage (with the addition of up to 20% of the limits of liability in respect of legal expenses in Israel only), for all of the directors and Office Holders in the Company from time to time. The engagement of the Company in the insurance policy shall be at a total annual premium of up to $250,000 and with a deductible of the Company with regard to legal action submitted in the United States and Canada of up to $350,000.

2.3.3.7. In addition to that stated above, the compensation package may include various benefits in amounts which are not material to the Company and which the Company customarily grants to Office Holders such as: holiday gifts, vacation, meals, parking, group days and so forth and the Company shall not be limited for such purpose.

2.3.3.8. Advance notice: The advanced notice period will be determined individually for each holder of office, taking into account performance of the Company and the additional compensation parameters of such Office Holder and the parameters specified in Clause 2.1 above. In any event, the advance notice period for Office Holders shall not exceed six months. In the framework of the period of the advanced notice, the Office Holder will be required to provide services to the Company in practice. However, the Company shall be entitled to waive the provision of services by the Office Holder in the advance notice period without detracting from the liability of the Company to pay the compensation in connection with such period but without detracting from the right of the Company to suspend such compensation subject to any law and agreement with the Office Holder.

2.3.3.9. Departure grant: the Company is entitled to determine in an agreement with an Office Holder a mechanism determining entitlement of an Office Holder to a departure grant in an instance of cessation of employment or service with the Company, for a reason other than one which does not entitle severance pay as specified in Clauses 16-17 of the Severance Pay Law, 5723 – 1963 and provided that the Office Holder has made available his services to the Company for a continuous period of at least 18 months.

In any event, the amount of the departure grant or the value thereof shall not be in excess of the monthly wage or gross monthly payment of such Office Holder, as specified below:

Office Holder	**Period of provision of services**	**Maximum amount / value of departure grant**
Active chairman of the Board of Directors / CEO	Three or more years	Up to eight months of work
Active chairman of the Board of Directors / CEO	18 months to three years	Up to four months of work
VPs and other Office Holders	Three or more years	Up to six months of work
VPs and other Office Holders	18 months to three years	Up to three months of work

Variable components (non-equity) – Grants

The compensation package may include grants. The grant may be an annual grant, an event-contingent grant or one which is issued during the course of the year on the basis of targets which were designated for each Office Holder.

Examination of the entitlement of the Office Holder to the grant shall be carried out in one of two dates and as shall be regulated in the terms of employment of the Office Holder: (a) Upon completion of a pre-determined period of time. For instance, in the event of an annual grant, the entitlement of the Office Holder shall be examined in the framework of the deliberation upon the annual financial reports of the Company. (b) Upon the achievement of a target set for the Office Holder. For instance, in the event that the issue of the grant is subject to completion of the raising of funds for the Company, the entitlement of the Office Holder shall be examined after completion of the raising of the funds, to such extent as he has reached the target and in instance of the realisation of holdings, the entitlement of the Office Holder shall be examined after completion of the transaction for the sale as mentioned and receipt of the consideration by the Company.

2.3.4. **Grant ceiling**:

With the exception of the departure grant as defined in Clause 2.3.3.9 above and special grants as per their definition below, the ratio between the total grants which may be approved for a single Office Holder in a calendar year, to the base salary, shall be up to 12 times the base salary or monthly payment, as the case may be, which the Office Holder receives, (hereinafter: "**annual grant**"). With regard to the annual grant, it is noted that to such extent as the Office Holder in the Company is employed or will grant services to the Company for a period which is less than 12 months, the annual grant ceiling with regard to such same Office Holder shall be reduced proportionately to the period of provision of services by him.

2.3.4.1. **Annual grants**

The grant will be based mostly, at least 80%, on quantifiable criteria and in non-material part: (a) up to 20% or (b) not to exceed three monthly wages of the Office Holder in such calendar year, the grant will be discretionary based on non-quantifiable criteria as specified below.

(a) Quantifiable criteria for grant:

The Company is entitled to determine at its discretion that the material part which shall not be less than 80% of the annual grant will be determined by quantifiable criteria as stated below.

With regard to each Office Holder, there shall be determined in advance in the employment contract of the Office Holder the quantifiable targets, and these from a list of quantifiable targets specified below.

- Increase in shareholders capital / asset value of the Company taking into account and setting off, as relevant, decrease in the share capital / asset value of the Company in the 12 months preceding the increase as mentioned.
- Decrease in expenses of the Company.
- Compensation based on income from sales of products of the Company.
- Compensation based on a transaction for receipt of licencing for new product to the Company and provided that in any event compensation as mentioned shall not be paid prior to the clinical trial stage and receipt of the IND approval in connection with the new product as mentioned.
- Compensation based on profit from sales of products of the Company or licensing and/or distribution agreements in connection with products of the Company.
- Compensation based on increase in the market capitalisation of the Company.
- Compensation based on success of clinical trials carried out by the Company.
- Compensation based on receiving of regulatory approvals for products of the Company.
- Compensation based on fulfilment of budgetary targets.
- Compensation based on registration for trading of shares of the Company on the United States Stock Exchange.
- Compensation based on registration of patents.

(b) Grant criteria which are non-quantifiable:

The Company is entitled to determine, at its discretion, that the non-material part which shall not exceed: (a) 20% of the annual grant, or (b) three monthly salaries of the Office Holder in that same calendar year will be determined in accordance with non-quantifiable criteria as specified below.

- Contribution of the Office Holder to the business of the Company, its profit, its fortitude and stability.
- The need of the Company to preserve an Office Holder with unique skills, knowledge or expertise.
- The level of responsibility imposed upon the Office Holder.

- The satisfaction with the performance of the Office Holder (including evaluation of the level of involvement and empathy which the Office Holder demonstrates in performance of his work).
- Assessment of the ability of the Office Holder to work in coordination and collaboration with a team.
- The contribution of the Office Holder to the corporate governance and proper control and ethics environment.

2.3.4.2. **"Special grants"** – are grants which are based upon quantifiable metrics specified below as are determined with regard to each Office Holder in his employment agreement or engagement agreement with such Office Holder:

- Compensation based on the raising of capital for the Company, whether private or public, in a minimal amount of $5 million (cumulative) independent of the value of the Company at the date of the raising of funds. To such extent as the Company shall enter into convertible loan agreements, the entitlement to compensation for this parameter shall be created only on the date of conversion of the loan to shares of the Company.
- Compensation based on a merger or a sale of the Company as per the definition below, at a company value of at least USD 25 million.
- Compensation based on a commercialisation transaction as per the definition thereof below.

A merger transaction shall mean – a transaction or a sequence of related transactions of (a) sale, lease, licensing or any other activity of transfer of all or most of the assets of the Company or the shares of the Company. (b) Merger of the Company in the manner where the shareholders holding 50% of the issued and paid up share capital of the Company prior to completion of the transaction as mentioned shall hold less than 50% of the issued share capital of the Company or some other corporation which shall absorb into it the Company after completion of the transaction as mentioned.

Commercialisation transaction shall mean – signature upon licensing and/or distribution agreements for products of the Company in a scope of revenue of at least $5 million, when the rights to compensation shall be created at the date upon which the Company shall in fact receive a cumulative amount of at least $5 million as a result of the commercialisation of its products as mentioned.

With regard to a grant which is based on raising of capital, the compensation shall be a % of the capital which is raised as follows:

(a) In the event that third party commissions are paid, the total compensation to the Office Holder shall not exceed 5% of the gross amount which is raised and the total compensation to Office Holders shall not exceed 5% of the amount which is raised and the compensation which is paid to each of them shall decrease proportionally to the total compensation which is paid, as necessary.

(b) In the event that third party commissions are not paid, the total compensation for Office Holders shall not exceed 7% of the amount raised with deduction of the entirety of the costs of raising of capital including professional fees of advisors, attorneys, accountants and so forth (hereinafter: "**the total net raised**") and the compensation which is paid to each of them shall decrease proportionally to the total compensation paid, as necessary.

(c) Notwithstanding that stated above, in any event, one Office Holder will not be entitled to compensation based on raising of funds at a rate exceeding 5% of the total net raised and in any event the compensation hall not exceed an amount of USD 300,000.

With regard to compensation based on **merger of the Company or its sale,** the compensation shall constitute a percentage of the value of the Company as shall be determined in the merger transaction (hereinafter: "**the value of the Company**") as follows:

(a) In the event that third party commissions are paid, the total compensation to the Office Holder shall not exceed 8% of the value of the Company and the total compensation to Office Holders shall not exceed 8% of the value of the Company and the compensation which is paid to each of them shall decrease proportionally to the total compensation which is paid, as necessary.

(b) In the event that third party commissions are not paid, the total compensation for Office Holders shall not exceed 10% of the value of the Company and the compensation which is paid to each of them shall decrease proportionally to the total compensation paid, as necessary.

(c) Notwithstanding that stated above, in any event, one Office Holder will not be entitled to compensation based on a merger transaction of the Company shall not exceed 6% of the value of the Company and in any event the compensation hall not exceed an amount of USD750,000.

With regard to compensation based on **a commercialisation transaction** the compensation shall constitute a percent of the extent of the cumulative income received in practice by the Company from the transaction as mentioned (hereinafter: "**the scope of actual revenue from the commercialisation transaction**") when the first compensation shall be paid at the date at which the Company shall actually receive a cumulative amount of at least $5 million as a result of commercialisation of its products (hereinafter: "**the minimal scope of revenue**"). To such extent as the Company shall receive additional income arising from then commercialisation transaction beyond the minimal scope of income, additional compensation shall be paid to the Office Holder in rates as specified below every month and this against income which shall be received by the Company as a result of the commercialisation transaction in the previous month at rates as follows:

(a) In the event that third party commissions are paid, the total compensation to the Office Holder shall not exceed 8% from the actual scope of revenue from the commercialisation transaction and the total compensation to Office Holders shall not exceed 8% of the amount which is raised and the compensation which is paid to each of them shall decrease proportionally to the total compensation which is paid, as necessary.

(b) In the event that third party commissions are not paid, the total compensation for Office Holders shall not exceed 10% of the actual scope of revenue from the commercialisation transaction and the compensation which is paid to each of them shall decrease proportionally to the total compensation paid, as necessary.

(c) Notwithstanding that stated above, in any event, one Office Holder will not be entitled to compensation based on a commercialisation transaction in an amount exceeding 6% of the actual scope of the revenue from the commercialisation transaction and in any event the compensation hall not exceed an amount of USD750,000.

2.3.4.3. It is clarified that the Company shall be entitled to grant Office Holders in the Company in one calendar year an annual grant, a special grant and a departure grant, provided that the Office Holder shall not receive double compensation in respect of the same criteria.

2.3.4.4. Upon the occurrence of any one of the events set out below, the Company shall be entitled, by resolution of the compensation committee and the Board of Directors of the Company, and provided that it has been passed with regard to all of the Office Holders in the Company, to decrease and/or not to grant the grants which are specified above, and this despite the fulfilment of the Office Holder of the targets. A provision with regard to this Clause shall be included in the employment agreements of each of the Office Holders in the Company.

(a) A decrease of the total cash in the Company to less than NIS 2 million (hereinafter: "**the minimum amount**"). Upon the increase of the total cash to an amount of NIS 2 million, the Company shall grant annual grants and/or special grants, as the case may be in respect of fulfilment of the parameters set out above and/or completion of the raising of capital and/or a merger transaction and/or a commercialisation transaction which was completed prior to the increase of the total cash to the minimal amount, such that in fact the decrease of the cash to below the minimum amount shall constitute a cause for deferment of the grant until the date of the increase of the total cash up to the minimal amount and not a cancellation of the grant.

(b) The reference by the accountant of the Company in the financial reports of the Company to the existence of significant doubts with regard to the continued existence of the Company as a going concern (hereinafter: "**a going concern remark**").

2.3.4.5. Notwithstanding that stated in Clause 2.3.4.4 above, in instances of registration of a going concern remark in the financial reports of the Company, the Company shall grant the annual grants to the Office Holders but shall not be able to grant special grants and this up until the date of the removal of the going concern remark. The Company shall grant the special grants upon the removal of the going concern remark with regard to the raising of capital, merger or commercialisation transactions completed prior to removal of the going concern remark.

2.3.4.6. For the sake of removal of doubt it is clarified that the provisions of Clauses 2.3.4.4 and 2.3.4.5 shall not apply to the variable capital grants.

2.3.4.7. Return of grant amounts in an instance of a restatement of the financial reports.

2.3.4.7.1 In an agreement with an Office Holder shall be determined a condition whereby an Office Holder will return to the Company, within 90 days, the amount of a grant or a part thereof which was paid to him on the basis of figures which during the course of the examination were discovered to be misleading and which were restated in the financial reports of the Company. With regard to this matter (**period of examination**) shall mean a period of 12 consecutive quarterly financial reports after the date of approval of the grant. It is noted that to such extent as the Company shall find that there is specific culpability with a certain Office Holder in respect of the actual preparation of the financial reports, the duty to return the grant shall apply to that same Office Holder even if the data was registered in financial reports which the Company published during a period which exceeds the examination period as determined above.

2.3.4.7.2 The extent of the surplus payment which shall be returned to the Company shall be determined in accordance with the difference between the amount which was received by the Office Holder and the amount which would have been received in accordance with the restated financial figures in the restated financial reports of the Company (hereinafter: "**the amount of return**").

2.3.4.7.3 Despite that stated above, a restatement due to a change in the law, regulations or accounting rules, which occurred after the date of publication of the financial report of the Company for the same year, shall not be viewed as applicable to that mentioned above.

2.3.4.7.4 The following is a summary of the ceilings of variable grants (non-capital):

Type of Grant	**Maximum Amount / Value per Office Holder**
Grant which is based on the raising of capital	5% of the net raised and in any event no more than USD 300,000
Grant which is based on completion of merger or sale transaction of the Company	6% of the value of the Company and in any event no more than USD 750,000
Grant which is based on commercialisation transaction	6% of the actual revenue arising from the commercialisation and in any event no more than USD 750,000
Annual grant	Up to 12 base salaries or monthly payments, as the case may be, of the Office Holder, save for an instance where the Office Holder made available services to the Company for a period of less than 12 months, in which case the ceiling shall decrease proportionately.

Variable components (equity) – share based compensation

2.3.5. Subject to adoption of an option plan by the Company, in accordance with the provisions of any law, the Company may allot options in the framework of the compensation package to Office Holders.

2.3.6. In the framework of the discussion regarding the granting of compensation based on shares to Office Holders in the Company, the compensation committee and the Board of Directors of the Company shall examine the considerations at the basis of the granting and in particular whether the aforementioned grant is a proper incentive for the maximisation of profit of the Company for the long term. In addition, the granting of share-based compensation shall be made after examination of other compensation alternatives and after examination of the extent of dilution anticipated, the economic value of the grant as mentioned, the exercise price and the period of allotment.

2.3.7. The value of share-based compensation for each Office Holder, at the date of the granting thereof, shall not exceed in one calendar year 5% of the value of the Company as shall be at the date of the granting or NIS 4 million, the higher of these.

2.3.8. The maximum cumulative possible extent of dilution in respect of the entirety of the granting of share-based compensation for employees and Office Holders of the Company under the option plan of the Company shall not exceed 25% in full dilution at any time (hereinafter: "**the maximal level**"). For the sake of removal of doubt it is clarified that this clause does not have the effect of limiting the Company from granting options, not under an option plan to anyone who is not an employee or an Office Holder in the Company, in circumstances where the extent of the maximal dilution in the Company arising from the exercise of options granted under the option plan is not lower than the maximal level.

2.3.9. The Board of Directors of the Company will examine, at the date of approval of the granting of share-based payment, that the dilution ratio between Office Holders and the remainder of the employees of the Company entitled to share-based payment is reasonable.

2.3.10. The compensation committee, the Board of Directors of the Company and the general assembly (to such extent as the approval thereof is required in accordance with the law as new compensation) are entitled to extend the date for expiry of the options.

2.3.11. The vesting period of the entirety of the capital grant shall not be less than 12 months.

2.3.12. The exercise prices shall be determined by the compensation committee and the Board of Directors of the Company for each Office Holder separately.

2.3.13. **The relation between the variable components and the fixed components**
Taking into account the sector in which the Company operates, the compensation customary today in the Company includes relatively low base salaries for Office Holders in the Company. In the business plan of the Company and the risk management policy, the Company believes that the weight of the variable components (capital and non-capital) shall constitute, at most, 90% of the total compensation of the entirety of the Office Holders (in a certain year) and may vary from one Office Holder to another.

2.4. **Updating of existing agreements with Office Holders**

2.4.1. The Company is entitled to revise the terms of employment of the Office Holders in the Company, taking into account and examining the parameters set out in Clause 2.1 above and provided that the maximum annual change of every Office Holder in the Company (with the exception of the CEO, director, controlling interest or his relation) shall not exceed 10% of the rate of the base salary prior to the change in each calendar year, and this solely upon the approval of the compensation committee. In the event that in a certain year a change as mentioned was not carried out, the change will accrue and add to the following calendar year. In any event, any change in wages in accordance with this agreement shall be subject to the ceilings set out in accordance with this plan, both with regard to the variable and the fixed components.

2.4.2. It is clarified that the Company is entitled to revise the terms of employment of the Office Holders in the Company (with the exception of director, controlling interest or his relation) and this in light of an increase or decrease in compensation in direct proportion to an increase or decrease in the extent of the employment of such Office Holder, and this solely upon the approval of the compensation committee.

3. **Authorities of the compensation committee and the Board of Directors of the Company with regard to the Compensation Policy**

3.1. The Compensation Committee and the Board of Directors of the Company shall examine, from time to time, the Compensation Policy and the need for its adjustment, *inter alia*, in accordance with the considerations and principles set out in this policy and including examination of changes in the aims of the Company, consideration of the profit and income thereof in the period prior thereto and in real time and any other relevant information.

3.2. For purposes of examination of the Compensation Policy of the Company, the Compensation Committee and the Board of Directors shall routinely follow up on the implementation of the Compensation Policy in the Company. For such purpose, there shall be presented once per annum the precise calculations of the payments and the options which have matured (if any).

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Exhibit 11.1

Kitov Pharmaceuticals Holdings Ltd.

Code of Ethics and Business Conduct

A. Purpose

The Board of Directors of Kitov Pharmaceuticals Holdings Ltd. (together with its subsidiary, the "Company" or "KITOV") has adopted this Code of Ethics and Business Conduct (the "Code") in order to:

(a) promote honest and ethical conduct, including the ethical handling of actual or apparent conflicts of interest;

(b) promote complete, fair, proper, timely and understandable disclosure in reports and documents that the Company files with, or submits to, the Securities and Exchange Commission (the "SEC"), the Israel Securities Authority ("ISA"), the NASDAQ, the Tel Aviv Stock Exchange (the "TASE") and in other public communications made by the Company;

(c) promote compliance with applicable governmental laws, rules and regulations;

(d) promote the protection of Company assets, including corporate opportunities and confidential information;

(e) promote fair dealing practices;

(f) deter wrongdoing; and

(g) ensure accountability for adherence to the Code.

In order to implement these principles and to support the measures by which the Company, its managers and employees will conduct themselves pursuant thereto, the Company has adopted this Code to anchor the fundamental norms conducted within the Company, including the ethical handling of actual or apparent conflicts of interest between personal and professional relationships; avoidance of conflicts of interest, including disclosure to the General Counsel of the Company (the "**Compliance Officer**") of any material transaction or relationship that reasonably could be expected to give rise to such a conflict; complete, fair, proper timely and understandable disclosure in periodic reports filed by Company as well as in its other public communications; compliance with all applicable governmental rules and regulations; prompt internal reporting of violations of this Code of Ethics; and accountability for adherence to this Code of Ethics, and to offer clear and readable rules thereunder.

The rules are not a closed or exhaustive list of principles that guide the Company's activities. When there is no clear answer in the rules to issues that require an employee to exercise discretion, such employee must act in order to fulfill the requirements of the law and the principles presented here, and the spirit of the rules.

These rules apply to the Company, its directors, managers and employees, in all aspects of the Company's operations, both relations within the Company and externally. All directors, officers and employees are required to be familiar with the Code. Additionally, key advisors and service providers ("**Service Providers**") will be informed in general or on an as needed basis about the Code and their cooperation will be required. KITOV expects its directors, managers, employees and Service Providers to comply with the Code. Violation of the Code by a manager, employee or Service Provider may result in, among other things and subject to applicable law, termination of the relationship with the Company.

B. Compliance with the Law

The uncompromising policy of KITOV is to meet all statutory requirements, including in the United States of America, in Israel and in other countries where the Company operates. As such, employees, officers and directors should comply, both in letter and spirit, with all applicable laws, rules and regulations in the cities, states and countries in which the Company operates. The Company utilizes, as appropriate, legal counsel, accounting advisors and regulatory consultants in order to enable it to best prepare for and comply with statutory requirements.

Advice should be requested from the Compliance Officer every time the legality of a particular activity is in question.

KITOV is aware that even apparent violations of applicable law are able to hurt its reputation as well as to undermine relevant third parties' trust in KITOV. Therefore KITOV urges its personnel to avoid even the appearance of any violation.

C. The Company and its Employees/Consultants

Equal Rights. According to Company policy, all employees at KITOV enjoy their fundamental and legal rights. KITOV is committed to providing every applicant for employment and every employee equal opportunities according to his or her personal qualifications, with respect to job recruitment and advancement within the Company, as applicable.

Preventing discrimination and harassment. The Company prohibits discrimination of any kind on the basis of age, race, ethnicity, religion, gender, marital status and so on. Employees are expected to relate to each other with respect, and to avoid any kind of rude or violent behavior, including sexual harassment and verbal and physical violence.

Safety at work. KITOV is committed to a safe working environment according to strict standards and proper supervision. KITOV managers and employees are committed to strictly complying with internal procedures and standards applicable for the purposes of workplace safety.

Confidentiality and maintaining the company's intellectual property. KITOV is a science research based high-tech company, and as such, protection of its intellectual property and trade secrets is a basic duty of all managers and employees. The Company's employees and managers: (a) shall act to ensure that intellectual property and trade secrets of KITOV and of its customers, suppliers, officers and employees will not be accessible to outsiders, nor to those within the Company that do not need that information in order to fulfill their role in the Company; (b) make sure that when required to disclose intellectual property or trade secrets to outsiders for business purposes, the scope of the disclosure will be approved in advance by the Company's management while protecting the rights of the company through a commitment of confidentiality by the third party and when in doubt as to whether an obligation to disclose confidential information exists, employees shall consult with the Compliance Officer; (c) refrain from any unauthorized disclosure of intellectual property or trade secrets; (d) immediately notify the Company concerning any information or invention which can and will require legal action such as patent registration in order to secure and protect the rights of the Company.

"Intellectual property" of the Company includes, among other, documents held by the Company, formulas, manufacturing processes, supplier and customer identities, programs, content, findings, test results, and other information generated during the operation of the company.

KITOV employees know that improper safeguarding of the Company's intellectual property rights, or negligent or deliberate leaking, can cause serious damage to the Company and can even completely thwart the Company's business activities.

Conflicts of interest. A conflict of interest occurs when an individual's private interest (or the interest of a member of his or her family) interferes, or even appears to interfere, with the interests of the Company as a whole. A conflict of interest can arise when an employee, officer or director (or a member of his or her family) takes actions or has interests that may make it difficult to perform his or her work for the Company objectively and effectively. Conflicts of interest also arise when an employee, officer or director (or a member of his or her family) receives improper personal benefits as a result of his or her position in the Company. Company officers, employees and consultants are strictly forbidden from deriving any personal benefit, whether for themselves or their immediate family members or other relatives, from any activity or transaction related to the Company. In addition, any officer, employee or consultant who is empowered to decide regarding an activity or transaction of the Company, in consequence of which he or she or his or her immediate family or his or her other relatives will or are likely to benefit directly or indirectly, shall refrain from the decision to engage in the activity or enter into the transaction, and instead shall present the matter to be decided to his or her superiors, while listing the benefits he or she or his or her immediate family or other relatives may benefit from in such instance.

Situations that should be avoided as they may constitute a conflict of interest include, among other things, the following:

1. Loans to or guarantees of obligations by KITOV of KITOV personnel and their respective family members.

2. KITOV personnel's engaging in other jobs, which interfere with their efficiency or the performance of their tasks in the Company.

3. KITOV personnel or their family members possessing ownership interests in any of KITOV's recent, current or prospective customers, competitors, suppliers or service providers.

4. The provision of services of any kind, including service as a director, officer, employee or consultant, to a recent, current or prospective customer, competitor, supplier or service provider of KITOV by KITOV personnel or their family members.

5. KITOV personnel or their family members acting as a broker, finder or other intermediary in a transaction involving KITOV.

6. Any investment, interest or association that interferes, might interfere, or might be thought to interfere, with the exercise of judgment in KITOV's best interests by KITOV personnel.

7. The receipt by KITOV personnel or their family members of money, loans, gifts, benefits, services or anything of monetary value from any of KITOV's recent, current or prospective customers, competitors, suppliers or service providers, including common courtesies and hospitalities if their scale or nature would in any way appear to affect the impartiality of KITOV personnel or imply a conflict of interest. Gifts that are received which are greater than nominal value should be returned immediately and reported. If immediate return is not practical, the gift should be given to KITOV for charitable disposition or other disposition as the Company believes appropriate. However, if there is no reasonable likelihood of improper influence in the performance of duties on the part of KITOV personnel on behalf of KITOV, it is acceptable to receive:

- normal business courtesies that are reasonable in nature, frequency and cost, such as meals, occasional athletic, social or cultural events, or participation in corporate promotional events, all involving no more than ordinary amenities;
- paid trips or guest accommodations in connection with proper company business with the prior written approval of the Compliance Officer;
- fees or other compensation received from any organization in which membership or an official position is held with the prior written approval of the Compliance Officer;
- loans from financial institutions made in the ordinary course of their business on customary terms and at prevailing rates; or
- gifts of nominal value (less than $200) during the holiday season.

KITOV prohibits bribery by its officers, employees and Service Providers in the conduct of its business. The use of Company funds or assets for gifts, gratuities or other favors to suppliers, customers or government officials is strictly prohibited, except to the extent such gifts, gratuities or other favors are of nominal value. No bribes, kickbacks or payments shall be made to or for the benefit of government employees, customers, physicians/health care providers or other persons for the purpose of influencing, obtaining or retaining business. This policy extends not only to direct payment, but also forbids indirect payments made through third parties.

When in doubt, employees are invited to consult with the Compliance Officer.

Conflicts of interest cannot always be avoided but it is KITOV's policy to try to avoid them as much as possible.

Prohibition of insider trading. KITOV is a public company and its securities are traded on the Tel Aviv Stock Exchange and on the Nasdaq Capital Market. As a result, various obligations under the securities laws apply to the Company, its directors, employees, consultants and significant shareholders, and those individuals are committed to strictly comply with these obligations. Included amongst these obligations, it is strictly forbidden for managers and employees to (i) trade in securities of the Company based on "inside information", i.e. information that is not available to the general public, which may, if revealed, affect the Company's share price, including, without limitation, information about future financial results, negotiations, business results, clinical trial results, regulatory information, etc. or (ii) directly or indirectly "tip" others who might make an investment decision on the basis of that information. These rules herein do not exhaust the obligations and prohibitions that apply to employees and directors in connection with securities and insider trading. It is recommended for Company employees to consult the Company's senior management when there is any doubt concerning whether the sale or purchase of securities of the Company is, or may be, considered using inside information.

D. The Company and its Products

Product Quality. KITOV is committed to the development and manufacturing of pharmaceutical products at the highest standard of quality, safety and efficiency, while ensuring that the rules and regulations applicable to its products and production processes and development are followed. Employees and consultants are required to immediately report to their superiors any concerns regarding actual or potential defects in products, manufacturing processes, or the non-compliance of relevant rules or standards.

Regulation. The development, manufacture and marketing of KITOV' products are subject to regulations and standards in the United States of America, Israel and elsewhere around the world. KITOV, its employees, consultants and Service Providers must conduct business in compliance with all applicable laws, rules and regulations, as well as in compliance with clinical and regulatory policies, including but not limited to the FDA, Good Clinical Practices (GCP), Good Laboratory Practices (GLP), and Good Manufacturing Practices (GMP). The Company, its consultants and its employees are responsible to comply with the obligations arising from such, including in connection with marketing authorizations, conducting clinical trials, compliance with regulations, monitoring design, labels, etc., all while ensuring maximum compliance with the procedures, rules and regulations applicable from time to time. An employee or consultant shall immediately inform his superiors about any concern regarding the non-compliance of such rules and procedures in full.

The Company and the Environment. KITOV has profound recognition of the importance of protecting the environment, and is committed to ensuring that its activities, including any production process procured by the Company and the handling of hazardous materials shall be performed in accordance with the law, regulations and licenses applicable to it at any time.

E. Fair Dealing

Antitrust and competition laws worldwide exist to ensure fairness in business practices. KITOV's policy is to compete fairly and comply with all such laws designed to regulate aspects of business, including competition and pricing. KITOV and KITOV personnel shall deal fairly with, and not take advantage of, KITOV's customers, suppliers, competitors, officers and employees. This includes, for example, abusing privileged information, concealing or misrepresenting facts, misusing trade secret information obtained without the owner's consent, etc. In order to avoid creating even the appearance of improper arrangements, KITOV prohibits: discussions or other contacts with competitors regarding establishing pricing levels or 'fixing', pricing stabilization; discussions or other contacts with suppliers and customers that illegally restrict trade or exclude competitors from the marketplace; agreements or arrangements with competitors regarding territories or markets in which competitive products are sold, allocating markets or customers; agreements with others to boycott customers or suppliers. Whenever there is a doubt regarding interactions as above mentioned, the individual must immediately report to the Company's General Counsel or through the Open Door Policy procedures and the issue will be brought to the attention of the Company's Audit Committee.

F. Proper Accounting and Financial Integrity

KITOV's books, records and accounts must reflect, properly and fairly and within KITOV's regular system of accountability, all of KITOV's transactions and the acquisition and disposition of its assets. All transactions shall be properly recorded to permit the preparation of financial statements in conformity with generally accepted accounting principles consistently applied and other applicable rules, regulations and criteria, and to insure full accountability for all assets and activities of KITOV. Under no circumstances shall there be any unrecorded funds or assets, regardless of the purposes for which such fund or asset may have been intended, or any improper entry, knowingly made on the books and records. No payment on behalf of KITOV shall be approved or made with the intention or understanding that any part of such payment is to be used for a purpose other than that described by the documents supporting the payment.

Complete, fair, proper, timely and understandable disclosure in the periodic reports filed with the SEC and NASDAQ, and the Israel Securities Authority and TASE must comply with applicable U.S. and Israeli securities laws and SEC, ISA, NASDAQ and TASE rules. Depending on their respective positions with the Company, employees, consultants, officers or directors may be called upon to provide information necessary to assure that KITOV's public reports are complete, fair, proper, timely and understandable. KITOV expects employees, consultants officers and directors to take this responsibility very seriously and to provide prompt and accurate answers to inquiries related to public disclosure requirements and to exercise the highest standard of care in preparing public reports in accordance with the following guidelines, including, without limitation: (i) all Company accounting records, as well as reports produced from those records, must be kept and presented in accordance with the laws of each applicable jurisdiction; (ii) all records must fairly and properly reflect the transactions or occurrences to which they relate; (iii) all records must fairly and properly reflect in reasonable detail the assets, liabilities, revenues and expenses of KITOV; (iv) accounting records must not contain any intentionally false or intentionally misleading entries; (v) no transaction may be intentionally misclassified as to accounts, departments or accounting periods; (vi) all transactions must be supported by proper documentation in reasonable detail and recorded in the proper accounts and in the proper accounting period; (vii) no information may be concealed from the internal auditors, the independent auditors, the Audit Committee of the Board of Directors or the Board of Directors; and (viii) compliance with generally accepted accounting principles and KITOV's system of internal accounting controls is required at all times.

G. Computers and the Internet

KITOV employees and consultants are expected to use approved mechanisms, tools and procedures for any activity or communication that goes through hardware and network belonging to the Company or for confidential material related to the company.

The Company may be required by law or other applicable regulations to review the emails or computer files of its employees. Employees and consultants are expected to maintain the highest standards of professionalism in all written communications.

Social Media. Social media are digital technologies and practices that enable people to create and share content, opinions, insights, experiences and perspectives in different ways (for example, blogs, social networks, etc.). Social media are occasionally used by KITOV and its employees and consultants for business purposes and by employees and consultants for various personal purposes. KITOV seeks to use the newest forms of technology and communication to reach our stakeholders. The Company also respects the rights of employees to engage in personal use of social media. Whether such use is for Company or personal purposes, users must adhere to KITOV's values and ensure ongoing compliance with applicable laws and Company policies. Use discretion and common sense regarding the potential consequences of any social media use. Be open and honest about any affiliation with KITOV when it is relevant to the issue. While disclosing any KITOV affiliation status, make it clear that any ideas or opinions expressed are personal, and may not represent the position of the Company on the issue. **Refrain from using social media to discuss issues that involve KITOV's confidential and proprietary information**.

H. Government, Analyst and Media Inquiries

KITOV must be made aware of any inquiries from the government, the financial/analyst community, or the news media so that it can respond in a timely manner and in line with its internal policy. If a representative of a governmental agency, financial/analyst community or the news media seeking an interview or making a request for information contacts an individual affiliated with the Company, such representative should immediately be referred to the Chairman of the Board, CEO, CFO of General Counsel.

I. Corporate and Individual Political Activity

KITOV respects the right of members of the Board of Directors, employees and Service Providers to participate in the political process and engage in political activities of their choosing. Many governments prohibit or regulate corporate monetary or in-kind political contributions. Any proposed corporate contribution or political activity should be reviewed and approved by KITOV's General Counsel and/or the Audit Committee. Lobbying activity on behalf of the interests of our Company is permissible, but highly regulated by law. Regulators are to be treated in a professional manner and with respect. One must obtain approval from the General Council and/or the Audit Committee before: (i) lobbying or meeting with a government official, whether individually or as part of a group (e.g., a trade association); (ii) engaging a lobbyist at any level of government; or (iii) inviting a government official to a KITOV facility.

Directors', Employees' and Service Providers' lawful, personal political activity in support of candidates or parties is allowed, as long as it is not on Company time or on Company property, and is not funded by Company resources. When such individuals are involved in their personal civic and political affairs, they must make it clear at all times that the views and actions are their own and not those of KITOV. KITOV does not use corporate funds, resources or facilities to support a governmental entity, political organization, party or candidate, except where permitted by law. All political contributions made by KITOV must comply with Company policies, including obtaining the prior written approval of the General Counsel and the Audit Committee.

J. Open Door Policy

General. In KITOV Company employees and consultants are encouraged to talk with managers at all levels about any possible ethical, legal and administrative shortcomings, without fear of reprisal on the part of the Company.

Filing a complaint. When possible, it is preferable for the employee or consultant to turn to his superior in the Company. If this is not possible, including when the employee or consultant feels uncomfortable with such an approach, the employee may apply directly to the Chairman of the Audit Committee of the Company whose contact details are set forth in Exhibit A. The complaint should include the relevant information, to the extent possible, needed to examine the deficiency.

Complaint Handling. After receiving a complaint about the deficiency, the Compliance Officer or the Chairman of the Audit Committee, as applicable, shall order an immediate and thorough investigation of the complaint, shall provide the complainant an update on the progress of the investigation, and will determine the actions to be performed to correct the deficiencies, to the extent any are found.

Confidentiality. In order to allow the complainant to provide detailed information that allows an effective investigation, such information (as well as the complainant's identity) will be kept confidential except as reasonably necessary to carry out the investigation and to correct deficiencies, to the extent any such are found.

Protection. KITOV is aware of the difficulty of the decision to warn of any deficiency, as stated above. The Company will not allow any retaliation, harassment or any pressures against the employee or consultant, and will work to provide protection against such actions as stated for any whistleblower who in good faith warns about any deficiency.

Document Retention. The Chairman of the Audit Committee (including acting through the Company Secretary who is obligated to maintain the confidentiality of the information), saves the documents relating to inquiries and any such investigations for at least 7 years.

K. Waivers

Any waiver of this Code for directors or executive officers must be approved by the board of directors and must be disclosed to shareholders.

These rules are for all Company employees, both men and women. Any wording of the rules in the masculine is for convenience only.

The above Code of Ethics and Business Conduct were adopted by the Audit Committee of the Company at its meeting on March 16, 2016 and by the Board of Directors on March 16, 2016.

Exhibit 12.1

CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER UNDER SECTION 302 OF THE SARBANES-OXLEY ACT

I, Isaac Israel, certify that:

1. I have reviewed this annual report on Form 20-F of Kitov Pharmaceuticals Holdings Ltd.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;
4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e) for the company and have:
    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b. [paragraph omitted in accordance with Exchange Act Rule 13a-14(a)]
    c. Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d. Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and
5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):
    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and
    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: March 18, 2016

/s/ Isaac Israel

Isaac Israel
Chief Executive Officer

Exhibit 12.2

CERTIFICATION OF THE CHIEF FINANCIAL OFFICER UNDER SECTION 302 OF THE SARBANES-OXLEY ACT

I, Simcha Rock, certify that:

1. I have reviewed this annual report on Form 20-F of Kitov Pharmaceuticals Holdings Ltd.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;
4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e) for the company and have:
    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b. [paragraph omitted in accordance with Exchange Act Rule 13a-14(a)]
    c. Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d. Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and
5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):
    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and
    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: March 18, 2016

/s/ Simcha Rock

Simcha Rock
Chief Financial Officer

Exhibit 13.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER UNDER SECTION 906 OF THE SARBANES-OXLEY ACT

Pursuant to 18 U.S.C. Section 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Kitov Pharmaceuticals Holdings Ltd. (the "Company") hereby certifies, to such officer's knowledge that:

1. The accompanying Annual Report on Form 20-F of the Company for the year ended December 31, 2015 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 18, 2016

/s/ Isaac Israel

Isaac Israel
Chief Executive Officer

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. Section 1350, and is not being filed for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference to any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Exhibit 13.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER UNDER SECTION 906 OF THE SARBANES-OXLEY ACT

Pursuant to 18 U.S.C. Section 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Kitov Pharmaceuticals Holdings Ltd. (the "Company") hereby certifies, to such officer's knowledge that:

1. The accompanying Annual Report on Form 20-F of the Company for the year ended December 31, 2015 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 18, 2016

/s/ Simcha Rock

Simcha Rock
Chief Financial Officer

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. Section 1350, and is not being filed for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference to any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.