* Unless otherwise indicated, all information contained in this Annual Report on Form 20-F gives retrospective effect to a consolidation of Kitov Pharma's 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 Pharma were consolidated into one ordinary share of Kitov Pharma; and (B) each of Kitov Pharma'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,				
	2017	2016	2015	2014	2013
	(U.S. Dollars, in thousands)				
Statement of Financial Position Data:					
Cash and cash equivalents	3,947	6,758	10,558	1,313	193
Working capital (*)	3,195	13,625	9,606	773	(946)
Total assets	14,183	14,914	10,812	1,759	311
Total liabilities	(5,590)	(1,529)	(1,383)	(986)	1,257
Accumulated loss	(38,567)	(26,200)	(14,054)	(9,852)	(4,600)
Total equity (deficit)	8,593	13,385	9,429	773	(946)

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

On July 11, 2013, Kitov Pharma, (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 Pharma presented in this Annual Report on Form 20-F include the financial results of Kitov Pharmaceuticals for the five years ended December 31, 2017, 2016, 2015, 2014, and 2013 and of Kitov Pharma for the period from July 11, 2013 to December 31, 2017. In January 2018, Kitov Pharmaceuticals Holdings Ltd. was re-named Kitov Pharma Ltd.

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, which could materially affect our business, financial condition and future results. If any of the following risks actually occur, our business, financial condition and results of operations could be materially and adversely affected. In that event, the trading price of Kitov Pharma's ordinary shares, American Depositary Shares and public warrants could decline.

Risks Related to Our Financial Condition and Capital Requirements

We are a 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 development stage biopharmaceutical company, and we are focused on the development of innovative pharmaceutical products. Our current therapeutic candidates are in the preclinical and clinical development stages, and have not been approved for marketing and are not being sold, marketed or commercialized. Our therapeutic candidates may require additional preclinical and/or clinical trials or other testing before we can obtain regulatory approval, if we are able to obtain regulatory approval at all. We must have regulatory approval for each product that we develop before we can sell such product. We have incurred losses from commencement of our pharmaceutical research and development activities through December 31, 2017 of approximately $38.6 million as a result of research and development activities, clinical trial related activities, investment/acquisition 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, including those we may acquire. 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, seek regulatory approval that is a prerequisite to selling any product, attract development or commercial partners and retain key personnel.

Our business presently generates no revenues, and we plan to continue expending substantial funds in research and development, including CMC, preclinical and 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 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 our current therapeutic candidates and any additional therapeutic candidates, and to 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 complete the required CMC development for 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 preclinical and/or 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 obtain approval, 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 and/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. We have entered into only one out-licensing agreement for marketing, manufacturing and distribution of our Consensi™ therapeutic candidate (previously known as KIT-302) in South Korea, which is dependent upon achieving regulatory clearance for the therapeutic candidate in South Korea. Our therapeutic candidates are subject to extensive governmental laws, regulations and guidelines relating to development, preclinical and 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 preclinical and 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. For example, even if the FDA grants its approval to market Consensi™ for certain indications of use, the South Korean regulatory authorities may impose additional requirements or place other limitations on the indications for use in South Korea, before our licensee and distributor in South Korea may commence manufacturing and selling Consensi™. 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.

Pre-clinical, CMC, and 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 CMC, preclinical and clinical trials that are required to commence commercial sales of our therapeutic candidates. CMC, preclinical and 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 CMC, preclinical and/or clinical trials that will cause delays, including suspension of preclinical and/or clinical trials, delays in recruiting patients into the preclinical and/or clinical trials, or delay of data analysis or release of the final report. The CMC, preclinical and 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 CMC, preclinical and/or clinical trial process that could delay or prevent commercialization of our current or future therapeutic candidates.

In connection with the CMC, preclinical and 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 manufacturing the drug substance and drug product for preclinical and clinical trials;
- delays in manufacturing the drug substance and drug product following NDA approval, if we receive such approval at all;
- delays in securing clinical investigators or trial sites for clinical trials that must be completed for us to obtain any approval that we seek;

- 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 and may not approve initiation of certain clinical trials;
- 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 leave 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 preclinical and/or 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 preclinical and/or 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. While we have entered into an out-licensing agreement for marketing, manufacturing and distribution of our Consensi™ therapeutic candidate in South Korea, we may not be successful in collaborations with other 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 or maintain 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 preclinical and 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. Additionally, we are responsible for any quality or regulatory issue that a collaborator may have that affects one or more of our therapeutic candidates. Relying upon collaborative arrangements to develop and commercialize our therapeutic candidates subjects 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 may experience quality or regulatory issues that negatively affect our therapeutic candidates;
- our collaborators may fail to secure adequate commercial supplies of our therapeutic candidates upon marketing approval, if at all;
- our collaborators may have a shortage of qualified personnel;
- we may be required to relinquish important rights, such as local trademark, 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 or other scenarios materialize, they could have an adverse effect on our business, financial condition or results of operations.

Our current business model is based largely upon the combination of drugs that have not been previously combined, as well as on new chemical entities (NCEs) that have not yet been administered to humans. Unexpected difficulties or delays in successfully developing or marketing such combination and new drugs could have an adverse effect on our business, financial condition and results of operations.

We are currently focused on the combination of drugs that have not been previously combined as well as on new chemical entities that have not yet been administered to humans. Since Consensi™ has APIs that have not previously been combined into one FDA-approved drug product or used at all in a clinical setting outside the scope of a clinical trial, and TyrNovo's chemical entity NT219 has never been used in a clinical setting, we cannot be certain whether Consensi™ and/or NT219 will be safe and efficacious. In addition, we cannot be certain that the market will consider our Consensi™ combination therapeutic candidate, TyrNovo's chemical entity NT219, or any other therapeutic candidate that we may develop or acquire in the future to be superior to the current gold standard of care or 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 or new chemical entities could have an adverse effect on our business, financial condition and results of operations.

In addition, as part of our strategy for growth, we may consider the acquisition of therapeutic candidates at various stages of development and in a variety of therapeutic areas. For example, on January 13, 2017, we announced that we had acquired a controlling interest in TyrNovo Ltd., a privately held Israeli developer of small molecules in the oncology therapeutic field. TyrNovo's NT219 therapeutic candidate is intended to work by overcoming tumors' cancer drug resistance and is expected to be developed to be used in combination with cancer drugs that are already approved and marketed. For more information see Item 4.B – Business Overview – NT219. We may also consider the acquisition or marketing rights of approved drug products as well. However, we may not be able to identify additional suitable acquisition candidates, complete acquisitions or integrate acquisitions successfully. In this regard, acquisitions involve numerous risks, including difficulties in the integration of the acquired therapeutic candidates and the diversion of management's attention from other business concerns. Although we will endeavor to evaluate the risks inherent in any particular transaction, there can be no assurance that we will properly ascertain all such risks. In addition, acquisitions could result in the incurrence of substantial additional indebtedness and other expenses or in potentially dilutive issuances of equity securities. There can be no assurance that difficulties encountered with acquisitions will not have a material adverse effect on our business, financial condition and results of operations.

We rely on third parties to conduct our CMC, preclinical and 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 CMC, preclinical or clinical trials for our product candidates, and we rely on third parties, such as contract manufacturing organizations, contract research organizations, medical institutions, contract laboratories, current and potential development or commercialization partners, clinical investigators and independent study monitors, to perform these functions. Our reliance on these third parties for development activities reduces our control over these activities. For example, on March 28, 2017, we announced that due to a delay in the provision of technical documentation from an external service provider, the Company's New Drug Application for Consensi™ for the FDA was expected to be submitted to the FDA later than initially anticipated by the Company. Similarly, the clinical study report for our Phase III/IV renal function clinical trial was initially prepared by third parties in a manner our management determined was not adequate for submission to the FDA. As a result, we intend to correct certain portions of the Phase III/IV renal function clinical study report, and we now expect to submit the report to the FDA within six to eight weeks of this Annual Report on Form 20-F, later than we initially anticipated.

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 preclinical and 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 laboratory, manufacturing, and clinical practices (GCP), for conducting, recording and reporting the results of preclinical and clinical trials to assure that data and reported results are credible and accurate and that the clinical trial participants are adequately protected. Regulatory authorities in other jurisdictions may have similar responsibilities and requirements. Our reliance on third parties does not relieve us of these responsibilities and requirements.

To date, we believe our contract manufacturing organizations, contract research organizations and other similar entities with which we are working have generally 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 CMC, preclinical and 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 preclinical, 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 completely 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 active pharmaceutical ingredients, or "APIs", compliant with the International Conference of Harmonization Q7 guidance and applicable law, 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 manufacturers and suppliers in the market, if these manufacturers or suppliers are incapable or unwilling to meet our current or future needs on acceptable terms or at all, we could experience delays in conducting additional clinical trials of our therapeutic candidates and incur additional costs.

While there may be several alternative manufacturers or suppliers of API in the market, we have not conducted extensive audits and investigations into the quality or availability of their APIs. In addition, we may acquire therapeutic candidates which already have long term commitments to a specific API supplier. As a result, we can provide no assurances that supply sources will not be interrupted from time to time. Changing API manufacturers or suppliers or finding and qualifying new API manufacturers or 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 manufacturers or suppliers of our APIs, 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 by third-party manufacturers.

To date, our third-party manufacturers have manufactured sufficient quantities of Consensi™ for formulation development, PK studies, clinical trials, and the required large scale production in support of our NDA package that we submitted to the FDA for the purposes of approving Consensi™ for marketing and commercial sale in the United States. We are also in discussions with third-party manufacturers for the manufacture of cGMP-grade NT219. If the FDA or other regulatory agencies approve for marketing and commercial sale, Consensi™ and/or any other therapeutic candidate that we may develop or acquire in the future, 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 therapeutic candidates that may be approved in the future 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 Consensi™ or any therapeutic candidate that we may develop or acquire in the future, or we are unable to establish alternative manufacturing capabilities, the commercial launch of any therapeutic candidates that are approved in the future 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 cGMPs. These laws, regulations and guidelines cover all aspects of the manufacturing, testing, quality control and recordkeeping relating to our therapeutic candidates or drugs that may be approved in the future. 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, unanticipated adverse reactions or serious adverse reactions that were not observed in preclinical and/or clinical trials may be observed during the commercial marketing of a therapeutic candidate that may be approved in the future.

As we develop our therapeutic candidates or commercialize our products that may be approved in the future, we may also periodically discuss with the FDA and other regulatory authorities certain clinical, regulatory and manufacturing matters and, our views may, at times, differ from those of the FDA and other regulatory authorities. For example, the FDA may seek to regulate our combination therapeutic candidates, like Consensi™, or any product we may sell or market that consist of two or more active ingredients as combination drugs under its Combination Drug Policy. The Combination Drug Policy requires that we demonstrate that each active ingredient in a drug product contributes to the product’s claimed effect. If the FDA raises questions regarding whether available data and information provided to the FDA demonstrate the contribution of each active ingredient in such combination drug products, we may be required to provide additional data, which may require us to conduct additional preclinical studies or clinical trials. If we are required to conduct additional clinical trials or other testing of our therapeutic candidates or drug products that may be approved in the future, we may face substantial additional expenses, be delayed in obtaining marketing approval or may never obtain marketing approval for such therapeutic candidate or drug products we may sell or market.

In addition, the manufacturer and the manufacturing facilities that we or our potential commercialization partners use or will use to manufacture any therapeutic candidate will be subject to periodic and unannounced 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 or changes to the drug's labeling.

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 acquire or develop in the future, are likely require new regulatory clearances or approvals before promotion or sale 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 therapeutic candidate that we may develop or acquire 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 manufacturers of approved drugs to make and document a determination of whether or not a modification requires a new approval, supplemental application 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 may disagree with the manufacturer's decision. 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 drug 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 drug product and to stop marketing the drug product 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 Consensi™, and the FDA has filed our New Drug Application (NDA) for Consensi™, this agreement and the filing of the NDA by the FDA do not guarantee approval of Consensi™ or any other particular outcome from the final regulatory review of the study or the therapeutic candidate.

We have reached an agreement with the FDA to conduct the Phase III clinical trial for Consensi™ 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 approval will require that the data will convince the FDA of the safety, efficacy and need for the therapeutic candidate for each of its intended use(s). 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 Consensi™ will receive marketing approval or that the approval process will be faster than conventional regulatory procedures. Further, we cannot make assurances that the reported results of our Phase III clinical trial of Consensi™, and the filing by the FDA of the NDA submission for Consensi™ with a PDUFA date set by the FDA for May 31, 2018, will result in any FDA approval for Consensi™. We also cannot make assurances that the uncertainty surrounding an investigation by the Israeli Securities Authority into our historical public disclosures concerning certain aspects of our Phase III clinical trial of Consensi™ will not have an impact on the FDA approval process for Consensi™, nor what such an impact might be. See "Item 8 – Financial Information – Legal Proceedings". Further, our recently completed Phase III/IV renal function clinical trial (See Item 4. Information on the Company – A. History and Development of the Company – Recent Developments – Phase III/IV Renal Function Clinical Trial), whose primary efficacy endpoint is comparable to that of our Phase III Clinical Trial, may have an impact on the FDA approval process for Consensi™.

During the NDA review period, as is common for NDA reviews, we have been responding to FDA information requests on an ongoing basis. In light of such information requests, we also cannot make assurances that the FDA will not require us to submit additional data, or complete additional studies in connection with Consensi™, prior to considering the issuance of marketing approval for Consensi™. For example, as part of the NDA review process the FDA has asked us to provide additional data in connection with the chemistry of the over-encapsulation of the pills given to the patients in the Phase III clinical trial.

Such requests and other possible requests for additional data or studies, as well as the possibility that the FDA may consider the submission of the Phase III/IV renal clinical study report to be a major amendment to the NDA which would allow the FDA to extend the PDUFA date by up to 90 days, may delay the FDA approval of our NDA, and otherwise impact the NDA submission for Consensi™ in a manner not currently known to us.

In addition, although our Phase III/IV renal function clinical trial was not required as part of the initial Consensi™ NDA submission to the FDA, we delivered the initial study results data to the FDA shortly following completion of the study, and we expect to submit the completed Phase III/IV renal function clinical study report to FDA within six to eight weeks of this Annual Report on Form 20-F, later than we initially anticipated. The FDA has indicated to us that a submission of this report at such time could possibly result in the extension of the PDUFA date by up to an additional 90 days, but have not definitely indicated that they would extend the PDUFA date.

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, and we believe that our Phase III/IV renal function clinical trial for Consensi™ produced results that are consistent with those of our Phase III clinical trial. We also believe that the submission of the Phase III/IV renal function clinical study report to the FDA has the potential to strengthen the drug's labeling and support future marketing of Consensi™, and that the potential labeling and marketing benefits that could be derived from submission of the Phase III/IV renal function clinical study report to the FDA are substantially more important to Consensi™'s commercial prospects than a possible short-term delay in obtaining marketing approval. We also believe that the investigation by the Israeli Securities Authority will not have any material impact on the FDA approval process, and we believe that we will be able to respond timely to all requests of the FDA for additional data or complete any requested additional studies in a timely manner. However, if the FDA revokes or alters its agreement under the SPA agreement, or if the FDA interprets the data collected from the clinical trials differently than we do, or if the FDA considers the submission of the Phase III/IV renal clinical study report a material amendment to the NDA, or otherwise considers the submission in six to eight weeks of this Annual Report insufficient time for them to review the submission prior to the current PDUFA date, or if the FDA requests additional data or studies which take longer than expected or produce unfavorable results, or if the Israeli Securities Authority investigation negatively impacts the NDA review process or causes questions to be raised about the validity of the data collected from the Phase III clinical trial, the FDA may extend the PDUFA date and thus delay the approval of our NDA, or may not deem the data sufficient to support an application for regulatory approval, or may not grant us the labeling which would indicate an expanded patient target market for Consensi™, any of which results 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.

Kitov Pharma's therapeutic candidate, and our subsidiary which owns the rights to 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.

If we cannot meet our obligations under our in-license agreement with Yissum, or if other events occur that are not within our control, we could lose our rights to our NT219 therapeutic candidate, experience delays in developing or commercializing our NT219 therapeutic candidate or incur additional costs, which could have a material adverse effect on our business, financial condition and results of operations.

We acquired rights to our NT219 therapeutic candidate from Yissum Research and Development Company of the Hebrew University of Jerusalem Ltd. ("Yissum"), the Hebrew University Technology Transfer Company pursuant to a license agreement. If we do not meet our obligations under this license agreement, or if other events occur that are not within our control we could lose the rights to our NT219 therapeutic candidate, experience delays in developing or commercializing our NT219 therapeutic candidate or incur additional costs, any of which could have a material adverse effect on our business, financial condition and results of operations.

In addition, Yissum is responsible under the license agreement for the filing and prosecuting certain patent applications and maintaining certain issued patents licensed to us. If Yissum does not meet its obligations in a timely manner or if other events occur that are not within Yissum's control, which impact Yissum's ability to prosecute certain patent applications and maintain certain issued patents licensed to us, our success of developing and commercializing the NT219 therapeutic candidate, could be jeopardized, which could have a material adverse effect on our business, financial condition and results of operations. Additionally, Yissum may decide to discontinue maintaining certain patents in certain territories for various reasons, such as a current belief that the commercial market for the therapeutic candidate will not be large or that there is a near-term patent expiration that may reduce the value of the therapeutic candidate. In the event Yissum discontinues maintaining such patents, we may not be able to enforce rights for our therapeutic candidates or protect our therapeutic candidates from competition in those territories.

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 CMC, preclinical and/or 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 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.

Uncertain geopolitical conditions in the Korean peninsula could have a material adverse effect on the marketing, manufacture and distribution of Consensi™ in South Korea.

Upon achieving regulatory clearance for Consensi™ in South Korea, we will rely on Kuhnil Pharmaceutical Co., Ltd. ("Kuhnil") for the marketing, manufacture and distribution of Consensi™ in South Korea. Accordingly, geopolitical and military conditions in South Korea and the surrounding region may directly affect our ability to effectively commercialize Consensi™ in South Korea. In recent months, there have been heightened security concerns regarding North Korea's nuclear weapons and long-range ballistic missile programs. This has resulted in increased uncertainty regarding both North Korea's actions and those of the United States. If one of the parties takes aggressive action, including acts of war, our promotion of Consensi™ may be adversely affected.

Our subsidiary, TyrNovo, has received and may continue to receive Israeli governmental grants to assist in the funding of its research and development activities. If TyrNovo loses funding from these research and development grants, we may encounter difficulties in the funding of future research and development projects and implementing technological improvements, which would harm our operating results and may restrict the activities of our subsidiary, TyrNovo. We may encounter difficulties in securing a commercialization partner for TyrNovo's therapeutic candidates as the grants received from the Israeli government need to be repaid as royalties from future revenue from the sale of products (and related services) developed (in whole or in part) as a result of such grants.

Our subsidiary, TyrNovo, has obligations to the Israel Innovation Authority, or IIA (formerly known as the Office of the Chief Scientist of the Ministry of Economy and Industry) with respect to grants it received from the IIA connection with TyrNovo's technology, in an aggregate amount of approximately NIS 5.5 million. The requirements and restrictions for such grants are found in the Encouragement of Research, Development and Technological Innovation in Industry Law 5744-1984 (formerly known as the Law for the Encouragement of Research and Development in Industry 5744-1984), or the Innovation Law, the IIA's rules and guidelines and the terms of these grants.

In general, the recipients of grants, or Recipient Company(ies), are obligated to pay the IIA royalties from the revenues generated from the sale of products (and related services) developed (in whole or in part) as a result of, a research and development program funded by the IIA at rates which are determined under the IIA's rules and guidelines (currently a yearly rate of 3% to 6% on sales of products or services developed under the approved programs, depending on the type of the Recipient Company, up to the aggregate amount of the total grants received by the IIA, plus annual interest (as determined in the IIA's rules and guidelines).

The technologies licensed to TyrNovo by Yissum were developed, at least in part, with funds from IIA grants, and accordingly is obligated to pay royalties on sales of any of its IIA funded products and related services. In addition, the Government of Israel may from time to time audit sales of products which it claims incorporate technology and know-how funded via IIA programs and this may lead to additional royalties being payable on additional products. As of December 31, 2017, the maximum royalty amount that would be payable by TyrNovo, excluding interest, is approximately NIS 5.5 million (USD 1.6 million), and as of such date TyrNovo had not paid any royalties to the IIA. We may encounter difficulties in securing a commercialization partner for TyrNovo's therapeutic candidates due to the requirement to pay royalties to the IIA.

Following the full payment of such royalties and interest, there is generally no further liability for royalty payments; however, other restrictions under the Innovation Law continue to apply. These are generally described in the risk factor below under "The IIA grants which TyrNovo's technology has received for research and development expenditures restrict its ability to manufacture products and transfer (including by way of license for R&D purposes) know-how outside of Israel and require it to satisfy specified conditions. In addition, we may encounter difficulties partnering TyrNovo's therapeutic candidates with entities outside of Israel due to certain restrictions regarding manufacturing and transferring of know-how (including by a way of license for R&D purposes) outside of Israel imposed due to the receipt of the IIA grants."

The IIA grants which TyrNovo's technology has received for research and development expenditures restrict its ability to manufacture products and transfer (including by way of license for R&D purposes) know-how outside of Israel and require it to satisfy specified conditions. In addition, we may encounter difficulties partnering TyrNovo's therapeutic candidates with entities outside of Israel due to certain restrictions regarding manufacturing and transferring of know-how (including by a way of license for R&D purposes) outside of Israel imposed due to the receipt of the IIA grants.

The research and development efforts underlying TyrNovo's technology have been financed, in part, through the grants received from the IIA. TyrNovo, therefore, must comply with the requirements of the Innovation Law and the IIA's rules and guidelines.

Under the IIA's rules and guidelines, TyrNovo is generally prohibited from manufacturing products developed using the IIA funding outside of the State of Israel without the prior approval of the IIA and subject to payment of increased royalties, as further described in Item 4.B – Business Overview – Government Regulations and Funding. TyrNovo may not receive the required approvals for any proposed transfer of manufacturing activities. This restriction may impair TyrNovo's ability to outsource manufacturing rights abroad.

Additionally, under the IIA's rules and guidelines, TyrNovo is prohibited from transferring the IIA-funded know-how and related intellectual property rights outside of the State of Israel, except under limited circumstances and only with the prior approval of the IIA. TyrNovo may not receive the required approvals for any proposed transfer, and even if received, TyrNovo may be required to pay the IIA a redemption fee, which may result in significant amounts, in accordance with the formulas stipulated under the IIA's rules and guidelines, while such fee will not exceed 600% of the grant amounts plus interest.

Approval of the transfer of know-how to an Israeli company is required, and may be granted if the recipient assumes all of our responsibilities towards the IIA including the restrictions on the transfer of know-how and the manufacturing rights outside of Israel and the obligation to pay royalties, and, although such transfer will not be subject to the payment of a redemption fee, there will be an obligation to pay royalties to the IIA from the income of such sale transaction as part of the royalty payment obligation. No assurance can be given that approval to any such transfer, if requested, will be granted.

These restrictions may impair our ability to perform or outsource manufacturing outside of Israel, or otherwise transfer or sell TyrNovo's IIA funded know-how outside of Israel. It may also require TyrNovo to obtain the approval of the IIA for certain actions and transactions and pay additional royalties and other amounts to the IIA. Furthermore, the consideration available to TyrNovo's and/or our shareholders in a transaction involving the transfer outside of Israel of know-how developed with IIA funding (such as a merger or similar transaction) may be reduced by any amounts that TyrNovo is required to pay to the IIA. If TyrNovo fails to comply with the requirements of the Innovation Law and the IIA's rules and guidelines, TyrNovo may be required to return certain grants previously received along with interest and penalties, and may become subject to criminal proceedings.

In August 2015, an amendment to the Innovation Law, or Amendment No. 7, was enacted and which came into effect on January 1, 2016. Pursuant to Amendment No. 7, the IIA became responsible for the activity which was previously under the OCS's responsibility. The IIA is authorized to amend the requirements and restrictions which were specified in the Innovation Law before Amendment No. 7 became effective, *inter alia*, with respect to ownership obligations of IIA funded know-how (including with respect to restrictions on transfer of IIA funded know-how and manufacturing activities outside of Israel), as well as royalty obligations which apply to companies that received grants from the IIA. In addition, the IIA has recently published new rules and guidelines for the granting of licenses to use know-how developed as a result of research financed by the IIA to foreign entities. According to such rules, we will be required to receive the IIA's prior approval for the grant of such use rights, and we will be required to pay the IIA certain amount in accordance with the formula stipulated under these rules and guidelines. Although the rules which were published by the IIA as of the date of this Form 20-F, generally adopted the principal provisions and restrictions specified in the Innovation Law prior to the effectiveness of Amendment No. 7, as of the date of this Form 20-F, we are unable to assess the effect on our business of any future rules which may be published by the IIA.

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 Consensi™, NT219, and/or any other therapeutic candidate that we may develop in the future, are approved for commercialization, they may not be 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 preclinical and/or 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 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.

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 platform or means of treating the same indications as Consensi™, NT219, or other therapeutic candidates that we may develop in the future. 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.

For example, since 2010, the opioid epidemic in the United States has increasingly been recognized as a major cause of death. The CDC estimates that from 2010 to 2016 over 600,000 Americans died from opioid overdoses. As a result, individuals, corporations, and the FDA have increasingly sought to decrease the over utilization of opioids. One method for decreasing the use of opioids is to increase the use of other analgesics. We believe that Consensi™ could potentially replace opioids for many types of chronic pain. However, it is possible that new drugs and new treatments that have been developed or that are in the process of being developed by others in order to reduce the use of opiods may render Consensi™ noncompetitive in this market.

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, among others:

- 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.

It has been reported the generic drug prices have fallen since 2010. As a result, profits of generic drug companies, such as Teva Pharmaceuticals (NYSE:TEVA; TASE:TEVA), have been falling over time. With the decrease in profits, the stock prices of publicly traded generic companies have often fallen in tandem. It is unclear to us how long this trend will continue, nor what effect this might have on the marketing of Consensi™ which, while patented, is comprised of two separate generic drug components.

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 (CMS) 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 CMS and other third-party payers may have sufficient market power to demand significant price reductions. Price reductions or other significant coverage policies or payment limitations could materially and adversely affect our business, financial condition and results of operations.

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 Healthcare Reform Law included a number of new rules regarding health insurance, the provision of healthcare, and conditions to reimbursement for healthcare services provided to Medicare and Medicaid patients and other healthcare policy reforms. Through the law 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 tens of millions of Americans who lacked insurance coverage and to contain or reduce healthcare costs (such as by reducing or conditioning reimbursement amounts for healthcare services and drugs and imposing additional taxes, fees, and rebate obligations on pharmaceutical and medical device companies). This legislation has been one of the most comprehensive and significant reforms ever experienced by the United States in the healthcare industry, and has significantly changed the way healthcare is financed by both governmental and private insurers. This legislation has impacted the scope of healthcare insurance and incentives for consumers and insurance companies, among others. 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 consumers and 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. Some of the provisions of the Healthcare Reform Law have not yet been fully implemented and regulatory guidance continues to be issued. At this stage, it is difficult to estimate the full extent of the direct or indirect impact of the Healthcare Reform Law on us.

These structural changes could entail further modifications to the existing system of private payors and government programs (such as Medicare, Medicaid and the State Children's Health Insurance Program), creation of a government-sponsored healthcare insurance sources, 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 or commercialization partners are currently developing. If reimbursement for our approved therapeutic candidates, if any, is substantially reduced or otherwise adversely affected in the future, or rebate obligations associated with them are substantially increased, it could have a material adverse effect on our business, financial condition and results of operations.

Extending medical benefits to those who previously lacked coverage may, in the long term, 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 and increased enforcement activities. Cost of care could be reduced further by decreasing the level of reimbursement for medical services or products (including those therapeutic candidates currently being developed by us or our development 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 material adverse effect on our business, financial condition and results of operations.

Several states and private entities initially mounted legal challenges to the Healthcare Reform Law, and they continue to litigate various aspects of the legislation. On July 26, 2012, the United States Supreme Court generally upheld the provisions of the Healthcare Reform Law at issue as constitutional. However, the U.S. 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 number 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 individuals. Many of these efforts to date have included the institution of Medicaid managed care programs. The manner in which these cost saving and coverage measures are implemented could have a material adverse effect on our business, financial condition and results of operations. Further, the healthcare regulatory environment has seen significant changes in recent years and is still in flux. Judicial challenges as well as legislative initiatives to modify, limit, or repeal the Healthcare Reform Law have been initiated and continue to evolve following the 2017 changes in the U.S. presidential administrations and U.S. Congress. One such initiative is an Executive Order signed by the current U.S. President directing executive departments and federal agencies to waive, defer, grant exemptions from, or delay the implementation of provisions of the Healthcare Reform Law that would impose a fiscal or regulatory burden on individuals and certain entities to the maximum extent permitted by law. These legislative and judicial challenges are likely to continue. We cannot predict the impact on our business of future legislative and legal challenges to the Healthcare Reform Law 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.

Upon the commencement of marketing products in the United States, we will become subject to additional healthcare regulation and enforcement by the U.S. 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 healthcare 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 healthcare 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 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;

- the so-called federal “Sunshine Act”, which requires certain pharmaceutical and medical device companies to monitor and report certain financial relationships with physicians and other healthcare providers to CMS for disclosure to the public;

- the federal Food, Drug, and Cosmetic Act, which, among other things, strictly regulates drug product and medical device marketing, prohibits manufacturers from marketing such products for off-label use, and regulates the distribution of samples;

- 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 payor, including commercial insurers.

Further, the 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 device and pharmaceutical manufacturers, among others, to make annual public disclosures of certain payments and 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 CMS by March 31 of 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.

Most recently, there has been a trend in federal and state legislation aimed at requiring pharmaceutical companies to disclose information about their production and marketing costs, and ultimately lowering costs for drug products. Several states have passed or introduced bills that would require disclosure of certain pricing information for prescription drugs that have no threshold amount or are above a certain annual wholesale acquisition cost, and in June 2016 Vermont became the first state to pass legislation requiring certain drug companies to disclose information relating to justification of certain price increases. The U.S. Congress has also introduced bills targeting prescription drug price transparency.

Any such implementation of legislation requiring publication of drug costs could materially and adversely impact our business, financial condition and results of operations by promoting a reduction in drug prices. As such, patients may choose to use other low-cost, established drugs or therapies.

The scope and enforcement of these laws are 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, financial condition nor results of operations 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 Legal Proceedings and Intellectual Property

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 also 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 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. Additionally, on February 16, 2017, we announced that four lawsuits and motions to approve the lawsuits as a class action lawsuit were filed against us and certain of our office holders at the Tel Aviv District Court (Economic Division), and served on us, with each such motion relating to the formal investigation by the Israeli Securities Authority (ISA) into our public disclosures. In addition, class actions lawsuits largely relating to the same matters were filed in the State of California and in the U.S. federal courts against us, our CEO and CFO, and in the California lawsuits, against the underwriters of our November 2015 initial public offering in the U.S.A. (collectively, “Investigation Motions”).

The above noted motions and class actions could result in significant legal defense costs and high punitive damage payments. For instance, during the year ended December 31, 2017, we incurred legal expenses of approximately $900,000 in connection with the ISA Investigation and ongoing class actions. Although we maintain directors’ and officers’ liability insurance, with an extension to cover the Company as well, and which is expected to cover much of our expected costs (legal and otherwise) in connection with the ISA Investigation and ongoing class actions after payment by us of the policy deductibles, the insurance companies may reject our claims for coverage under the policy or the coverage may not be adequate to cover future claims. Furthermore, we are required to indemnify our underwriters for their legal defense costs or any other damages in the California Investigation Motion, and such indemnification will not be covered under the policy. To date we have received requests from our underwriters to indemnify them for their legal costs in connection with the California putative class actions in an aggregate amount of approximately $135,000, most of which amount has already been paid by us as of the date of this Annual Report on Form 20-F. Additionally, we may be unable to maintain our existing directors’ and officers’ liability insurance in the future at satisfactory rates or adequate amounts. With respect to the motion from December 2015, we have been advised by our attorneys that the likelihood of the Company not incurring any financial obligation as a result of such 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 probability of success or the scope of potential exposure, if any, of any of the Investigation Motions. 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 material fines, penalties and other sanctions and other adverse consequences arising out of the Company's ongoing Israeli Securities Authority investigation, related class action lawsuits and related matters.

We operate in a complex legal and regulatory environment, and any failure or possible failure to comply with applicable laws, rules and regulations may result in civil and/or criminal legal proceedings. In Israel, Kitov Pharma is currently subject to a formal investigation by the Israeli Securities Authority (respectively, the "Investigation" and the "ISA") into its public disclosures around certain aspects of the studies related to its lead therapeutic candidate, Consensi™. We have not yet been advised by the ISA of the full scope and focus of the Investigation. However, in order to provide additional information regarding the investigation to the Company's investors and the public, we had discussions with the ISA in order to obtain certain additional information which may be disclosed to our shareholders. Based on these discussions with the ISA, we believe that the Investigation with respect to Kitov Pharma relates to the Data Monitoring Committee ("DMC") appointed in connection with our Phase III trial of Consensi™.

We cannot predict at this time the impact on us as a result of the Investigation and accordingly cannot assure you that we will not be materially and adversely affected. Responding to such an investigation is costly and involves a significant diversion of management's attention. Such proceedings are unpredictable and may develop over lengthy periods of time. Future settlements may involve large cash penalties. The ISA has a broad range of civil and criminal penalties it may seek to impose (on Kitov Pharma and/or individuals), and Kitov Pharma and/or its officer holders may be required to pay material fines and/or penalties. Kitov Pharma and/or its office holders may be subject to injunctions or limitations on future conduct, or suffer other criminal or civil penalties or adverse impacts, including additional lawsuits by private litigants. Any one or more of the foregoing could have a material adverse effect on our reputation and our business, financial condition or results of operations. For more information on the Investigation see "Item 8 – Financial Information – 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. 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. 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.

We are developing some of our therapeutic candidates in collaboration with academic and other research institutes. While we attempt to ensure that our intellectual property is protected under the terms of our collaboration agreements with such institutes, these institutes may have claims to our intellectual property.

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.

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

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.

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 its 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 class action motions and lawsuits or other claims which may be filed against our directors and officers, as well as the Investigation, 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 the risk factor titled "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" under the risk factor section titled "Risks Related to Legal Proceedings and Intellectual Property".

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.

In the event we do not satisfy the requirements for a tax-free merger of Kitov Pharmaceuticals with and into Kitov Pharma, Kitov Pharmaceuticals may be subject to a material tax liability.

The board of directors of each of Kitov Pharma and Kitov Pharmaceuticals approved the merger of Kitov Pharmaceuticals with and into Kitov Pharma, with Kitov Pharma as the surviving company. The merger was completed in December 2017. Based on our analysis, we notified the Israeli Tax Authority that the merger satisfied the requirements for a tax-free merger under Israeli tax law, which includes amongst other requirements, which are applicable to Kitov: that the merger was considered for business and economic purposes and that the primary goal of the merger was not tax avoidance or tax reduction; compliance with certain limitations on selling off most of each of the companies' assets should not be sold during the period two years after the end of the tax year in which the change in the structure occurs; the merged company will continue its main business activity in the same way it did prior to the merger; and operating losses carried forward (of both the participating companies) may be deducted in the reports of the merged company, at the lower of a rate of 20% of the losses transferred each year, or up to 50% of the taxable income of the merged company. In the event the Israel Tax Authority does not agree with our analysis, Kitov Pharmaceuticals may be subject to a material tax amount on account of the sale equal to the value of its assets on the date of transfer minus the cost basis for such assets. Such a tax liability may have a material adverse effect on our financial results.

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 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.

Kitov Pharma owns a majority interest in its subsidiary, TyrNovo. As a majority shareholder under the Israeli Companies Law, Kitov Pharma owes certain fiduciary duties to the non-controlling shareholders of TyrNovo and must share dividends and distributions with these non-controlling shareholders. In addition, in a stay of proceedings, reorganization or bankruptcy scenario, certain controlling shareholder loans may become subordinated to other obligations of TyrNovo.

Kitov Pharma presently owns a controlling majority stake in TyrNovo, as well as the majority of TyrNovo's presently outstanding debt obligations. All the ordinary shares of TyrNovo that are not owned by Kitov Pharma are privately held. In order to satisfy whatever fiduciary obligations Kitov Pharma may have under applicable law or other governing documents to the non-controlling shareholders of TyrNovo, Kitov Pharma endeavors to deal with TyrNovo at "arm's-length." Some transactions between Kitov Pharma and TyrNovo, including any cancellation of such transactions, may require the approval of the boards of directors of TyrNovo and/or Kitov Pharma, and, under certain circumstances, approval of the shareholders of TyrNovo and/or Kitov Pharma by special vote and are subject to the receipt of applicable permits and approvals, and therefore Kitov Pharma's ability to control TyrNovo may be limited.

For example, the current articles of association of TyrNovo require that any loans taken by TyrNovo receive unanimous consent of all shareholders present at a shareholders meeting called in order to approve such loan. The same special majority would be required in order to amend such provision in the articles of association. It is unclear if these provisions apply to the Convertible Loan which was provided to TyrNovo by Kitov Pharma and which may be provided to TyrNovo by Taoz, a minority shareholder of TyrNovo, pursuant to a Binding Term Sheet between TyrNovo, Taoz and Kitov Pharma which was confirmed under a final judgment entered into by the Economic Division of the Tel Aviv District Court in February 2017. As such, it is presently unclear if Kitov Pharma and/or Taoz can make investments into TyrNovo in the form of such Convertible Loans, nor what might be the terms of any equity investments into TyrNovo in place of such Convertible Loans if they are deemed to have not been approved in accordance with the articles of association of TyrNovo. For more information on the Convertible Loans and the Court approved settlement, see Item 7. Major Shareholders and Related Party Transactions B. – Related Party Transactions – TyrNovo Ltd.

In addition, any dividend or distribution from TyrNovo requires the approval of the directors of TyrNovo and may be subject to restrictions imposed other agreements to which they are party, and therefore there may be limits on the dividends or distributions Kitov Pharma receives from TyrNovo and from any commercialization of NT219. In addition, in a stay of proceedings, reorganization or bankruptcy scenario, certain controlling shareholder loans may become subordinated to other obligations of the subsidiary, and Kitov Pharma's priority rights over loans it has made to TyrNovo may be pushed back in such proceedings.

Provisions of Israeli law and Kitov Pharma's amended and restated articles of association or TyrNovo's articles of association may delay, prevent or otherwise impede a merger with, or an acquisition of, the Company or TyrNovo, or an acquisition of a significant portion of Kitov Pharma's or TyrNovo's shares, which could prevent a change of control, and negatively affect the market price of Kitov Pharma's 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.

Kitov Pharma's 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, such as Kitov Pharma's staggered board of directors, the appointment by Kitov Pharma's board of directors of additional directors to fill vacancies on the board of directors, the size of the Kitov Pharma's board of directors, the terms of office of Kitov Pharma's directors and the special majority of Kitov Pharma's voting rights required to amend such provision in its 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.

In addition, Kitov Pharma has 1,000,000,000 shares of non-voting senior preferred shares authorized, which can be issued by its board of directors, who can establish conversion, redemption, optional and other special rights, qualifications, limitations or restrictions, if any, of the non-voting senior preferred shares, without further actions by Kitov Pharma's shareholders, unless shareholder approval is otherwise required by applicable law, the rules of any exchange or other market on which its securities may then be listed or traded, its articles of association then in effect, or any other applicable rules and regulations. Furthermore, in a merger between Israeli corporations, if the non-surviving entity has more than one class of shares, the merger may need to be approved by each class of shareholders, including any classes of otherwise non-voting shares, such as the non-voting senior preferred shares authorized in Kitov Pharma's share capital.

Kitov Pharma's subsidiary, TyrNovo, has obligations to the IIA with respect to grants from the IIA for certain research and development expenditures in connection with TyrNovo's technology. The terms of these grants may require us to satisfy specified conditions in order to manufacture products and transfer technologies outside of Israel, which may impede our acquisition by, or a merger with, a foreign company. For more information, see the risk factors in connection with IIA funding found under "Risks Related to Our Financial Condition and Capital Requirements."

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. 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.

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.

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

In the past, we identified a material weakness in our internal control over financial reporting which while remediated, any other material weaknesses, if not remediated, could adversely affect our reputation, business or stock price.

As described in our Annual Report for 2016 on Form 20-F,under "Item 15 - Controls and Procedures," based on our evaluation of 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, our management, including the chief executive officer and chief financial officer, concluded that our disclosure controls and procedures as of the end of 2016, reflected a material weakness in internal control over financial reporting that required us to enhance our procedures and systems relating to financial reporting, primarily due to the factor described below. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim consolidated financial statements will not be prevented or detected on a timely basis.

A deficiency was identified in the past in connection with our internal control over financial reporting related to the operation of the control to review the accounting for significant non-routine and complex transactions to ensure proper application of IFRS. This control did not operate effectively with respect to the 2016 financial statements due to the lack of timely involvement of the qualified technical resources to perform the required management review. As a result, during the audit process for 2016, an error was detected in the accounting for equity and derivative instruments, which was corrected prior to filing our audited financial statements for 2016.

Although we developed and implemented a plan to remediate this material weakness and believe, based on our evaluation to date, that this material weakness was remediated during 2017, we cannot assure you that we will not identify additional material weaknesses in our internal control over financial reporting in the future, nor 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. The occurrence of or failure to remediate any material weaknesses may adversely affect our reputation and business and the market price of our ordinary shares, public warrants and any other securities we may issue.

We 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.

Kitov Pharma's ADSs and public warrants have been traded on The NASDAQ Capital Market since November 20, 2015. As a public company whose securities are listed in the United States, we incur accounting, legal and other expenses, including costs associated with our reporting requirements under the Exchange Act. We also 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.

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 thus incur 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, our management is 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.

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, requires 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.

We cannot predict the outcome of evaluations we will conduct, and whether we will need to implement additional 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 Kitov Pharma's ordinary shares, ADSs and public 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 may be classified as a Passive Foreign Investment Company, or PFIC, for U.S. federal income tax purposes in 2018 and may continue to be, or become, a PFIC in future years, 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 may be classified as a PFIC in future years. If we are treated as a PFIC for any taxable year during which a U.S. investor held our ADSs, certain adverse U.S. federal income tax consequences could apply to the U.S. investor. See "Item 10. Additional Information – E. Taxation and Government Programs – Passive Foreign Investment Company Consequences."

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

The stock market in general, and the market price of Kitov Pharma's ordinary shares on the TASE and its ADSs and Series A warrants on NASDAQ in particular, are subject to fluctuation, and changes in the price of its listed securities may be unrelated to our operating performance. The market prices of Kitov Pharma's ordinary shares on the TASE and its ADSs and public warrants on NASDAQ have fluctuated in the past, and we expect it will continue to do so. The market price of Kitov Pharma's ordinary shares, 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 by 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 Kitov Pharma's 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 Kitov Pharma's ordinary shares and ADSs and public warrants and result in substantial losses by 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 Kitov Pharma's ordinary shares or ADSs or other warrants or convertible securities could reduce the market price of its ordinary shares and ADSs and other listed securities.

As of February 28, 2018, we had an aggregate of 229,152,462 issued and outstanding ordinary shares (including 21 dormant ordinary shares held in treasury) (such number of ordinary shares would be represented by 11,457,623 of Kitov Pharma's ADSs), no non-voting senior preferred shares, 6,835,669 Series A or public warrants, representative's warrants to purchase 157,945 of its ADSs, which were granted to the underwriters as part of Kitov Pharma's initial U.S. offering in November 2015, placement agent's warrants to purchase 141,176 of its ADSs, which were granted to the placement agent as part of its follow-on U.S. offering in July 2016, non-listed warrants to purchase 1,005,597 of its ADSs, which were granted to the investors in conjunction with its registered direct offering in July 2017, placement agent's warrants to purchase 170,222 of its ADSs, which were granted to the placement agent as part of its registered direct offering in July 2017, and 17,640,676 non-tradable options and RSUs to purchase 22,930,285 ordinary shares, (such number of non-tradable options or RSUs and their underlying ordinary shares would be represented by 1,146,514 of its ADSs). We also expect to issue up to an aggregate of 13,169,689 additional ordinary shares of Kitov Pharma to certain minority shareholders of TyrNovo with whom we entered into an agreement in October 2017 to acquire their shares in TyrNovo in exchange for such ordinary shares of Kitov Pharma, the closing of which share exchange agreement, is expected to take place by March 15, 2018. We may also issue additional ordinary shares or ADSs of Kitov Pharma to the remaining shareholders of TyrNovo who were not party to our October 2017 agreement to acquire additional shares from TyrNovo shareholders, should we seek to acquire remaining shares of TyrNovo not currently held by us. Substantial sales of Kitov Pharma's ordinary shares or ADSs or other warrants or securities convertible into ordinary shares or ADSs, or the perception that such sales may occur in the future, including sales of ordinary shares or ADSs issuable upon the exercise of options or the conversion of convertible securities, may cause the market price of Kitov Pharma's ordinary shares or ADSs or other listed securities to decline. Moreover, the issuance of shares or ADSs in connection with the future acquisition of additional shares of TyrNovo or pursuant to the conversion or exercise of options, RSUs, warrants or any other convertible securities Kitov Pharma and/or TyrNovo may issue will also have a dilutive effect on Kitov Pharma's shareholders, which could further reduce the price of its ordinary shares and ADSs and other listed securities on their respective exchanges.

Future sales of TyrNovo's ordinary shares or other warrants or convertible securities could dilute our holdings in TyrNovo, and reduce the value of TyrNovo reflected in our holdings of TyrNovo and also reduce the market price of Kitov Pharma's ordinary shares and ADSs and other listed securities.

As of February 28, 2018, Kitov Pharma held a controlling equity interest in TyrNovo representing approximately 65% of its issued and outstanding share capital. In addition, we held a Convertible Loan to TyrNovo of $1,000,000. We also expect to acquire additional ordinary shares of TyrNovo from certain minority shareholders of TyrNovo with whom we entered into an agreement in October 2017 to acquire their shares in TyrNovo representing approximately 27% of the outstanding shares of TyrNovo as of February 28, 2018, in exchange for ordinary shares of Kitov Pharma. The closing of this share exchange agreement is expected to take place by March 15, 2018. In addition, Kitov Pharma and TyrNovo entered into a Revolving Secured Facility and Pledge Agreement on March 1, 2017, pursuant to which Kitov Pharma has made loans to TyrNovo with a balance of $1,000,000 as of February 28, 2018, and which is expected shortly to be converted to an equity holding in TyrNovo following the completion of an equity issuance by TyrNovo to Kitov Pharma. As part of our settlement arrangements with Taoz – Company for Management and Holdings of Companies Ltd. ("Taoz"), a minority shareholder in TyrNovo, Taoz is entitled for a certain period of time to invest up to an additional $1,750,000 in TyrNovo by way of loans which are convertible into TyrNovo equity. Such arrangements with Taoz could serve to dilute Kitov Pharma's holdings in TyrNovo. In addition, the failure to close the agreement with the minority shareholders could reduce our holdings in TyrNovo below what we have expected to acquire. Substantial sales of TyrNovo's ordinary shares or other warrants or securities convertible into ordinary shares of TyrNovo, may cause the holdings of Kitov Pharma in TyrNovo to be diluted, and such dilution, or the perception that such sales may occur in the future, including sales of ordinary shares of TyrNovo issuable upon the exercise of options or the conversion of convertible securities into shares of TyrNovo may cause the market price of Kitov Pharma's ordinary shares or ADSs or other listed securities to decline.

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 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) 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 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 (2) 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.

In the future we may elect to follow additional home country corporate governance practices instead of those otherwise required under the NASDAQ Listing Rules for U.S domestic issuers. Following our home country governance practices as opposed to the requirements that would otherwise apply to a U.S. company listed on 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. As our ordinary shares are traded on the Tel Aviv Stock Exchange ("TASE"), while our ADSs and Series A warrants are traded on NASDAQ, we currently also report to the ISA and the TASE in accordance with the provisions of Section 35XXXIII of the Israel Securities Law, 5728-1968 and the Securities Regulations (Periodic and Immediate Reports of a Foreign Body Corporate) 5761-2000, promulgated thereunder (the "Dual-Listed Reporting Requirements"). Pursuant to the Dual-Listed Reporting Requirements, we prepare our periodic and immediate reports in accordance with U.S. securities laws and reporting requirements, as applicable to a foreign private issuer. We intend to file with the SEC, within 120 days after the end of each fiscal year ending December 31, 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. In accordance with NASDAQ Listing Rules, as a foreign private issuer we are required to submit on a Form 6-K an interim balance sheet and income statement as of the end of the second quarter of each fiscal year. 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, we, at our expense, will announce its financial information for each of the first three fiscal quarters consistent with the practices of companies which are dual-listed on both the Tel Aviv Stock Exchange and a domestic U.S. securities exchange and report in accordance with the Dual-Listed Reporting Requirements; provided that the foregoing shall not apply in the event we enter into a merger transaction in which we are the non-surviving entity that would cause our ADSs and warrants to no longer be registered under the Exchange Act. The Representative of the underwriters of our initial U.S public offering which was completed in November 2015 has previously waived the announcement by us with respect to the filing of quarterly financial information, and may issue such waivers to us in the future. It is noted that recent amendments to the Israel Securities Law and regulations enacted thereunder, dispense with the requirement for the announcement of financial results for each of the first and third fiscal quarters of a calendar year for certain smaller sized TASE listed companies which report under TASE only listed reporting requirements. We believe that, were we reporting under the TASE only listed reporting requirements (and not the Dual Listed Reporting Requirements), we would qualify for such dispensation based on our company size as set forth in the regulation. In addition, the SEC has recently announced that it is seeking comment for the dispensation of the requirement for the announcement of financial results for each of the first and third fiscal quarters for certain U.S. domestic issuers. Thus it remains uncertain as to how companies dual-listed on both the Tel Aviv Stock Exchange and a domestic U.S. securities exchange, and report in accordance with the in accordance with the Dual-Listed Reporting Requirements, will continue their practices with respect to the announcements of financial information for each of the first and third fiscal quarters, and it is possible that we may adopt practices for the announcement (if any) of financial information for each of the first and third fiscal quarters which are different than what we have provided in the past.

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 provide voting instructions, 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 provide voting instructions, 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 notice 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 receive delivery of 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 and Series A warrants are traded on different markets and this may result in price variations.

Our ordinary shares trade on the TASE, and our ADSs and Series A 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 Series A warrants have a relatively short prior trading history in the U.S., and present level of market activity may not be sustained, which may limit the ability of our investors to sell our ADSs in the U.S.

Although our ADSs and Series A warrants have been traded on NASDAQ since November 20, 2015, the present level of market activity for our ADSs and Series A warrants may not be sustained. If an active market for our ADSs and Series A warrants is not sustained, it may be difficult for an investor to sell its ADSs, Series A warrants or the ADSs underlying the warrants being issued in this offering.

We can issue non-voting senior preferred shares without shareholder approval, which could adversely affect the rights of holders of ordinary shares.

Our amended and restated articles of association permit us to establish the rights, privileges, preferences and restrictions of future series of our non-voting senior preferred shares, which contain superior liquidation and dividend rights, and may contain other rights, including conversion, redemption, optional and other special rights, qualifications, limitations or restrictions, equivalent or superior to our ordinary shares and to issue such non-voting senior preferred shares without further approval from our shareholders. The rights of holders of our ordinary shares may suffer as a result of the rights granted to holders of non-voting senior preferred shares that we may issue in the future. In addition, we could issue non-voting senior preferred shares containing rights that prevent a change in control or merger, thereby depriving holders of our ordinary shares of an opportunity to sell their shares at a price in excess of the prevailing market price.

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

The trading market for our ADSs and Series A 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 Series A warrants could decline if such research or reports are not published or if one or more securities analysts downgrade our ADSs or Series A 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 previous offerings, and may not use them effectively.

We currently intend to use the net proceeds from our previous offerings to expand our clinical development program, finance our business development activities to enable out-licensing of our therapeutic candidates, expand our clinical development pipeline for additional drug products, including by way of possible acquisitions, and for general corporate purposes, including working capital requirements. We currently have no binding agreements or commitments to complete any transaction for the possible acquisition of new therapeutic candidates. There is no certainty that we will be able to complete any transactions for the possible acquisition of new therapeutic candidates. However, our management will have broad discretion in the application of the net proceeds from our previous offerings. Our shareholders may not agree with the manner in which our management chooses to allocate the net proceeds from the public offerings. The failure by our management to apply these funds effectively could have a material adverse effect on our business, financial condition and results of operations. Pending their use, we may invest the net proceeds from the public offerings in a manner that does not produce income. The decisions made by our management may not result in positive returns on any investment by shareholders and shareholders will not have an opportunity to evaluate the economic, financial or other information upon which our management bases its decisions.

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 shareholder 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 our November 2015 initial public 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 $1.07 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 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.