

\* Restated due to retrospective method of adoption of IFRS 15, Revenue from Contracts with Customers, adopted as of January 1, 2018. See "Item 5. Operating and Financial Review and Prospects - Components of Statement of Operations".

\*\* Unless otherwise indicated, all information contained in this Annual Report on Form 20-F gives retrospective effect to:

(i) a consolidation of Kitov Pharma's share capital at a ratio of 1:13, which was effected on November 30, 2014, or the 2014 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 2014 Consolidation was adjusted by multiplying the number of ordinary shares into which such option was exercisable by 1/13 (rounded to 0.07692); and

(ii) a consolidation of Kitov Pharma's share capital at a ratio of 1:20, which was effected on January 4, 2019, or the 2019 Consolidation, so that: (A) each 20 ordinary shares of Kitov Pharma were consolidated into one ordinary share of Kitov Pharma and (B) each 20 Kitov Pharma's options (tradable and non-tradable) exercisable into ordinary shares outstanding immediately prior to the 2019 Consolidation were consolidated into one option exercisable into one ordinary share of Kitov Pharma at an exercise price equal to the pre-2019 Consolidation exercise price multiplied by 20.

	As of December 31,				
	2018	2017	2016	2015	2014
	(U.S. Dollars, in thousands)				
Statement of Financial Position Data:					
Cash and cash equivalents	5,163	3,947	6,758	10,558	1,313
Working capital (*)	5,200	4,010 (**)	13,625	9,606	773
Total assets	14,723	14,183	14,914	10,812	1,759
Total liabilities	(3,719)	(5,495) (**)	(1,529)	(1,383)	(986)
Accumulated loss	(43,672)	(38,472) (**)	(26,200)	(14,054)	(9,852)
Total equity	11,004	8,688 (**)	13,385	9,429	773

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

(\*\*) Restated due to full retrospective method of adoption of IFRS 15, Revenue from Contracts with Customers, adopted as of January 1, 2018. See "Item 5. Operating and Financial Review and Prospects - Components of Statement of Operations".

#### 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 adversely 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 pharmaceutical 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 pharmaceutical company, and we are focused on the development and commercialization of innovative pharmaceutical drugs. We have one FDA-approved drug, Consensi™ for which we have entered into commercialization agreements with respect to the United States and in several territories in Asia (subject to regulatory approval in such territories) but we have not commenced drug sales in such territories. Additionally, we currently have one therapeutic candidate, NT219. NT219 is in the preclinical development stage, has not been approved for marketing and is not being sold, marketed or commercialized. NT219 will require 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 obtain regulatory approval for NT219 or any other therapeutic candidate that we may develop or acquire in the future, before we can sell NT219 or any other therapeutic candidate. We have incurred losses from commencement of our pharmaceutical research and development activities through December 31, 2018 of approximately \$43.7 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 NT219 or other therapeutic candidates that we may develop or acquire in the future. Our ability to generate revenue and achieve profitability depends mainly upon our ability, alone or with others, to successfully develop, and obtain the required regulatory approvals for, our NT219 therapeutic candidate in the United States and various other territories and then to successfully commercialize our NT219 therapeutic candidate; through our U.S. commercialization partner, to successfully market and sell our FDA-approved drug Consensi™ in the United States; and to obtain, either by us or by our commercialization partners, the required regulatory approvals in various territories other than the United States and then commercialize and sell Consensi™ in such other territories. We may be unable to achieve any or all of these goals with regard to NT219 or any other therapeutic candidates that we may develop in the future and our FDA-approved drug Consensi™. 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, and we depend on the success of a limited portfolio of products for our revenue, which could impair our ability to achieve profitability***

We have a limited operating history as a pharmaceutical research and development company, and our operations to date have been limited primarily to developing, gaining regulatory approval, and commercializing Consensi™; developing our NT219 therapeutic candidate; research and development; raising capital; and recruiting scientific and management personnel and third party partners. Though we have plans for the development of additional therapeutic candidate products, to date, the only revenue we have received has been the initial milestone payments in connection with commercialization agreements for Consensi™. We have not yet demonstrated an ability to successfully sell our FDA-approved drug, Consensi™, which was approved on May 31, 2018. We have not yet demonstrated an ability to commercialize or obtain regulatory approval for our NT219 therapeutic candidate. Our future growth and success depend upon the successful commercialization of Consensi™ and our therapeutic candidates. If we are unable to achieve increased commercial acceptance of our products, obtain regulatory clearances or approvals for our therapeutic candidates and future products, or experience a decrease in the utilization of our products, our revenue would be adversely affected. 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 limited revenues, and we plan to continue expending substantial funds in research and development, including CMC, preclinical and clinical trials of our NT219 therapeutic candidate, and for manufacturing of our FDA-approved drug Consensi™. We plan to fund our future operations through commercialization and out-licensing of our therapeutic candidates and by 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 NT219 therapeutic candidate and our FDA-approved drug Consensi™, we will need to raise substantial additional funds to develop and/or commercialize our therapeutic candidates and to acquire or in-license any additional therapeutic candidates, as our current cash and short-term investments are not sufficient to complete the research and development of our therapeutic candidates in their current phase of development and any additional therapeutic candidates that we may acquire, in-license or develop in the future, 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 our NT219 therapeutic candidate or any other therapeutic candidates that we may develop in the future;
- our ability successfully to complete the required CMC development for our NT219 therapeutic candidate or any other therapeutic candidates that we may develop in the future;
- our ability successfully to commercialize our therapeutic candidates, or any other therapeutic candidates that we may develop in the future, including securing commercialization agreements with third parties and favorable pricing and market share;
- the ability of our U.S. partner to successfully launch and commercialize Consensi™;

- our ability to successfully meet our post marketing commitments to FDA for Consensi™ and to obtain approvals for marketing of Consensi™ in other territories than the U.S.;
- 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 or any other therapeutic candidates that we may develop in the future and addressing regulatory and other issues that may arise post-approval for such therapeutic candidates or from commercializing Consensi™;
- the costs of obtaining and enforcing our issued patents and defending intellectual property-related claims;
- the costs of developing and maintaining cGMP commercial manufacturing capabilities and sales, marketing and distribution channels;
- our consumption of available resources more rapidly than currently anticipated, resulting in the need for additional funding sooner than anticipated;
- our ability to obtain recommendations and publish studies regarding the efficacy and/or safety of our approved products, or our NT219 therapeutic candidate or any other therapeutic candidates that we may develop in the future that may be published by government agencies, professional organizations, academic or medical journals or other key opinion leaders;
- patient acceptance of and demand for Consensi™;
- sufficient coverage and reimbursement by third-party payers; and
- maintaining FDA marketing approval of Consensi™.

If we are unable to obtain approval, commercialize or out-license our therapeutic candidates, or any other therapeutic candidates that we may acquire, in-license or develop in the future; maintain approval; 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.***

Although we recently entered into an exclusive marketing and distribution agreement with respect to the commercialization of Consensi™ in the U.S. market, to date, we have not marketed, distributed or sold any therapeutic candidate or drug product. In addition to that agreement, we have entered into only two other out-licensing agreements for marketing, manufacturing and distribution of Consensi™ in South Korea and China, which are dependent upon achieving regulatory clearance or approval for Consensi™ in each of those respective countries. Our NT219 therapeutic candidate is 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 though the FDA has granted its approval to market Consensi™ for certain indications of use, the South Korean and/or the Chinese regulatory authorities may impose additional requirements or place other limitations on the indications for use in such countries, before our licensee and distributors in such countries 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 studies, 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 results. We and/or our potential commercialization partners will not be able to commercialize our therapeutic candidates without developing CMC satisfactory to regulatory authorities, completing preclinical studies and clinical trials and then seeking to obtain regulatory approval if such trials show that our therapeutic candidates are safe and effective.***

We have limited experience in conducting and managing the CMC, preclinical studies and clinical trials that are required to commence commercial sales of our therapeutic candidates. Developing and implementing CMC, and planning and conducting preclinical studies 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 studies and/or clinical trials that will cause delays, including suspension of preclinical studies and/or clinical trials, delays in recruiting patients into the clinical trials, or delay of data analysis or release of the final report in our preclinical studies or clinical studies. The CMC, preclinical studies 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 studies, and/or clinical trial process that could delay or prevent commercialization of our current or future therapeutic candidates.

In connection with the CMC, preclinical studies 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 studies 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 preclinical and/or 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;
- failure to manufacture our drug product, to maintain the drug product, or contamination to our drug product;
- 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 studies 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 studies 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 NT219 therapeutic candidate or any other therapeutic candidates that we may develop in the future, or otherwise raise substantial additional capital, we will likely need to alter our development and any commercialization plans.***

Our drug development programs, including our commercialization of Consensi™ and the potential commercialization of our NT219 therapeutic candidate, or any other therapeutic candidates that we may develop in the future, 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 exclusive marketing and distribution agreement with respect to the commercialization of Consensi™ in the U.S. market and out-licensing agreements for marketing, manufacturing and distribution of Consensi™ in South Korea and China, 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 our therapeutic candidates or Consensi™ in foreign jurisdictions where we do not have approval for commercialization, or any other therapeutic candidates that we may develop in the future or failure to develop, market and commercialize such therapeutic candidates; or failure to market and commercialize our Consensi™ drug product in the U.S. market 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, manufacturing and commercialization of our Consensi™ drug product, our NT219 therapeutic candidate or any other therapeutic candidates that we may develop in the future, outside our control, and 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/or commercialize our Consensi™ drug product, our NT219 therapeutic candidate or any other therapeutic candidates that we may develop in the future 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 drug product or therapeutic candidates;
- we may be held liable should a collaborator fail to comply with applicable laws, rules, or regulations when performing services for us;
- 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 in a timely manner for our drug products 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 and increase the cost of development of 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 development and commercialization of new combination products and NCEs that have mostly not yet been administered to humans. Unexpected difficulties or delays in successfully developing or commercializing such combination and new drugs could have an adverse effect on our business, financial condition and results of operations.***

We are currently focused on combination products and NCEs that have mostly not yet been administered to humans. Consensi™ has the combination of APIs celecoxib and amlodipine besylate that had not previously been combined into one FDA-approved drug product or used at all in a clinical setting outside the scope of the clinical trials before we obtained FDA-approval to commercialize Consensi™ on May 31, 2018. We cannot guarantee that Consensi™ will be safe and efficacious when administered outside of a clinical trial setting. In addition, we cannot be certain that the market will consider our Consensi™ drug product to be superior to the current gold standard of care or to treatment with the separate drug components rather than in combination.

Our NT219 therapeutic candidate has never been used in a clinical setting, and in addition we cannot be certain whether NT219 will be safe and efficacious when used in combination with other known cancer treatments. In addition, we cannot be certain that the FDA or any foreign regulatory body will consider our NT219 therapeutic candidate combined with a particular cancer treatment, or any other therapeutic candidate that we may develop or acquire in the future to be superior to the current gold standard of care. 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, and we may also consider the acquisition or marketing rights of approved drug products as well. However, we may not be able to identify suitable acquisition candidates, complete acquisitions or integrate acquisitions successfully into our business. In this regard, acquisitions involve numerous risks, including difficulties in the integration of the acquired therapeutic candidates and/or drug product 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 mainly on third parties to conduct our CMC, preclinical studies 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 studies or clinical trials for our product candidates, and we rely mainly 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.

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 studies and clinical trials is conducted in accordance with its general investigational plan and protocol. Moreover, the FDA requires us and our applicable third-party collaborators, to comply with regulations and standards, commonly referred to as current good laboratory practices (cGMP), current good manufacturing practices (cGMP), and current good clinical practices (cGCP), for manufacturing and 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. We cannot guarantee that our third-party collaborators will remain compliant with the applicable regulations. 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 third party entities that support our manufacturing, preclinical or clinical practices 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 not meet our deadlines or 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, finding replacements may result in a delay of clinical trials, meeting post marketing commitments to the FDA and/or commercialization of products and additional costs. Accordingly, we may be delayed in obtaining regulatory approvals for our NT219 therapeutic candidate or any therapeutic candidate that we may develop in the future and we may be delayed in our efforts to successfully commercialize such therapeutic candidates for targeted diseases or fail to maintain marketing authorization to our drug products.



In addition, we rely substantially on third-party data managers for the CMC, preclinical study 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 prevent regulatory approval or cause revocation of already approved marketing authorization.

***If third parties do not manufacture our current therapeutic candidates or any other therapeutic candidate that we may develop in the future in sufficient quantities in the required timeframe, at the required quality standards 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 NT219 therapeutic candidate or any other therapeutic candidate that we may develop in the future. 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 NT219 therapeutic candidate or any other therapeutic candidate that we may develop in the future may adversely affect our future profit margins, if any, and our ability to develop such therapeutic candidates and commercialize any such 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, and in receiving regulatory approval for such replacements.

***We rely on third party contract vendors to manufacture and supply us with APIs to be compliant with the International Conference of Harmonization Q7 guidance and applicable laws and regulations, 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 Consensi™ drug product and our NT219 therapeutic candidate. 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, or the current or future demand of the public, if any, we could experience delays in conducting additional clinical trials of our Consensi™ drug product and NT219 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 Consensi™ drug product to meet the current or future demands of the public, or produce enough supplies of our NT219 therapeutic candidate to meet our needs for further development and/or to conduct clinical trials, 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/or other regulatory agencies for NT219 or any other therapeutic candidates we may develop in the future.***

To date, our NT219 therapeutic candidate has been manufactured in relatively small quantities by third-party manufacturers. We are also in discussions with third-party manufacturers for the manufacturing of our NT219 therapeutic candidate under cGMP conditions. Once NT219 and/or any other therapeutic candidate that we may develop or acquire in the future is approved for marketing and commercial sale, if at all, we still expect that we would continue to rely, at least initially, on third-party manufacturers to produce commercial quantities of such approved therapeutic candidates. These manufacturers may not be able successfully to increase the manufacturing capacity for any such 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 we are unable successfully to increase the manufacturing capacity for our NT219 therapeutic candidate or any therapeutic candidate that we may develop or acquire in the future, or we are unable to establish alternative manufacturing capabilities and in a timely manner, the commercial launch of any such therapeutic candidates that are approved in the future may be delayed or there may be a shortage in supply.

***We anticipate continued reliance on third-party manufacturers to manufacture our Consensi™ drug product at commercial scale to meet the demand in the United States or any foreign jurisdiction in which we may commercialize our Consensi™ drug product in the future.***

Before our Consensi™ drug product was approved on May 31, 2018, our third-party manufacturer produced 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 have recently engaged such third party suppliers for the manufacturing of sufficient quantities of Consensi™ in order to comply with FDA post-marketing approval requirements and at commercial scale in anticipation of the upcoming U.S. launch of Consensi™ by our commercialization partner in the United States. We anticipate that we will continue to rely on our third-party manufacturer to manufacture our Consensi™ drug product at commercial scale under cGMP conditions. Our third party supplier may not be able to successfully increase the manufacturing capacity for our Consensi™ drug product to meet the demand in the United States. Though we can attempt to ensure the availability of suppliers or manufacturers for Consensi™, the number of suppliers with suitable manufacturing capacity and capability is often very limited, and therefore we may be dependent on one or a few such suppliers. Furthermore, any changes to the manufacturing process to increase the manufacturing capacity for Consensi™, including changing or including additional manufacturers, or any other changes with respect to manufacturing may require additional validation studies, which the FDA must review and approve. If third-party manufacturers are unable to successfully increase the manufacturing capacity for Consensi™ or we are unable to establish alternative manufacturing capabilities, our efforts to meet the demand for our Consensi™ drug product in the United States 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 third-party 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 Consensi™ drug product and our NT219 therapeutic candidate to the extent we initiate clinical trials for our NT219 therapeutic candidate 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.

***Our FDA-approved Consensi™ drug product and our NT219 therapeutic candidate and/or any other therapeutic candidate that we may develop in the future, if approved, 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 the FDA approval(s) we have obtained (or will obtain, if any), and our business would be seriously harmed.***

Our FDA-approved Consensi™ drug product is subject to ongoing post-marketing surveillance programs and regulatory review. In addition, if our NT219 therapeutic candidate and/or any other therapeutic candidate that we may develop in the future, receives regulatory approval to commercialize, such therapeutic candidate will be subject to ongoing post-marketing surveillance programs and regulatory review. We and our commercialization partners, as applicable, are subject to ongoing reporting obligations, including pharmacovigilance, or drug safety, and our manufacturing operations, and those of contract manufacturers that we select, will be subject to continuing regulatory review, including inspections by the FDA and other foreign regulatory authorities if Consensi™ is approved for commercialization in such foreign jurisdictions. The results of this ongoing review may result in the withdrawal of Consensi™ from the market, the interruption of manufacturing operations or the imposition of labeling or marketing limitations. In addition, since many more patients are exposed to drugs following their marketing post-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 Consensi™.

As we move forward with commercializing our Consensi™ drug product, 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. If we are required to conduct additional clinical trials or other testing of Consensi™, we may face substantial additional expenses, and/or we have our approval to commercialize Consensi™ revoked by the FDA or a foreign regulatory body, should we obtain approval to commercialize in such foreign jurisdiction.

In addition, the manufacturer and the facilities that we or our commercialization partners use or may use to manufacture our Consensi™ drug product 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 Consensi™, the manufacturer or manufacturing process, or failure to comply with our post-approval requirements, rules and regulatory requirements, may result in actions such as:

- restrictions on such therapeutic candidate, manufacturer or manufacturing process;
- Form 483 observations, untitled letters, 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;
- refusal to permit the import or export of our therapeutic candidates;
- product seizure or detentions;
- injunctions or the imposition of civil or criminal penalties and fines; or
- adverse publicity or changes to the drug's labeling.

The FDA or foreign regulatory authorities' policies may change, or additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our NT219 therapeutic candidate or regulations may be enacted or changed that could hinder our ability to commercialize our Consensi™ drug product. 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 our Consensi™ drug product and/or our NT219 therapeutic candidate or any other therapeutic candidate that we may develop in the future that obtain regulatory approval, resulting in decreased or lost revenue from milestones, product sales or royalties and could also result and other civil or criminal sanctions, including fines and penalties.

***Regulatory approval of our Consensi™ drug product is limited by the FDA and similar foreign authorities to those specific indications and conditions for which clinical safety and efficacy have been demonstrated, and the promotion of Consensi™ (or other products or product candidates, as applicable) for off-label uses, or in a manner that otherwise violates applicable FDA regulations, could adversely affect our business.***

Any regulatory approval of therapeutic candidates is limited to those specific diseases and indications for which such therapeutic candidates have been deemed safe and effective by the FDA or similar foreign authorities. We received FDA approval on May 31, 2018 to commercialize Consensi™ only for the simultaneous treatment of two clinical conditions: pain caused by osteoarthritis and hypertension, or high blood pressure. Marketing or commercializing Consensi™ to treating a new symptom, or indication that is not pain caused by osteoarthritis and hypertension would be considered promotion of off-label, or unapproved use, and would require us to file a supplemental new drug application and obtain regulatory approval. We rely on physicians to prescribe and administer Consensi™ as the product labeling directs and for the indications described on the labeling. To the extent any physicians prescribe Consensi™ to patients for off-label uses, or the use of Consensi™ departs from the approved uses, this may increase the risk of injury or other adverse events to the patients and product liability claims brought against us. Product liability claims are expensive to defend regardless of merit and could result in substantial damage awards against us or harm our reputation. Furthermore, the use of Consensi™ for indications other than those approved by the FDA or foreign authorities, if any, may not effectively treat the conditions associated with the off-label use, which could harm our reputation in the marketplace among physicians and patients, adversely affecting our operations.

While physicians may choose to prescribe drugs for uses that are not described in the product's labeling and for uses that differ from those approved by regulatory authorities, our ability to promote Consensi™ is limited to those indications that are specifically approved by the FDA or other regulatory authorities. Although regulatory authorities generally do not regulate the behavior of physicians, they do restrict communications by companies on the subject of off-label use. If the promotional activities related to Consensi™ fail to comply with these regulations or guidelines, we may be subject to warnings from, or enforcement action by, the FDA or other regulatory authorities. In addition, failure to follow FDA rules and guidelines relating to promotion and advertising can lead to other negative consequences that could adversely affect our operations, such as the suspension or withdrawal of Consensi™ from the market, enforcement letters, and corrective actions. Other regulatory authorities may impose separately penalties including, but not limited to, fines, disgorgement of money, operating restrictions, or criminal prosecution.

The FDA also requires that our sales and marketing efforts, as well as promotions, comply with various laws and regulations. Prescription drug promotions must be consistent with and not contrary to labeling, present "fair balance" between risks and benefits, be truthful and not false or misleading, be adequately substantiated (when required), and include adequate directions for use. In addition to the requirements applicable to approved drug products, we may also be subject to enforcement action in connection with any promotion of an investigational new drug. A sponsor or investigator, or any person acting on behalf of a sponsor or investigator, may not represent in a promotional context that an investigational new drug is safe or effective for the purposes for which it is under investigation or otherwise promote the drug candidate.

If the FDA investigates the marketing and promotional materials or other communications for our current or future commercial products and finds that any of our commercial products are being marketed or promoted in violation of the applicable regulatory restrictions, we could be subject to FDA enforcement action. Any enforcement action (or related lawsuit, which could follow such action) brought against us in connection with alleged violations of applicable drug promotion requirements, or prohibitions, could harm our business and our reputation, as well as the reputation of any approved drug products we may promote or commercialize.

***Modifications to our Consensi™ drug product or to our NT219 therapeutic candidate or any other therapeutic candidate(s) that we may acquire or develop in the future, if approved, will likely require new regulatory approvals before we may continue marketing such product or may require us, or our current or potential development and commercialization partners, as applicable, to recall or cease marketing our Consensi™ drug product or such therapeutic candidates until approvals are obtained.***

Modifications to our Consensi™ drug product, our NT219 therapeutic candidate or any other therapeutic candidate(s) that we may acquire or develop in the future, after they have been approved for marketing, if at all, may require new regulatory approvals, and may result in the recall or suspension of marketing of the 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 Prior Approval Supplement, a Changes Being Effected in 30 Days Supplement, or a report in the subsequent Annual Report depending on the impact of the change to the identity, strength, quality, purity, or potency of the approved drug product. A manufacturer may determine in conformity with applicable laws, regulations and guidelines that a modification may be implemented without approval of a Prior Approval Supplement by the FDA or a similar supplement submitted to 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 an approval is required before commencing commercialization of the modified drug product. If the FDA or other foreign regulatory authorities require an approval 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.

***We may be subject to additional risks because Consensi™ is a combination of two FDA-approved drugs.***

Consensi™ is comprised of two FDA-approved drugs, celecoxib (the active ingredient in Pfizer's Celebrex®) and amlodipine besylate (the active ingredient in Pfizer's Norvasc®). Either of these two drugs could independently be found defective or, for a number of other reasons beyond our control, removed from the market and, thus, become unavailable for commercial use as a component of Consensi™. Additionally, adverse action of any kind against one of the companies responsible for the drugs of which Consensi™ is comprised could affect our ability to obtain the applicable drug and/or public perception of us and/or Consensi™ based on our association with the company at-issue or the use of the applicable drug as a component of Consensi™. The outcome and cost of developing a product comprised of existing FDA-approved compounds is difficult to predict and dependent on a number of factors that are beyond our reasonable control.

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

We own the rights to FDA-approved drug Consensi™ which we acquired as a therapeutic candidate in 2013, and our NT219 therapeutic candidate which we acquired in 2017, each of which was acquired by us from a third party. 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 technology transfer company of the Hebrew University of Jerusalem, 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 studies 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 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 other 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.

***The pharmaceutical industry in China is highly regulated and such regulations are subject to change which may affect approval and commercialization of our drug candidate, Consensi™.***

The pharmaceutical industry in China is subject to comprehensive government regulation and supervision, encompassing the approval, registration, manufacturing, packaging, licensing and marketing of new drugs. In recent years, the regulatory framework in China regarding the pharmaceutical industry has undergone significant changes, and we expect that it will continue to undergo significant changes in the future. There is uncertainty as to the regulatory approach in China with respect to combination drug products. Any such uncertainty, changes or amendments may cause delays in or prevent the market authorization or the successful commercialization of our Consensi™ drug product in China and reduce the current benefits we believe are available to us from our definitive License, Development and Commercialization Agreement with Hebei Changshan Biochemical Pharmaceutical Co., Ltd. (Changshan Pharma). Chinese authorities have become increasingly vigilant in enforcing laws in the pharmaceutical industry and any failure by Changshan Pharma to maintain compliance with applicable laws and regulations or obtain and maintain required licenses and permits may prevent the receipt of market authorization for Consensi™ in China or otherwise result in the suspension of the commercialization of Consensi™ in China.

***Changes in the political and economic policies of the Chinese government may materially and adversely affect the commercialization of Consensi™ in China.***

The Chinese economy differs from the economies of most developed countries in many respects, including the extent of government involvement, level of development, growth rate, control of foreign exchange and allocation of resources. Although the Chinese government has implemented measures emphasizing the utilization of market forces for economic reform, the reduction of state ownership of productive assets, and the establishment of improved corporate governance in business enterprises, a substantial portion of productive assets in China is still owned by the government. In addition, the Chinese government continues to play a significant role in regulating industrial development by imposing industrial policies. The Chinese government also exercises significant control over China's economic growth by allocating resources, controlling payment of foreign currency-denominated obligations, setting monetary policy, regulating financial services and institutions and providing preferential treatment to particular industries or companies.

While the Chinese economy has experienced significant growth in the past three decades, growth has been uneven, both geographically and among various sectors of the economy. The Chinese government has implemented various measures to encourage economic growth and guide the allocation of resources. Some of these measures may benefit the overall Chinese economy but may also have a negative effect on us and our products. For example, our commercialization of Consensi™ in China could be materially and adversely affected by government control over capital investments or changes in tax regulations.

***Our subsidiary, TyrNovo, has received and may continue to receive Israeli governmental grants to assist in the funding of its research and development activities. 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 (or approximately \$1.6 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).



TyrNovo's technologies were developed, at least in part, with funds from IIA grants, and accordingly TyrNovo 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, 2018, 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.

***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. 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 of up to 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. Although the rules which were published by the IIA as of the date of this annual report 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 annual report, we are unable to assess the effect on our business of any future rules which may be published by the IIA.



In addition, the IIA in 2017 published 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 amounts in accordance with the formula stipulated under these rules and guidelines. In August 2018, the IIA updated the abovementioned rules and established a new mechanism with respect to the grant of a license by a company (which is part of a multinational corporation) that received grants from the IIA to its group entities to use its funded know-how. Such license is subject to the IIA's prior approval and to the payment of 5% royalties from the income deriving from such license. Such mechanism includes certain restrictions which must be met in order to be able to enjoy such lower royalty payment.

#### **Risks Related to Our Industry**

***Even though Consensi™ received regulatory approval in the United States and even if our NT219 therapeutic candidate or any other therapeutic candidate that we develop in the future receive regulatory approval or do not require regulatory approval, they may not become or remain commercially viable products.***

Even though Consensi™ is approved by the FDA for marketing in the United States, it may not be a commercially viable product that is accepted by physicians and patients in the United States. Even though we believe that the FDA approved Consensi™ for a commercially viable purpose in the simultaneous treatment of pain caused by osteoarthritis and hypertension, we cannot predict whether the FDA may limit the use of Consensi™ to treatments that are not commercially viable, which would severely affect our operations and revenue.

Likewise, even if our NT219 therapeutic candidate and/or any other therapeutic candidate that we may develop in the future are approved for commercialization by the FDA or a foreign authority in the future, 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 studies 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 Consensi™, our NT219 therapeutic candidate or any other therapeutic candidates that we may develop in the future. If we are unable, either on our own or through third parties, to manufacture, commercialize and market such products when planned, or develop commercially viable therapeutic candidates, we may not achieve any market acceptance or generate revenue.

***The market for our Consensi™ drug product and our NT219 therapeutic candidate 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 treated by Consensi™ and for which we are currently developing our other therapeutic candidates. 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 Consensi™ drug product or 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 Consensi™ drug product or 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, and that in 2017, this number reached 70,237. 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 opioids 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 Consensi™ drug product or our therapeutic candidates to receive widespread acceptance.

***If third-party payers do not adequately reimburse customers for our Consensi™ drug product, or our NT219 therapeutic candidate, if approved, or any of other therapeutic candidates that may be approved for marketing in the future, 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 coverage and reimbursement for the use of our Consensi™ drug product that is approved for commercialization, and of our NT219 therapeutic candidate, if approved, or any of other therapeutic candidates that may be approved for marketing in the future, if at all, from governmental and/or other third-party payers, both in the U.S. and in foreign markets. Our Consensi™ drug product has not yet received reimbursement from government or other third party payers. There may be significant delays in obtaining coverage for newly approved therapeutic candidates. Moreover, eligibility for coverage does not necessarily signify that an approved product will be reimbursed in all cases or at a sufficient rate, including one that covers our costs, such as research, development, manufacture, sale, and distribution costs. Accordingly, even if we succeed in bringing one or more of our therapeutic candidates to the market, they may not be considered cost-effective, and the amount reimbursed may be insufficient to allow us to sell our approved products on a competitive basis. 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 product 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 an approved product 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 an approved product to each payer. Even when a payer determines that an approved product is eligible for reimbursement, the payer may impose coverage limitations that preclude or restrict 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 approved product and the clinical setting in which it is 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.

Increasingly, the third-party payers who reimburse patients or healthcare providers, such as government and private insurance plans, are seeking greater upfront discounts, additional rebates, and other concessions to reduce the prices for approved products. If the price we are able to charge for any approved product, or the reimbursement provided for such approved product, is inadequate or becomes inadequate in light of our development and other costs, our return on investment could be adversely affected.

It has been reported that generic drug prices have fallen for the past few years. 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 pharmaceutical companies have in the past often fallen in tandem. It is unclear to us 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 Consensi™ drug product in the U.S. or our NT219 therapeutic candidate, if approved. We believe that legislation that reduces reimbursement for our Consensi™ drug product or our NT219 therapeutic candidate, if approved, could adversely impact how much or under what circumstances healthcare providers will prescribe or administer our Consensi™ drug product, or our NT219 therapeutic candidate, 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 Consensi™ drug product, or our NT219 therapeutic candidate, 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, coverage and reimbursement policies are subject to change and are not always consistent across different payers or even federal healthcare programs. For example, the Centers for Medicare and Medicaid Services (CMS) frequently change product descriptors, coverage policies, product and service codes, payment methodologies and reimbursement values which may be revised or interpreted in ways that could significantly affect our business and products. Government and private third-party payers often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Moreover, both CMS and other third-party payers may have sufficient market power to demand significant price reductions. Such price reductions and/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.***

A number of legislative and regulatory changes in the healthcare system in the U.S. have been proposed and adopted in recent years, and efforts of the legislature and third-party payers to contain or reduce the cost of healthcare and broaden the availability of healthcare continue. These developments could, directly or indirectly, affect our ability to sell our Consensi™ drug product or our NT219 therapeutic candidate, if approved, in the U.S. On March 23, 2010, the Patient Protection and Affordable Care Act (P.L. 111-148) was signed into law, followed by the Health Care and Education Reconciliation Act (P.L. 111-152) on March 30, 2010 (referred to, collectively, as the "Healthcare Reform Law." The Healthcare Reform Law was enacted with the intent to broaden access to health insurance, reduce or constrain the growth of health spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare industry, impose new taxes and fees, and impose additional policy reforms, among others. In addition, 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, largely designed to encourage providers to find cost savings in their clinical operations.

The Healthcare Reform Law sparked one of the most comprehensive and significant reforms in the history of the U.S. healthcare industry, has significantly changed the way healthcare is financed and has impacted the scope of healthcare insurance and incentives, among others. Pharmaceuticals represent a significant portion of the cost of providing healthcare. The environment created by the Healthcare Reform Law 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 in relation to pharmaceuticals. This attention may result in our Consensi™ drug product or our NT219 therapeutic candidate, if approved, being chosen less frequently or the pricing being substantially lowered. Continued restructuring of medical care coverage in the U.S. could further impact the reimbursement for the types of prescribed drugs and pharmaceuticals that we and our development or commercialization partners are developing. If reimbursement for our Consensi™ drug product or our therapeutic candidates, if approved, is substantially reduced or otherwise adversely affected in the future, or rebate or similar obligations or fees associated with them are imposed or substantially increased, it could have a material adverse effect on our business, financial condition, and operational success.

Certain facets of the Healthcare Reform Law and subsequent legislation, such as the extension of medical benefits to those who previously lacked coverage may, in the long term, result in substantial costs to the U.S. government, which may force significant additional changes to the U.S. healthcare system. 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 our Consensi™ drug product or those therapeutic candidates currently being developed by us or our development or commercialization partners, if approved), or by restricting coverage (and, thereby, utilization) of medical services or products. In either case, a reduction in the utilization of, or reimbursement for, our Consensi™ drug product or 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.

Further, the U.S. healthcare 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. There is still uncertainty with respect to the impact the current U.S. presidential administration and the U.S. Congress may have, if any, and the effects of any changes will likely take time to unfold. Such reforms could have an adverse effect on anticipated revenues from our Consensi™ drug product or our therapeutic candidates that we may successfully develop and for which we may obtain regulatory approval in the future, and may affect our overall financial condition and ability to develop and commercialize therapeutic candidates. While these legislative and judicial challenges are likely to continue, we cannot predict the extent to which our business will be impacted by future legislative and legal challenges to the Healthcare Reform Law or other changes to the current laws and regulations.

***We may be subject to additional federal and state healthcare 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. Healthcare providers, physicians, and third-party payers play a primary role in the recommendation and prescription of any therapeutic candidates for which we obtain marketing approval. Our current or future arrangements with healthcare providers, physicians, marketers or sales personnel, third-party payers, patients, and others in a position to refer, recommend, purchase, or use our products may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our approved products. 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 payments and other transfers of value to physicians and teaching hospitals and ownership or investment interests held by physicians or their immediate family members to CMS for disclosure to the public;
- the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) and its implementing regulations, which impose obligations on certain covered entities and their business associates with respect to safeguarding the privacy, security, and transmission of individually identifiable health information, and require notification to affected individuals, regulatory authorities, and potentially the media of certain breaches of security of individually identifiable health information;

- HIPAA's fraud and abuse provisions, which impose criminal and civil liability for executing a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;
- the federal Food, Drug, and Cosmetic Act, which, among other things, strictly regulate 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, false claims, transparency and reporting laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, many of which differ from each other in significant ways, thus complicating compliance efforts.

Compliance efforts may involve substantial costs, and if our operations or business arrangements are found to be in violation of any such requirements, we may be subject to penalties, including civil or criminal penalties, monetary damages, the curtailment or restructuring of our operations, or exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid, any of which could adversely affect our financial results. Any action against us for an alleged or suspected violation could cause us to incur significant legal expenses and could divert our management's attention from the operation of our business, even if our defense is successful. In addition, achieving and sustaining compliance with applicable laws and regulations may be costly to us in terms of money, time, and resources.

Most recently, there has been a trend in federal and state legislation aimed at lowering costs for drug products, including by requiring pharmaceutical companies to disclose information about their pricing and production and marketing costs. Many states have passed or introduced bills that require disclosure of certain pricing information for prescription drugs, 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. These laws and any other such 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 or encouraging purchasers to use other low-cost, established drugs or therapies.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians or others in a position to refer, purchase, or recommend drug products. For example, some states impose a legal obligation on companies to adhere to voluntary industry codes of behavior (e.g., the PhRMA Code), which apply to pharmaceutical companies' interactions with healthcare providers, some 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. Further, the Healthcare Reform Law, among other things, amended the intent requirement of the federal Anti-Kickback Statute so that 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 Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

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 guidance in many areas. We cannot predict the impact that new legislation or any changes in existing legislation will have on our business, financial condition, or results of operations. 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 and could negatively and adversely affect our business and results of operations.

***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, conducted or may have to conduct, and the testing, manufacturing, marketing and commercial sale of our Consensi™ drug product, or our NT219 therapeutic candidate or any other therapeutic candidates that we may develop in the future, involve and will involve an inherent risk that significant liability claims may be asserted against us. Should we decide to seek additional insurance against such risks before we initiate clinical trials or commence our product sales, 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 Consensi™ drug product, or our therapeutic candidates or any other therapeutic candidate that we may develop in the future, regardless of their outcome and merit, 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 Consensi™ drug product, or our therapeutic candidates or any other therapeutic candidates that we may develop in the future. A product liability claim could also significantly harm our reputation and delay market acceptance of our Consensi™ drug product, or our therapeutic candidates or any other therapeutic candidate that we may develop in the future.

***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 Our Pending Acquisition of FameWave

***The announcement and pendency of the transactions for our acquisition of FameWave and the concurrent investment in the Company by certain shareholders of FameWave in a private placement (collectively, the “Transaction”), whether or not consummated, may adversely affect our business.***

The announcement and pendency of the Transaction, whether or not consummated, may adversely affect the trading price of our ordinary shares and/or ADSs, our business or our relationships with customers, suppliers and employees. In addition, pending the completion of the Transaction, the focus and attention of our management and employee resources may be diverted from operational matters during the pendency of the Transaction. Should they occur, any of these matters could adversely affect the businesses of, or harm the financial condition, results of operations or business prospects of Kitov or FameWave.

***We cannot be sure if or when the Transaction will be completed. Failure to complete the Transaction could negatively affect the value of our ordinary shares and our future business and financial results.***

The closing of the Transaction is subject to the satisfaction or waiver of various conditions, including approval of our shareholders which is being sought at the special general meeting of our shareholders which is scheduled to be held on April 29, 2019. We cannot guarantee that the closing conditions set forth in the acquisition agreement, dated March 14, 2019, between us and FameWave (the “Acquisition Agreement”) will be satisfied. If we are unable to satisfy the closing conditions in the FameWave’s favor or if other mutual closing conditions are not satisfied, FameWave will not be obligated to complete the Transaction. In the event that the Transaction is not completed, the announcement of the termination of the Acquisition Agreement may adversely affect the trading price of our ordinary shares and/or ADSs, our business and operations or our relationships with customers, suppliers and employees; we may be subject to reputational harm due to the adverse perception of any failure to successfully complete the acquisition; and we would have to incur certain costs relating to the transaction, such as legal, accounting, financial advisory, filing and printing fees without completion of the transaction.

***The purchase price is not adjustable based on the market price of our ADSs so the consideration at the closing may have a greater value than at the time the Acquisition Agreement was signed.***

The Acquisition Agreement has set the consideration formula for the FameWave share capital. Any changes in the market price of our ADSs before the completion of the Transaction will not affect the number of ADSs the sellers will be entitled to receive pursuant to the Acquisition Agreement. Therefore, if before the completion of the Transaction the market price of our ADSs increases from the market price on the date of the Acquisition Agreement, then sellers could receive consideration with substantially more value for their shares of FameWave capital stock than the parties had negotiated for in the establishment of the consideration in the Transaction.

***Our shareholders may not realize a benefit from the Transaction commensurate with the ownership dilution they will experience in connection with the Transaction.***

If the combined company is unable to realize the strategic and financial benefits currently anticipated from the Transaction, our shareholders will have experienced substantial dilution of their ownership interest without receiving any commensurate benefit. Due to the substantial number of the ADSs (including ADSs issuable upon exercise of the warrants to purchase ADSs) being issued to FameWave shareholders in the Transaction and the private placement, the ownership stake and relative voting power of each ordinary share held by our current shareholders will be significantly reduced. However, significant management attention and resources will be required to integrate and operate the combined company. Delays in this process could adversely affect the combined company’s business, financial results, financial condition and price of our ordinary shares and/or ADSs following the Transaction. Even if the combined company is able to integrate the business operations successfully, there can be no assurance that this integration will result in the realization of the full benefits of synergies, innovation, and operational efficiencies that may be possible from this integration and that these benefits will be achieved within a reasonable period of time.



***Because the lack of a public market for FameWave's capital stock makes it difficult to evaluate the fairness of the Transaction, FameWave's stockholders may receive consideration in the Transaction that is greater than the fair market value of FameWave's capital stock.***

The outstanding share capital of FameWave is privately held and is not traded in any public market. The lack of a public market makes it extremely difficult to determine the fair market value of FameWave. Since the percentage of our equity to be issued to FameWave's stockholders was determined based on negotiations between the parties, it is possible that the value of our ADSs and warrants to be issued in connection with the Transaction will be greater than the fair market value of FameWave. Alternatively, it is possible that the value of the ADSs and warrants to be issued in connection with the Transaction will be less than the fair market value of FameWave.

***We will incur significant expenses in connection with the Transaction, regardless of whether the Transaction is completed.***

We expect to incur significant expenses related to the Transaction. These expenses include, but are not limited to, legal fees, accounting fees and expenses, certain employee expenses, filing fees, printing expenses and other related fees and expenses. Many of these expenses will be payable by us regardless of whether the Transaction is completed.

#### **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 or delay us in developing or commercializing our therapeutic candidates. An adverse result in any infringement claim or 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. A separate, similar claim in the amount of NIS 1.1 million was filed against us in May 2018 by an individual shareholder seeking to separate from the purported class in the Motion. 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, in February 2017 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 former 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 proceedings could result in significant legal defense costs and high punitive damage payments. For instance, through December 31, 2018, we incurred legal expenses of approximately net \$906,000 (after deducting amount already received as reimbursement from our insurance) 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 and related lawsuits 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 \$185,000, most of which amount has already been paid by us as of the date of this annual report

We entered into a settlement agreement with respect to the class actions lawsuits which were filed in the State of California and in the U.S. federal courts against us, our CEO and former CFO, and in the California lawsuits, against the underwriters of our November 2015 initial public offering in the United States, which was approved by the court on March 22, 2019. Under the terms of the proposed settlement, the classes in all of the actions will receive aggregate consideration of \$2.0 million. The settlement consideration, as well as ancillary expenses will be funded by our insurance carriers, who have indicated to us that they have already made reserves for the settlement consideration. We do not expect the settlement to have a material impact on the Company's statement of operations. The settlement contains no admission of wrongdoing and reiterates that we have always maintained and continue to believe that we did not engage in any wrongdoing or otherwise commit any violation of federal or state securities laws or other laws, including, without limitation, vigorous denials that our public statements were misleading; that we failed to disclose any material information from investors; that we acted in any deceitful manner; that any investment losses sustained by the classes were caused by our or other defendants' alleged misconduct, and that they have any liability to the classes in these actions. The settlement also reiterates that our counsel also has researched the applicable law and believes that we and other defendants can successfully defend against all claims in the actions, and that they continue to believe that the claims asserted in the actions have no merit, and the classes have no evidence to support their claims. We and the other defendants agreed to the settlement on the basis of the advice and recommendations of our insurance carriers, who are indemnifying us for the expenses of conducting a defense in the actions, as well as paying judgments which may be assessed as a result of the actions. As such, we and the other defendants believe that further litigation of the actions would be protracted, burdensome, and expensive for us as well as our insurers, and that it is desirable and beneficial that the claims asserted in the actions be fully and finally settled and terminated in the manner of the settlement, with no additional costs to us or to the other defendants. Pursuant to the settlement, we and our directors and officers as well as the other defendants named in the actions will be released from the claims that were asserted or could have been asserted in the actions by class members participating in the settlement. The settlement is subject to the completion of final documentation, funding of the \$2.0 million in cash by our insurance carriers, and other customary closing conditions.

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 stage, and other than with respect to the settlement of the Investigation Motions in the U.S., 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.

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 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™.

In September 2018, we announced that, following a filing by Kitov's Chairman of the Board and Chief Medical Officer, Dr. Paul Waymack, of a motion to quash a subpoena for documents and testimony served on Dr. Waymack by the Securities and Exchange Commission ("SEC"), the SEC has commenced an action to enforce the subpoena. As stated by the SEC, the application does not reflect a determination by the SEC or its staff that Dr. Waymack or we have violated any provisions of the federal securities laws or any provisions at issue in the Israel Securities Authority's investigation. The formal order issued by the SEC, which authorizes the SEC Staff to issue subpoenas and take testimony, states that the Israel Securities Authority ("ISA") has requested assistance in connection with an investigation and does not cite any other reason for issuing the formal order. In February 2019, a hearing was held with respect to these motions involving Dr. Waymack, and the court issued a ruling granting Dr. Waymack's motion that the subpoena is overly broad but denying other arguments raised by Dr. Waymack. The parties were given a period of time to discuss and agree on a revision to the scope of the subpoena. Dr. Waymack has informed us that he intends to file an appeal of that decision.

We cannot predict at this time the impact on us as a result of the Investigation, including with respect to the proceedings involving Dr. Waymack, 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 rulings by the courts and/or ISA, or 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.

***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.

***We do not have patent protection in certain countries, and we may not be able to effectively enforce our intellectual property rights in certain countries, which could significantly erode the market for our product candidates.***

We are seeking or intend to seek regulatory approval to market Consensi™ or our therapeutic candidates in a number of foreign countries, including China and South Korea. Consensi™ and our therapeutic candidates are not protected by patents in certain countries, including China and South Korea, which means that competitors may be free to sell products that incorporate the same technology that is used in our products in those countries. In addition, the laws and practices in some foreign countries may not protect intellectual property rights to the same extent as in the United States. We or our licensors may not be able to effectively obtain, maintain or enforce rights with respect to the intellectual property relating to our product candidates in those countries. In that regard, we believe that although China is one of the largest potential markets for some of our products under development, none of our product candidates is protected by patents in China and it may be difficult to enforce intellectual property rights in China. Our lack of patent protection in one or more countries, or the inability to obtain, maintain or enforce intellectual property rights in one or more countries, could adversely affect our ability to commercialize our products in those countries and could otherwise have a material adverse effect on our business.

***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. In addition, monitoring infringement of intellectual property rights is difficult, and we cannot be certain that the steps we have taken will prevent unauthorized use of our know-how, particularly in China and other countries in which the laws may not protect our proprietary rights as fully as the laws of the United States. Accordingly, other parties, including competitors, may improperly duplicate our products using our proprietary technologies. Pursuing legal remedies against persons infringing our patents or otherwise improperly using our proprietary information is a costly and time-consuming process that would divert management's attention and other resources from the conduct of our normal business.

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.

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. These conflicts have often involved missile strikes against civilian targets in various parts of Israel, and negatively affected business conditions in Israel. The tension between Israel and Iran or extremist groups in the region, such as Hamas in Gaza and Hezbollah in Lebanon, may escalate in the future and turn violent, which could affect the Israeli economy generally and us in particular. Any armed conflicts, terrorist activities or political instability in the region could adversely affect business conditions and could harm our results of operations. Parties with whom we may do business have sometimes declined to travel to Israel during periods of heightened unrest or tension, forcing us to make alternative arrangements when necessary. The conflict situation in Israel could cause situations where medical product certifying or auditing bodies could not be able to visit manufacturing facilities of our subcontractors in Israel in order to review our certifications or clearances, thus possibly leading to temporary suspensions or even cancellations of our product clearances or certifications. The conflict situation in Israel could also result in parties with whom we have agreements involving performance in Israel claiming that they are not obligated to perform their commitments under those agreements pursuant to force majeure provisions in such agreements.

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

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

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

***Provisions of Israeli law and Kitov Pharma's amended and restated articles of association may delay, prevent or otherwise impede a merger with, or an acquisition of the Company, or an acquisition of a significant portion of Kitov Pharma'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,

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.

In addition, Kitov Pharma has 50,000,000 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.

***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.



***Our Amended and Restated Articles of Association designate courts located either within the State of Israel, or the Federal District Courts of the United States, as the exclusive forum for certain litigation that may be initiated by our shareholders, which could limit our shareholders' ability to bring a favorable or convenient judicial forum for disputes with us.***

Our Amended and Restated Articles of Association provide that, unless we consent in writing to the selection of an alternative forum, the Tel Aviv District Court (Economic Division in the State of Israel (or, if the Tel Aviv District Court does not have jurisdiction, and no other Israeli court has jurisdiction, the federal district court for the District of New York) shall be the sole and exclusive forum for (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our shareholders, and (3) any action asserting a claim arising pursuant to any provision of the Companies Law or the Israeli Securities Law 5728-1968, in all cases subject to the court's having personal jurisdiction over the indispensable parties named as defendants. In addition, the federal district courts of the United States for the District of New York shall be the exclusive forum for any complaint asserting a cause of action arising under the Securities Act of 1933. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and consented to these provisions. This forum selection provision will limit shareholders' choice in selecting a judicial forum for disputes with us that it finds favorable or convenient and may have the effect of discouraging lawsuits against us or our directors and officers.

#### **Risks Primarily Related to Our ADSs and Ordinary Shares and Other Listed Securities**

***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;
- our need to raise additional capital;
- 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, 2019, we had an aggregate of 19,515,267 issued and outstanding ordinary shares (including 1 dormant ordinary share held in treasury), no non-voting senior preferred shares, 6,835,669 Series A or public warrants, 5,498,178 non-listed warrants issued to investors, the underwriters and placement agents as part of a number of public and registered direct offerings by us since November 2015, and non-tradable options and RSUs to purchase 1,192,494 ordinary shares pursuant to our equity based incentive compensation plans and arrangements.

Pursuant to the proposed transactions for our acquisition of FameWave and the concurrent investment in the Company by certain shareholders of FameWave in a private placement, subject to our shareholder approval, we agreed to issue 10,921,138 ADSs representing an equivalent number of our ordinary shares, or approximately 56% of our outstanding ordinary shares as of March 20, 2019. In addition, we will issue warrants and service provider options to purchase up to an additional 4,119,513 ADSs representing an equivalent number of our ordinary shares, representing approximately 21% of our outstanding ordinary shares as of March 20, 2019. These issuances and any future sales or issuances of a substantial number of ADSs and/or ADSs underlying warrants or service provider options in the public market, or the perception that such sales may occur, could materially adversely affect the price of our ADSs and ordinary shares. We cannot predict the effect, if any, that market sales of those ADSs and warrants to purchase ADSs or the availability of those ADSs and warrants for sale will have on the market price of our ADSs and ordinary shares.

Any other 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.

***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 then 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, and that we have not identified any additional material weaknesses in our internal control over financial reporting since such time, 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 are and will continue to be required to devote substantial time to 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 2019 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.

***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 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.

***Our ADS holders may not be able to fully exercise their voting rights to the same extent as our ordinary shareholders. 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.***

Our ADS holders may instruct the depositary how to vote the number of deposited ordinary shares their ADSs represent. Except by instructing the depositary, you will not be able to exercise voting rights unless you surrender your ADSs and withdraw the shares. However, you may not know about the meeting enough in advance to withdraw the shares. We cannot assure you that you will receive the voting materials in time to ensure that you can instruct the depositary to vote your shares. In addition, the depositary and its agents are not responsible for failing to carry out voting instructions or for the manner of carrying out voting instructions. This means that you may not be able to exercise voting rights and there may be nothing you can do if your shares are not voted as you requested, and you cannot vote in person at meetings as a holder of ADSs.

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 notify the depositary that:

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

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 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 have been traded on NASDAQ since November 20, 2015, the present level of market activity for our ADSs may not be sustained. If an active market for our ADSs is not sustained, it may be difficult for an investor to sell its ADSs.

***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, the price of our ADSs could decline.***

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

#### **Risks Related to FameWave’s Business and Product Candidate**

***FameWave is a development stage company with a limited operating history, which makes it difficult to evaluate its prospects.***

FameWave is a clinical-stage biopharmaceutical company. FameWave has no products approved for commercial sale and has not generated any revenue. FameWave does not expect to generate any meaningful product sales or revenues for the foreseeable future, if ever. FameWave expects to incur significant additional operating losses in the future as it expands development and clinical trial efforts.

***FameWave may encounter substantial delays in its clinical trials or may not be able to conduct its trials on the timelines it expects.***

Clinical testing is expensive, time-consuming, and subject to uncertainty. FameWave cannot guarantee that any clinical studies will be conducted as planned or completed on schedule, if at all. The previous owners of the CM-24 platform conducted the first human clinical trials for FameWave’s therapeutic candidate, CM-24, which were initiated in 2015, and discontinued in 2017. Following the Transaction, we may resume clinical testing of CM-24 but issues may yet arise that could delay or prevent future clinical trials. A failure of one or more clinical studies can occur at any stage of testing, and FameWave’s future clinical studies may not be successful. Events that may prevent successful or timely completion of clinical development include:

- delays in reaching a consensus with regulatory agencies on study design;
- delays in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical study sites;
- delays in obtaining required Institutional Review Board, or IRB, approval at each clinical study site;
- the departure of a principal investigator from a clinical site, which could cause delays in conducting the clinical trial at a particular clinical site;
- imposition of a temporary or permanent clinical hold by regulatory agencies;
- delays in recruiting suitable patients to participate in FameWave’s clinical studies;



- failure by Famewave's CROs, other third parties, or Famewave to adhere to clinical study requirements;
- failure to perform in accordance with the FDA's current good clinical practices, or cGCPs, requirements, or applicable regulatory guidelines in other countries;
- patients dropping out of a study;
- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;
- the cost of clinical studies of Famewave's therapeutic candidates being greater than Famewave anticipates;
- clinical studies of Famewave's therapeutic candidates producing negative or inconclusive results, which may result in Famewave's deciding, or regulators requiring Famewave, to conduct additional clinical studies or abandon product development programs;
- delays in manufacturing, testing, release, validating, or import/export of sufficient stable quantities of Famewave's therapeutic candidates for use in clinical studies or the inability to do any of the foregoing, including any quality issues associated with contract manufacturers.

Famewave also may conduct clinical research in collaboration with other biotechnology and biologics entities in which Famewave combines its technologies with those of Famewave's collaborators. Such collaborations may be subject to additional delays because of the management of the trials or the necessity of obtaining additional approvals for therapeutics used in the combination trials. These combination therapies will require additional testing and clinical trials will require additional FDA regulatory approval and will increase Famewave's future expenses.

Any inability to successfully complete clinical development could result in additional costs to Famewave or impair Famewave's ability to generate revenue. In addition, if Famewave makes manufacturing or formulation changes to its therapeutic candidates, Famewave may be required, or may elect, to conduct additional studies to bridge its modified therapeutic candidates to earlier versions. Clinical study delays could also shorten any periods during which Famewave's products have patent protection and may allow Famewave's competitors to bring products to market before Famewave does, which could impair Famewave's ability to commercialize its therapeutic candidates successfully and may harm Famewave's business and the results of its operations.

***It may take longer and cost more to complete Famewave's clinical trials than Famewave's projections, or Famewave may not be able to complete them at all.***

For budgeting and planning purposes, Famewave has projected the dates for the commencement, continuation, and completion of Famewave's various clinical trials. However, a number of factors, including scheduling conflicts with participating clinicians and clinical institutions, and difficulties in identifying and enrolling patients who meet trial eligibility criteria, may cause significant delays. Famewave may not commence or complete clinical trials involving any of Famewave's products as projected or may not conduct them successfully.

Famewave may experience difficulties in patient enrollment in Famewave's future clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on Famewave's ability to enroll a sufficient number of patients who remain in the study until its conclusion. In addition, Famewave's clinical trials will compete with other clinical trials for therapeutic candidates that are in the same therapeutic areas as Famewave's therapeutic candidates, and this competition will reduce the number and types of patients available to Famewave, because some patients who might have opted to enroll in Famewave's trials may instead opt to enroll in a trial being conducted by one of Famewave's competitors. Accordingly, Famewave cannot guarantee that the trial will progress as planned or as scheduled. Delays in patient enrollment may result in increased costs or may affect the timing or outcome of Famewave's ongoing clinical trial and planned clinical trials, which could prevent completion of these trials and adversely affect Famewave's ability to advance the development of Famewave's therapeutic candidates.

Famewave expects to rely on medical institutions, academic institutions, or clinical research organizations to conduct, supervise, or monitor some or all aspects of clinical trials involving Famewave's products. Famewave may have less control over the timing and other aspects of these clinical trials than if Famewave conducted them entirely on its own. If Famewave fails to commence or complete, or experience delays in, any of its planned clinical trials, Famewave may experience delays in its clinical development and/or commercialization plans.

***Famewave's clinical trials may fail to demonstrate adequately the safety and efficacy of its therapeutic candidates, which would prevent or delay regulatory approval and commercialization.***

The clinical trials of Famewave's therapeutic candidates are, and the manufacturing and marketing of its products will be, subject to extensive and rigorous review and regulation by numerous government authorities in the United States and in other countries where Famewave intends to test and market its therapeutic candidates. Before obtaining regulatory approvals for the commercial sale of any of Famewave's therapeutic candidates, Famewave must demonstrate through lengthy, complex, and expensive preclinical testing and clinical trials that its therapeutic candidates are both safe and effective for use in each target indication. In particular, because Famewave's therapeutic candidates are subject to regulation as biological drug products, Famewave will need to demonstrate that they are safe, pure and potent for use in their target indications. Each product candidate must demonstrate an adequate risk versus benefit profile in its intended patient population and for its intended use. The risk/benefit profile required for product licensure will vary depending on these factors and may include not only the ability to show tumor shrinkage, but also adequate duration of response, a delay in the progression of the disease, and/or an improvement in survival. For example, response rates from the use of Famewave's therapeutic candidates may not be sufficient to obtain regulatory approval unless Famewave can also show an adequate duration of response. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of Famewave's therapeutic candidates may not be predictive of the results of later-stage clinical trials. The results of studies in one set of patients or line of treatment may not be predictive of those obtained in another. Famewave expects that there may be greater variability in results for products processed and administered on a patient-by-patient basis, as anticipated for Famewave's therapeutic candidates, than for "off-the-shelf" products, like many other drugs. There is typically an extremely high rate of attrition from the failure of therapeutic candidates proceeding through clinical trials. Therapeutic candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most therapeutic candidates that begin clinical trials are never approved by regulatory authorities for commercialization.

In addition, even if such trials are successfully completed, Famewave cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as Famewave does, and more trials could be required before Famewave submits its therapeutic candidates for approval. To the extent that the results of the trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, Famewave may be required to expend significant resources, which may not be available to Famewave, to conduct additional trials in support of potential approval of its therapeutic candidates.

***If FamWave encounters difficulties enrolling patients in FamWave's clinical trials, its clinical development activities could be delayed or otherwise adversely affected.***

The timely completion of clinical trials in accordance with their protocols depends, among other things, on FamWave's ability to enroll a sufficient number of patients who remain in the trial until its conclusion. FamWave may experience difficulties in patient enrollment in FamWave's clinical trials for a variety of reasons, including:

- the size and nature of the patient population;
- the patient eligibility criteria defined in the protocol;
- the size of the study population required for analysis of the trial's endpoints;
- the proximity of patients to trial sites;
- the design of the trial;
- FamWave's ability to recruit clinical trial investigators with the appropriate competencies and experience;
- competing clinical trials for similar therapies or other new therapeutics;
- clinicians' and patients' perceptions of the potential advantages and side effects of the product candidate being studied in relation to other available therapies, including any new drugs or treatments that may be approved for the indications FamWave is investigating;
- FamWave's ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will not complete a clinical trial.

In addition, FamWave's clinical trials will compete with other clinical trials for therapeutic candidates that are in the same therapeutic areas as FamWave's therapeutic candidates. This competition will reduce the number and types of patients available to FamWave, because some patients who might have opted to enroll in FamWave's trials may instead opt to enroll in a trial being conducted by one of FamWave's competitors. Moreover, because FamWave's therapeutic candidates represent a departure from more commonly used methods of cancer treatment, potential patients and their doctors may be inclined to use conventional therapies, such as chemotherapy and approved immunotherapies, rather than enroll patients in any future clinical trial.

Even if FamWave can enroll a sufficient number of patients in FamWave's clinical trials, delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect FamWave's ability to advance the development of its therapeutic candidates.

***FamWave will depend on a joint collaboration partner to conduct clinical trials with CM-24, and we may enter into future collaboration agreements collaboration partners to develop and conduct clinical trials with, obtain regulatory approvals for, and market and sell the CM-24 therapeutic candidate. If such collaboration fails to perform as expected, FamWave's clinical trials and/or development plans will be delayed and we will be required to seek other collaboration partners, which we may not be able to engage in a timely manner, or at all, and which may delay FamWave's development plan and therefore the potential for us to generate future revenue the CM-24 therapeutic candidate would be significantly reduced and our business would be significantly harmed.***

FamWave intends to enter into a joint clinical collaboration agreement, which is now in an advanced stage of negotiation with a major pharmaceutical company, for a planned Phase I/II study of CM-24 in combination with a PD-1 antibody in early 2020, with preliminary data expected in late 2020. For FamWave's therapeutic candidates and clinical development programs, FamWave does, and may in the future continue to, rely on its collaboration partners to develop, conduct clinical trials of, and commercialize its therapeutic candidates and approved products. We may also enter into collaboration agreements with other parties in the future relating to such therapeutic candidates. Ultimately, if such therapeutic candidates are advanced through clinical trials and receive marketing approval from the FDA or similar regulatory authorities, certain of the collaboration partners may have certain rights in connection with the commercialization of the therapeutic candidate, such as rights of first offer to be responsible for commercialization of these therapeutic candidates. If these collaboration partners do not perform in the manner we expect or fail to fulfill their responsibilities in a timely manner or at all, if the agreements with them terminate or if the quality or accuracy of the clinical data they obtain is compromised, the clinical development, regulatory approval and commercialization efforts related to FamWave's therapeutic candidates could be delayed or terminated, and it could become necessary for us to assume the responsibility at our own expense for the clinical development of such therapeutic candidates and seek replacement collaboration and/or development partners. In that event, we would likely be required to limit the size and scope of efforts for the development and commercialization of such product candidate; we would likely be required to seek additional financing to fund further development or identify alternative strategic collaboration partners; our potential to generate future revenue from such therapeutic candidates would be significantly reduced or delayed; and it could have a material adverse effect on our business, financial position, results of operations and future growth prospects.

Collaborations involving Famewave's therapeutic candidates pose a number of risks, including the following:

- collaboration partners have significant discretion in determining the efforts and resources that they will apply to these partnerships;
- collaboration partners may have limited supply of products, such as a PD-1 antibody, which Famewave requires for the development of its therapeutic candidates;
- collaboration partners may not perform their obligations as expected;
- collaboration partners may not pursue development of Famewave's therapeutic candidates or may elect not to continue or renew development programs, based on clinical trial results, changes in the collaboration partners' strategic focus or available funding or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaboration partners may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaboration partners may have or could independently develop, or develop with third parties, products that compete directly or indirectly with Famewave's out-licensed therapeutic candidates;
- disagreements with collaboration partners, including disagreements over proprietary rights, contract interpretation or the conduct of product research, development or commercialization programs, may cause delays or lead to termination of such programs, or require us to assume unplanned expenditures, responsibilities or liabilities with respect to therapeutic candidates Famewave has out licensed, or may result in costly and time consuming litigation or arbitration;
- collaboration partners may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- collaboration agreements may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable therapeutic candidates.

In addition, collaboration agreements may provide the collaboration partners with rights to terminate such agreements and licenses granted under such agreements under various conditions, which, if exercised, would adversely affect Famewave's product development efforts, could make it difficult for us to attract new collaboration partners and may adversely affect our reputation. A collaboration partner may have the right to terminate its collaboration agreements. Any such termination of any agreement or any future agreement that we may enter into with collaboration partners could have a material adverse effect on our business, financial position and results of operations.

***Famewave's therapeutic candidates may cause undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, limit their commercial potential, or result in significant negative consequences.***

Undesirable side effects or adverse events caused by Famewave's therapeutic candidates, or related to the combination therapy or to the PD-1 inhibitor, could cause Famewave or regulatory authorities to interrupt, delay, or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authorities. Results of Famewave's trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics.

If unacceptable toxicities arise in the development of Famewave's therapeutic candidates, the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of its therapeutic candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff, as toxicities resulting from personalized cell therapy are not normally encountered in the general patient population and by medical personnel. Any of these occurrences may harm our business, financial condition and prospects significantly.

***The manufacture of Famewave's therapeutic candidates is complex, and we may encounter difficulties in production, particularly with respect to process development or scaling-out of Famewave's manufacturing capabilities. If Famewave, or any of our third-party manufacturers encounter such difficulties, Famewave's ability to supply its therapeutic candidates for clinical trials, or its products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.***

Famewave's therapeutic candidates are biologics, and the process of manufacturing its products is complex, highly regulated and subject to multiple risks. The manufacture of Famewave's therapeutic candidates involves complex processes, including drawing blood from patients/donors, manufacturing the clinical product, and ultimately infusing the product into a patient. As a result of the complexities, the cost to manufacture biologics is generally higher than traditional small molecule chemical compounds, and the manufacturing process is less reliable and is more difficult to reproduce. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects, and other supply disruptions.

Developing commercially viable processes is a difficult and uncertain task, and there are risks associated with scaling to the level required for advanced clinical trials or commercialization, including, among others, cost overruns, potential problems with process scale-out, process reproducibility, stability issues, lot consistency, and timely availability of raw materials. As a result of these challenges, we may experience delays in Famewave's clinical development and/or commercialization plans. We may ultimately be unable to reduce the cost of goods for Famewave's therapeutic candidates to levels that will allow for an attractive return on investment if and when those therapeutic candidates are commercialized.

***Because Famewave's current therapeutic candidates represent a novel approach to the treatment of disease, there are many uncertainties regarding the development, the market acceptance, third-party reimbursement coverage and the commercial potential of Famewave's therapeutic candidates.***

There is no assurance that the approaches offered by Famewave's products will gain broad acceptance among doctors or patients or that governmental agencies or third-party medical insurers will be willing to provide reimbursement coverage for proposed therapeutic candidates. Since Famewave's current therapeutic candidates and any future therapeutic candidates will represent new approaches to treating various conditions, it may be difficult, in any event, to accurately estimate the potential revenues from these therapeutic candidates. Accordingly, Famewave may spend large amounts of money trying to obtain approval for therapeutic candidates that have an uncertain commercial market. The market for any products that Famewave may successfully develop will also depend on the cost of the product. Famewave does not yet have sufficient information to reliably estimate what it will cost to commercially manufacture Famewave's current therapeutic candidates, and the actual cost to manufacture these products could materially and adversely affect the commercial viability of these products. Our goal is to reduce the cost of manufacturing Famewave's therapies. However, unless we are able to reduce those costs to an acceptable amount, Famewave may never be able to develop a commercially viable product. If we do not successfully develop and commercialize Famewave's therapeutic candidates based upon this approach, or find suitable and economical sources for materials used in the production of these therapeutic candidates, Famewave will not become profitable.